Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

Coramed Technologies, LLC
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847-647-8800 | 847-510-0502 fax

CORA|MED

FDA CDRH DMC
JAN 23 2015
Received

K150041/A001

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 22, 2015

RE: 510(k) #K150041 Amendment

The enclosed documentation and eCopy (on CD) is being submitted as an amendment to 510(k) #K150041 for Coramed's CORA® System. The eCopy is an exact duplicate of the paper copy, except that data line listings and statistical data were only provided in the eCopy "Statistical Data" folder. This cover letter provides references connecting appropriate sections of the paper copy back to the Statistical Data folder in the eCopy for information supporting those sections.

This amendment is in response to the FDA's email of November 21, 2015 requesting additional line data and study protocols.

1. **Precision Study Protocol and Line Data**
   The Precision protocol is provided in section 1 of this Amendment, and an Excel file containing Precision line data is provided in the "Statistical Data" folder of the eCopy, in a ZIP file labeled "Precision". The Precision statistical report was included in the initial K150041 submission.
2. **Stability Protocol and Line Data**
   The Stability protocol is provided in section 2 of this Amendment, and Excel files containing Stability data records are provided in the "Statistical Data" folder of the eCopy, in a ZIP file labeled "Stability".
3. **Interference Protocols and Line Data**
   Interference Protocols are provided in section 3 of this Amendment, and Excel files containing Interference data records are provided in the "Statistical Data" folder of the eCopy, in a ZIP file labeled "Interference".
4. **CKH Neutralization Protocol and Line Data**
   The CKH (Citrated Kaolin with Heparinase) Neutralization protocol is provided in section 4 of this Amendment, and an Excel file containing the Neutralization data record is provided in the "Statistical Data" folder of the eCopy, in a ZIP file labeled "Neutralization".

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5. CFF Linearity Protocol and Line Data

A document explaining the fibrinogen concentrations used for the CFF (Citrated Functional Fibrinogen) Linearity protocol and statistical analysis is provided in Section 5 of this Amendment. Also, the statistical analysis (written by Myraqa, Inc. – consultants) and CFF Linearity protocol are provided in section 5, and Excel files containing the Myraqa statistical analysis data and the Coramed CFF Linearity data record are provided in the "Statistical Data" folder of the eCopy, in a ZIP file labeled "Linearity".

Sincerely,



Norman E. Brunner
Director of RA/QA
Coramed Technologies, LLC
nbrunner@coramedtech.com
(847) 647-8800 ext. 16

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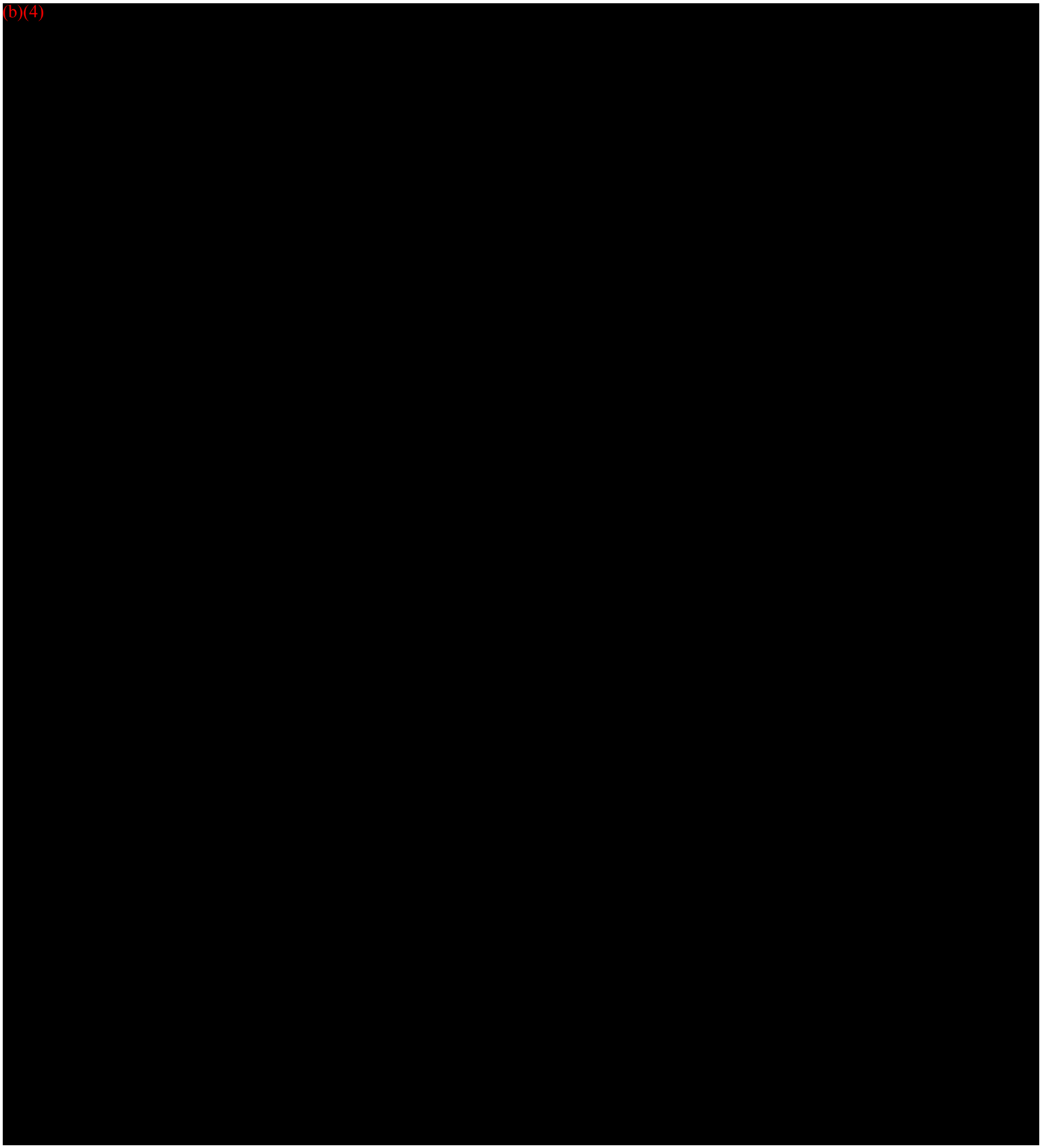
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Citrated Reagent Precision Protocol

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Protocols for Determining the Stability of CORA® System Cartridges

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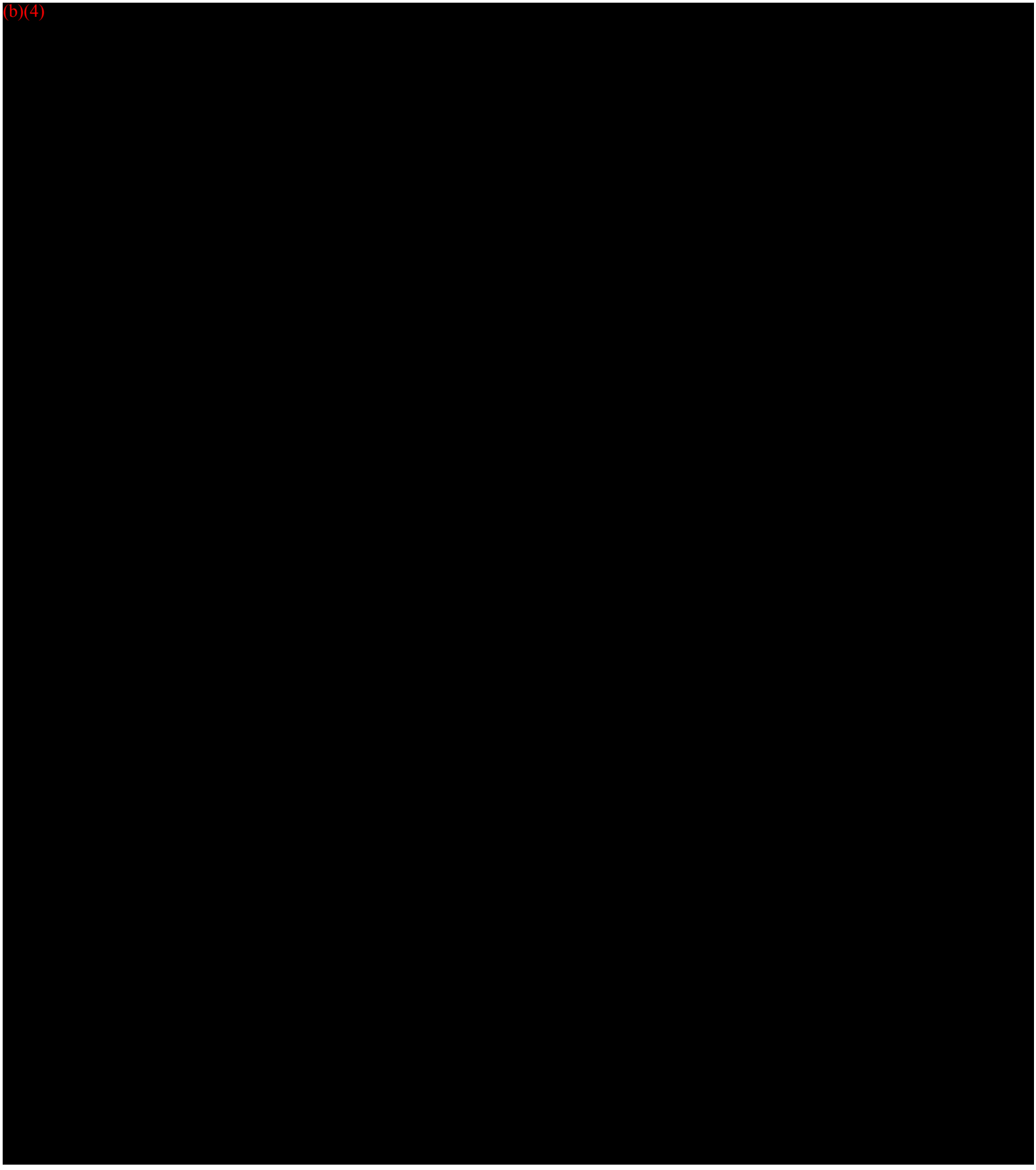
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Kaolin Reagent Interference Protocol

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RapidTEG® Reagent Interference Protocol

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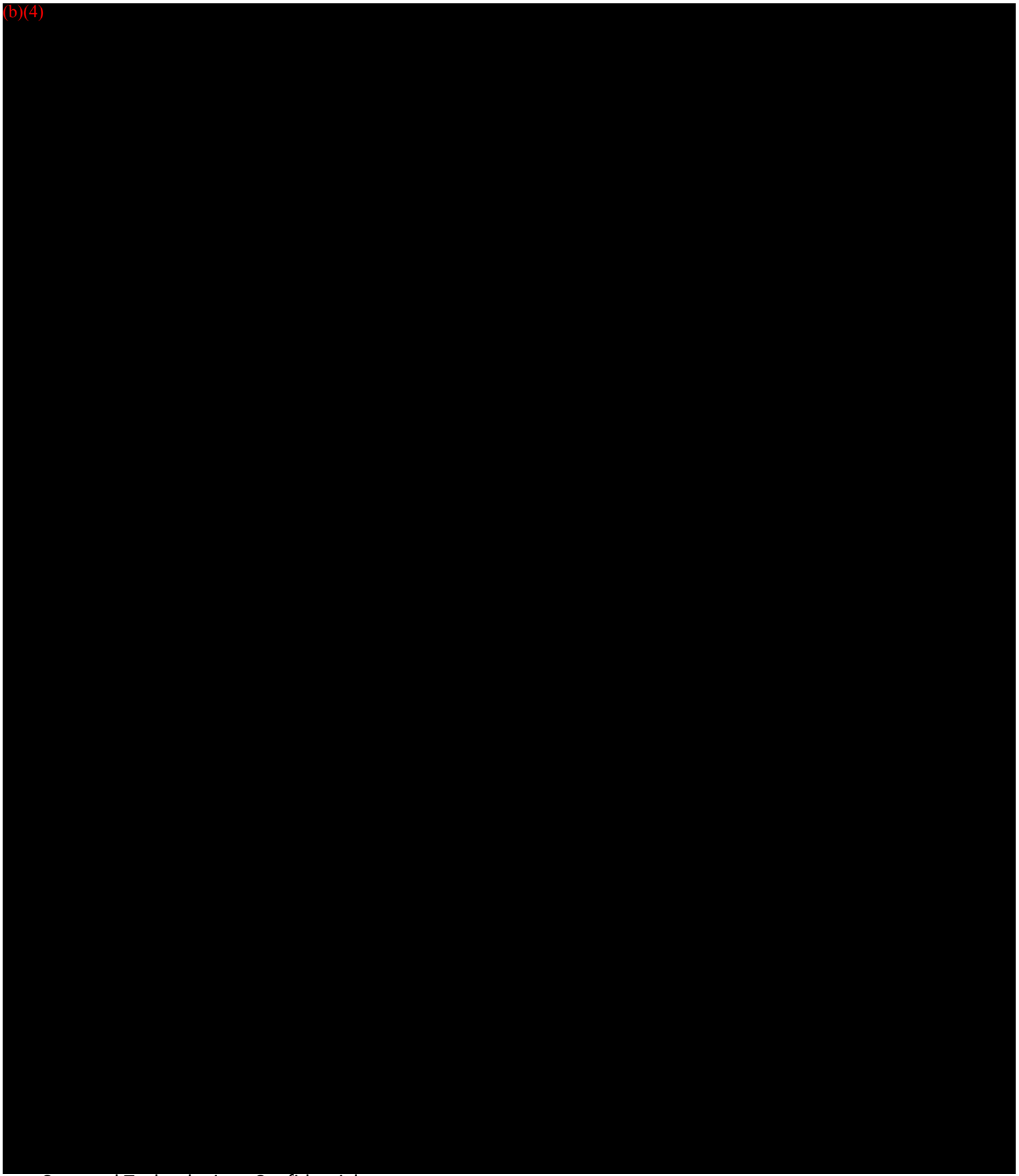
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Kaolin+$CaCl_2$+Heparinase Reagent Interference Protocol

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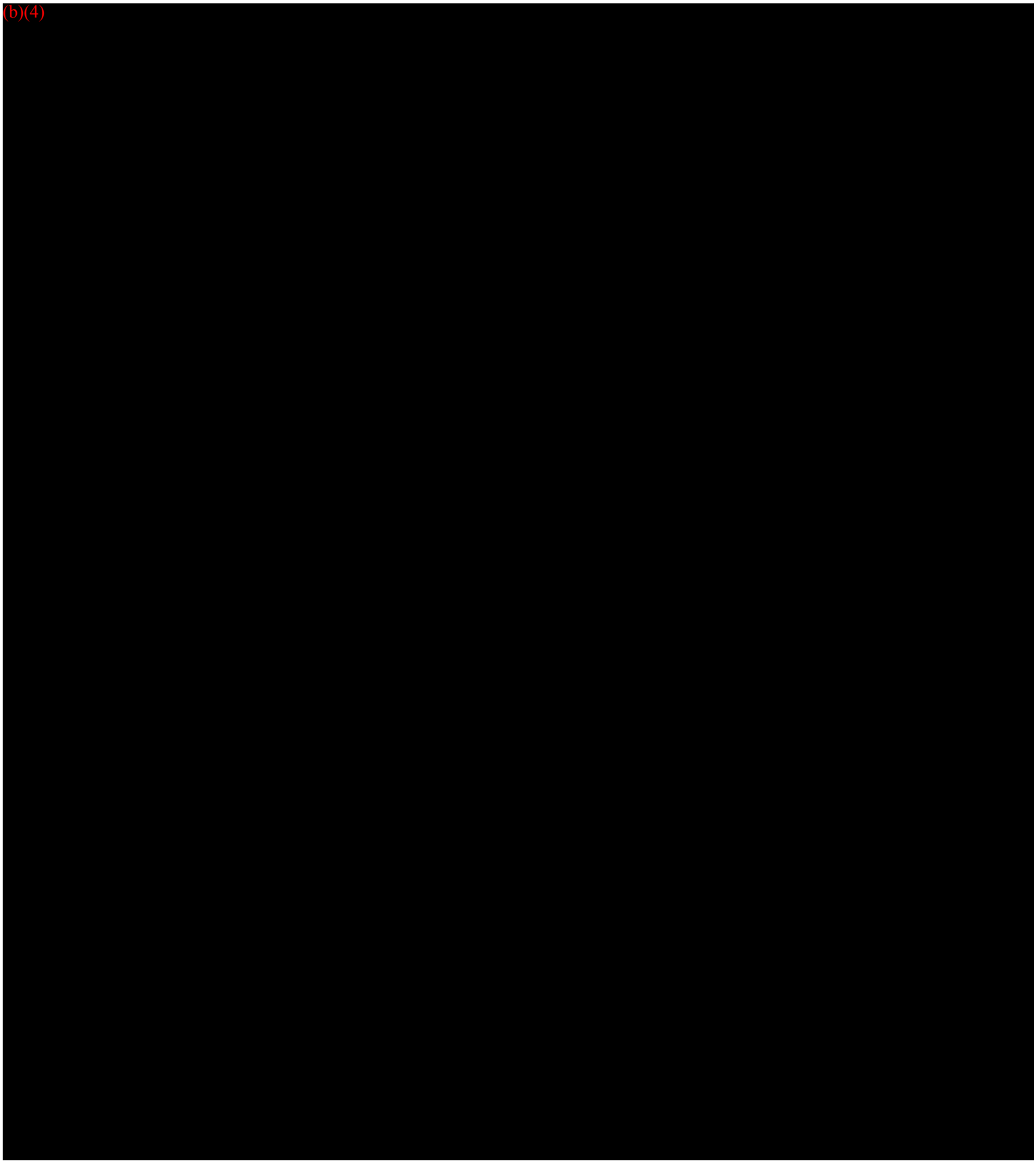
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Functional Fibrinogen (FF) Reagent Interference Protocol

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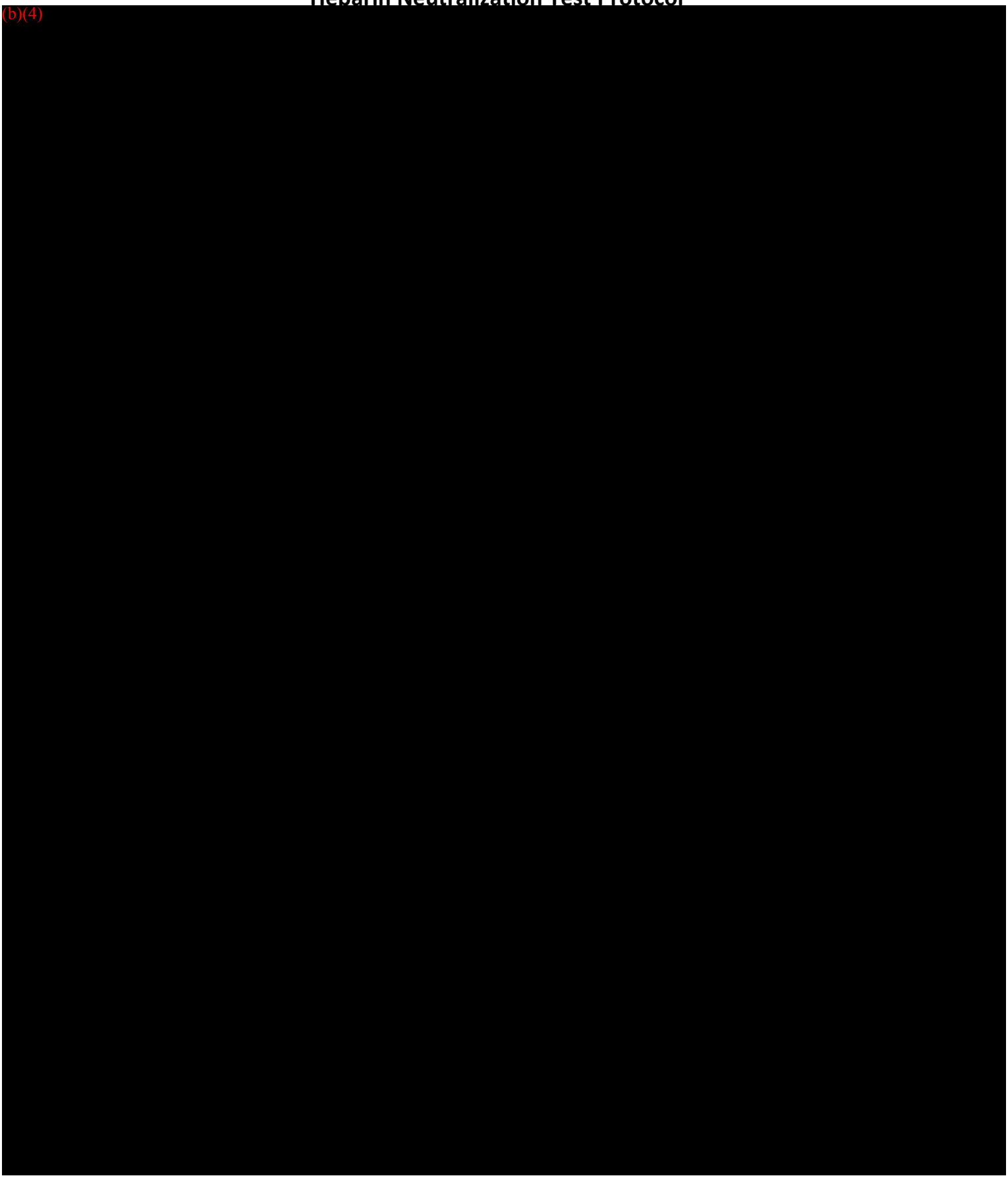
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Heparin Neutralization Test Protocol

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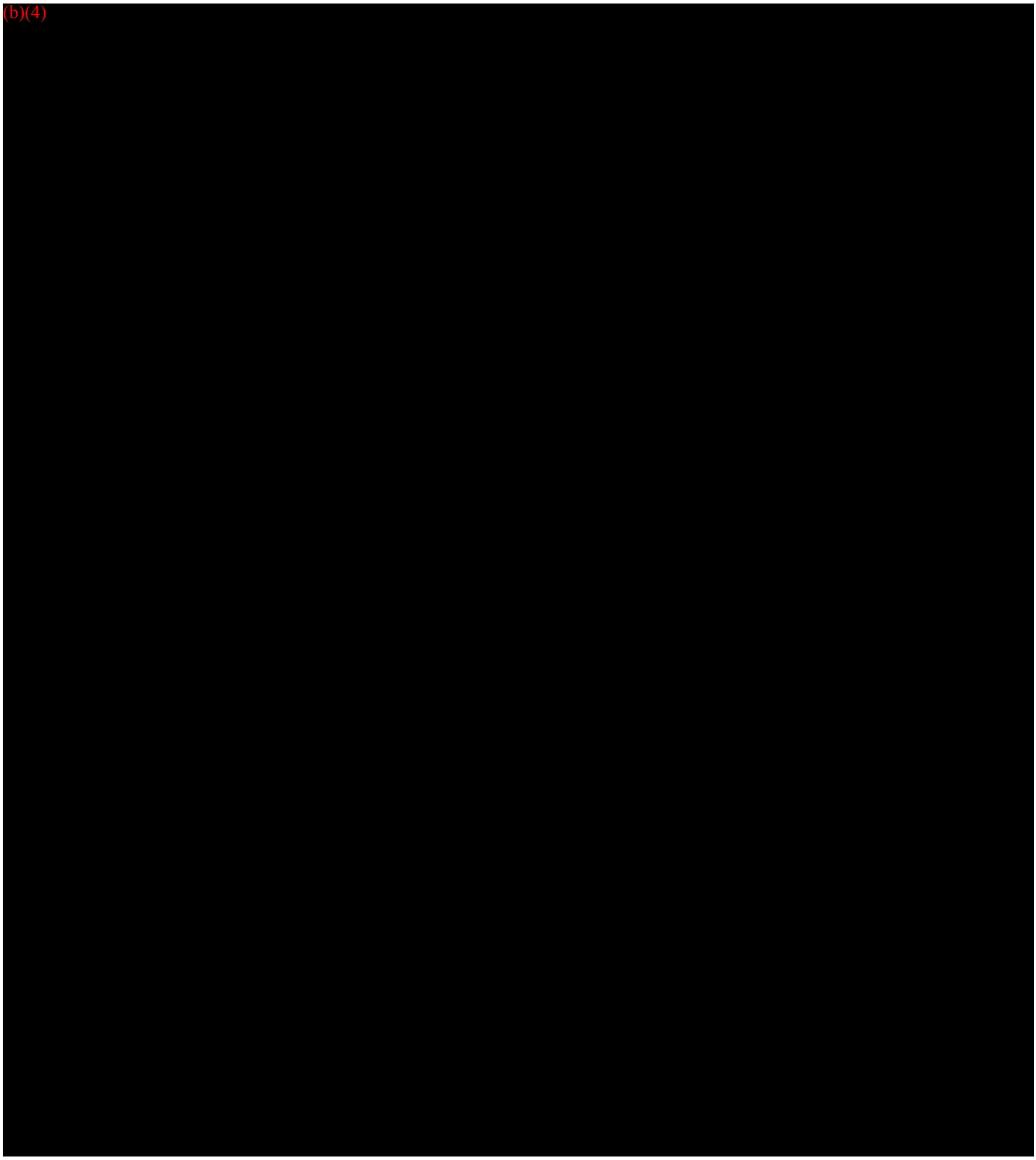
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Functional Fibrinogen (CFF) Linearity Fibrinogen Concentrations

(b)(4)



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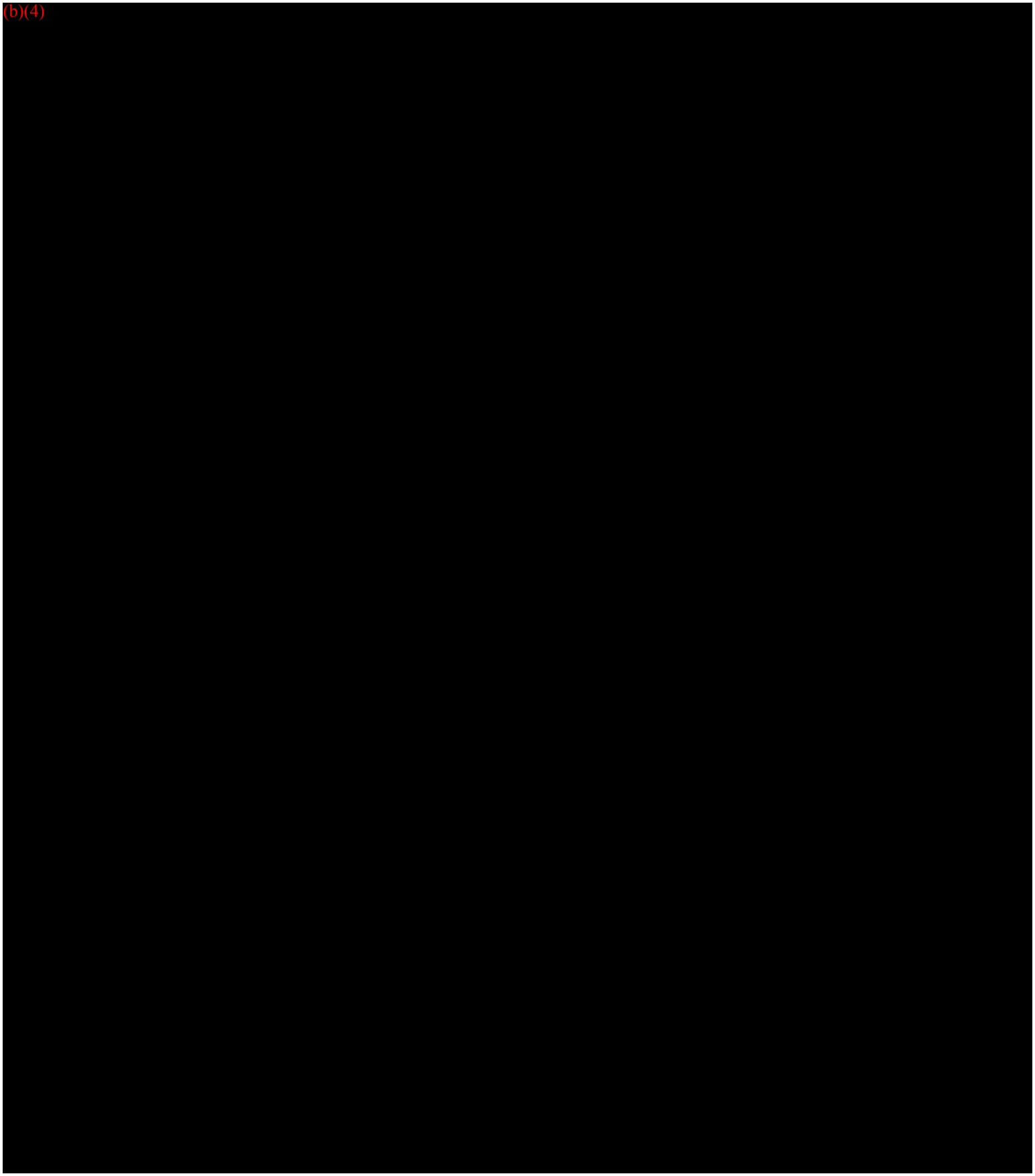
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Functional Fibrinogen (CFF) Reagent Linearity Protocol

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June 5, 2015

RE: 510(k) #K150041 Supplement: Additional Information

The enclosed documentation and eCopy (on CD) is being submitted as a supplement to 510(k) #K150041 for Coramed's CORA® System. The eCopy is an exact duplicate of the paper copy, except that statistical data files are only provided in the eCopy "Statistical Data" folder.

This supplement provides formal documentation of information already sent to FDA via email over the period 6/3/2015 – 6/5/2015. It includes the following.

(b)(4)

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We believe that this supplement contains all the information requested by FDA, and look forward to your favorable response. Please let us know if anything needs further clarification or if more information is required

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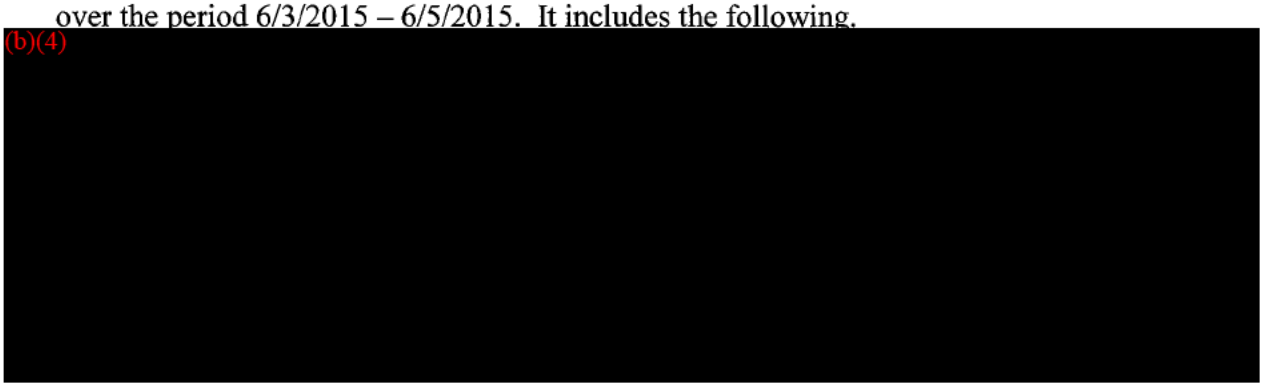
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Proprietary Name and Established Name

Proprietary Name: CORA® (Coagulation Resonance Analysis) System and the following citrated assays and reagents

CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent

Established Name: Whole Blood Hemostasis System

Intended Use

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The Citrated Multichannel Cartridge, to be used with the CORA System analyzer, contains four independent assays (CK, CRT, CKH and CFF), described below.

The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).

The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CKH assay monitors the effects of heparin in 3.2% citrated whole blood specimens on the CORA System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests.

The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Summary and Explanation of the Test

The CORA System and the Citrated Multichannel Cartridge are used to test the hemostasis properties of citrated blood samples using four different assays/reagents simultaneously, one in each of the four cartridge channels. For the CK assay, Kaolin-activated test methods are used to reduce variability and to reduce the running time of a native whole blood sample. The CRT assay maximally accelerates the clotting process by simultaneously activating the intrinsic and extrinsic coagulation pathways, allowing

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for the maximum clot strength to be reached more quickly. CKH is similar to CK but with the addition of heparinase, to neutralize the effects of heparin in the blood. If there is heparin present, the R time for CK will be significantly longer than the R time for CKH. The CFF assay fully inhibits all the platelets, thereby excluding their contribution to clot strength, and therefore measures only the functional fibrinogen contribution to clot strength.

Principles of the Procedure

CK Principle

Kaolin is a standardized reagent consisting of dry Kaolin and 0.85% Saline solution. Kaolin-activated test methods are used to reduce variability and to reduce the running time of a native whole blood sample. Use of these particles of hydrated aluminum silicate shortens coagulation time because Kaolin acts as a contact surface activator (intrinsic pathway), which activates Factor XII and platelets and stimulates the reserve clotting ability of a blood sample. Kaolin is combined with $CaCl_2$ to neutralize any sodium citrate in the blood.

CRT Principle

RapidTEG maximally accelerates the clotting process by simultaneously activating the intrinsic and extrinsic coagulation pathways using a high concentration of Kaolin and Tissue Factor (TF). This closely reflects the physiological clotting process and yields results significantly faster than a native, Kaolin, and/or TF activated test. $CaCl_2$ is included to neutralize any sodium citrate in the blood.

CKH Principle

Heparin is commonly used as an anticoagulant in surgical procedures. Even very low concentrations of Heparin, fractions of IU/mL of blood, can noticeably increase the R time and can even completely anticoagulate the blood, making it difficult if not impossible to monitor developing coagulopathies that are masked by high levels of therapeutic Heparin. The Kaolin with Heparinase assay will rapidly and specifically neutralize the anticoagulant property of Heparin. $CaCl_2$ is included to neutralize any sodium citrate in the blood

CFF Principle

The Functional Fibrinogen reagent activates the extrinsic pathway using tissue factor and inhibits platelet aggregation using a platelet inhibitor that binds to GPIIb/IIIa receptors. The Functional Fibrinogen reagent fully inhibits all the platelets, thereby excluding their contribution to clot strength (MA), and therefore measures only the functional fibrinogen contribution (MA_{PI}) to clot strength. Functional Fibrinogen is combined with $CaCl_2$ to neutralize any sodium citrate in the blood. Determining the independent contribution of platelets and fibrinogen further improves the use of the CORA System in helping to detect and diagnose hemostasis defects.

Reagents

CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
Dried Kaolin and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 35.45% Kaolin (concentration 0.011896% w/w), 21.97% water, and 42.58% Calcium Chloride 2 M solution.

CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
Dried Kaolin, Tissue Factor and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 11.73% Kaolin (concentration 14.098 % w/w), 46.92% Tissue Factor (concentration 3.88 µg/mL), and 41.35% Calcium Chloride 2M solution.

CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
Dried Kaolin and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 57.42% Kaolin (concentration 0.012854% w/w) and 42.58% Calcium Chloride 2 M solution; dried Heparinase,

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900 nL spot in blood well of channel, consisting of 23.66% Heparinase (concentration 0.38 IU) and 76.34% water.

CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent
Dried Tissue Factor and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 58.65% Tissue Factor (concentration 0.00055 µg/mL) and 41.35% Calcium Chloride 2 M solution; dried ReoPro®, 900 nL spot in blood well of channel, consisting of 100% ReoPro®.

Warnings or Precautions:

For In-Vitro Diagnostic Use

Sources of Reagent Error

Cartridges should be refrigerated (2° C to 8° C) when not in use.

Sources of Procedural Error

Use only citrated tubes. Do not collect blood samples into heparin tubes or any other tubes not specifically recommended.

Instructions for reconstitution, mixing, dilution, etc.

None required.

Handling Instructions:

While operating the CORA system, wear powder-free examining gloves and wash hands immediately after removing the gloves. Also, operators should switch gloves between patients and after completion of testing, and wear fluid-resistant clothing.

Storage instructions

CORA Citrated Multichannel cartridges are for single use only and should be stored refrigerated at 2°C to 8°C prior to removal from storage for use. Cartridges should be discarded after use.

Analyzer

Refer to CORA System User's Manual

Specimen Collection and Preparation for Analysis

Use only citrated tubes for blood draws. No additives or preservatives are necessary to maintain the integrity of the sample, but samples must be used within 2 hours of draw to maintain in-use stability.

Known Interfering Factors

CK assay was tested for interference factors according to CLSI EP7-A2. Potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Only Hemolysis, and Hemodilution levels above 20%, were found to be interferents.

CRT assay was tested for interference factors according to CLSI EP7-A2. Potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). All except EACA and Absence of a Discard Tube were found to be interferents, with Hemodilution being an interferent above 20% concentration.

CKH assay was tested for interference factors according to CLSI EP7-A2. The potential interferent tested was Protamine. Results show that Protamine is an interferent at concentrations above 0.062 mg/mL.

CFF assay was tested for interference factors according to CLSI EP7-A2. Potential interferents tested were Heparin and Hemodilution. Heparin was found to be an interferent for Functional Fibrinogen above Heparin concentrations of 1 IU/mL, and Hemodilution was found to be an interferent above hemodilution levels of 30%.

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Procedure

Materials Provided

One (1) Citrated Multichannel cartridge sealed with desiccant pack in foil pouch. Cartridge contains the following dried reagents: Kaolin, RapidTEG, Kaolin with Heparinase and Functional Fibrinogen, all with Calcium Chloride.

Materials Required (but not supplied)

CORA® Analyzer (Coramed Technologies) – see User's Manual for instructions for use.
Transfer pipette(s) (Samco Scientific #212 or equivalent)
Blood drawing supplies (any medical supplier)

Test Procedure

1. Remove the cartridge from refrigerated storage.
2. Tear open the pouch, remove the cartridge and discard the pouch and desiccant pack.
3. From the main menu on the CORA analyzer, select "new test".
4. Select the patient ID you wish to use. If the patient is not listed, you may add a new patient by selecting the "+" option and entering a patient ID on the screen. Then press "next".
5. Insert the cartridge into the slot as indicated on the screen with the bar code on the left side.
6. After the cartridge pretest is completed and you have verified that the assay is what you intended to run, press "next". If the cartridge is not the desired assay, press "stop" and start over.
7. Add blood to the cartridge sample port to above the level indicated on the cartridge.
8. After loading the sample press "next".
9. The test will run and results will be displayed as they become available.
10. When the test is completed, the analyzer will prompt to remove the cartridge and will return to the table of results.
11. Remove the used cartridge from the slot as demonstrated on the LCD display, and discard the cartridge.
12. Press "done" from the results screen to return to the home page.

Calibration

The CORA analyzer does not require routine calibration.

Quality Control Procedures

The CORA analyzer performs internal QC checks during a pretest when the cartridge is inserted. This verifies that all electromechanical and pneumatic functions of the analyzer-cartridge combination are operating satisfactorily. Laboratories should perform additional QC testing as required by their laboratory's procedures. Coramed provides Abnormal WQC materials to be used for this purpose.

Whereas the internal QC of the analyzer effectively tests analyzer functions, a QC methodology is required to verify that reagents in cartridges are still viable at time of use. This ensures that cartridges have not been mishandled between production and arrival at the lab, or have not been subject to adverse environmental conditions or otherwise mishandled while in lab storage. This can supplement the laboratory's development of its own Individualized Quality Control Plan (IQCP) based on the lab's risk analysis, in accordance with CLSI EP23. This risk analysis would take into account the lab's specific situations that could affect reagent quality, such as environmental storage controls.

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Coramed recommends that normal and abnormal donor control checks be performed for each new shipment of citrated multichannel assay cartridges. Additional QC checks may be performed on a monthly, weekly, daily or shift basis based on the laboratory's quality control policies. The end user should follow the recommendations of local and state regulatory agencies as well as facility policies.

Coramed recommends that the lab perform two levels of QC testing whenever indicated by the IQCP using the following procedure.

i. Establish a known normal quality control using blood drawn from healthy adults.
ii. The normal donor control should not have taken any medication known to affect coagulation levels and should have prior citrated multichannel cartridge tests that have fallen within the established normal reference ranges.
iii. Prepare an abnormal quality control using Abnormal WQC material, representing an abnormal sample, following instructions in the Abnormal QC Material Product Insert, #01-182.
iv. The "normal" donor should have test results that fall within established reference ranges. For the Abnormal WQC sample, reagent performance is verified if parameters fall within the following Reference Ranges

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (degrees)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563 - 873

Results

No calculations are necessary to obtain test results; these are displayed on the CORA analyzer display, and may be printed if a printer is attached.

CK Test Results

The R, K, Angle and MA parameters are measured and displayed at the conclusion of the test, along with the corresponding reference ranges established for these parameters.

CRT Test Results

The MA parameter is measured and displayed at the conclusion of the test, along with the corresponding reference ranges established for these parameters.

CKH Test Results

The R parameter is the only one of importance for this test. It is measured and displayed at the conclusion of the test, along with the corresponding reference range established for the R parameter for Kaolin with Heparinase.

CFF Test Results

The MA parameter and the estimated Functional Fibrinogen Level (FLEV) are measured and displayed at the conclusion of the test.

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Limitation of the Procedure

Use of Results

CORA results should always be considered within the clinical context of the individual patient's case. In the event of inconsistencies with the patient's clinical status, samples should be repeated or supplemented with additional clinical information and/or data.

Expected Values

Expected values for test results are within the Reference Ranges for a reference population that were established according to CLSI C28-A3c. The following tables contain the reference range data for each reagent and parameter. It is recommended that customers validate reference ranges based on their local population.

CK Reference Ranges

Citrated Blood Parameter	N	Range
R (min)	157	4.6 – 9.1
K (min)	157	0.8 – 2.1
Angle (deg)	155	63 - 78
MA (mm)	151	52 - 69

CRT Reference Ranges

Citrated Blood Parameter	N	Range
MA	152	52 - 70

CKH Reference Ranges

Citrated Blood Parameter	N	Range
R	155	4.3 – 8.3

CFF Reference Ranges

Citrated Blood Parameter	N	Range
MA	151	15 - 32
FLEV	152	278 - 581

Specific Performance Characteristics

CK Precision

The precision of the CORA Kaolin test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the Kaolin Assay was CV less than 15% for the R parameter, less than 10% for the MA parameter, less than 10% for the Angle parameter and less than 25% for the K parameter.

CK Sensitivity and Specificity

The Kaolin reagent is often used in conjunction with tests performed on blood samples from patients administered with heparin, with the goal of either determining heparin effect (titration of dose) or determining full reversal (post-protamine) of heparin administered. It is, therefore, important that the Clinical Sensitivity and Specificity for the presence of heparin be determined. Five different heparin spiked samples were examined, with concentrations spread across the heparin therapeutic ranges (0.2 to

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6.0 IU/mL). 0.2 IU/mL is the lowest therapeutic dose typically used and 6.0 IU/mL represents a typical dose of heparin used when patients are fully heparinized during cardio-pulmonary by-pass. In addition, five (5) non-heparin spiked samples were analyzed. Kaolin's sensitivity to Heparin was 100%, with the R parameter elongated and out of range for all concentrations. Specificity was also 100%, with all un-spiked samples having an R parameter within normal range.

CRT Precision

The precision of the CORA RapidTEG test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the RapidTEG Assay was less than 10% for the MA parameter.

CKH Precision

The precision of the CORA Kaolin with Heparinase test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the Kaolin with Heparinase Assay was CV less than 15% for the R parameter.

CKH Neutralization

The Kaolin with Heparinase assay was tested to verify that 6 IU of Heparinase per 1 mL of blood will effectively neutralize the effects of both Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) on Kaolin-activated citrated whole blood samples. This is the amount of Heparinase used in the Kaolin with Heparinase assay. Tests were performed using UHF and LMWH spiked samples and un-spiked samples. All tests reported R parameter values within the normal range, confirming the neutralization effectiveness of the assay.

CFF Precision

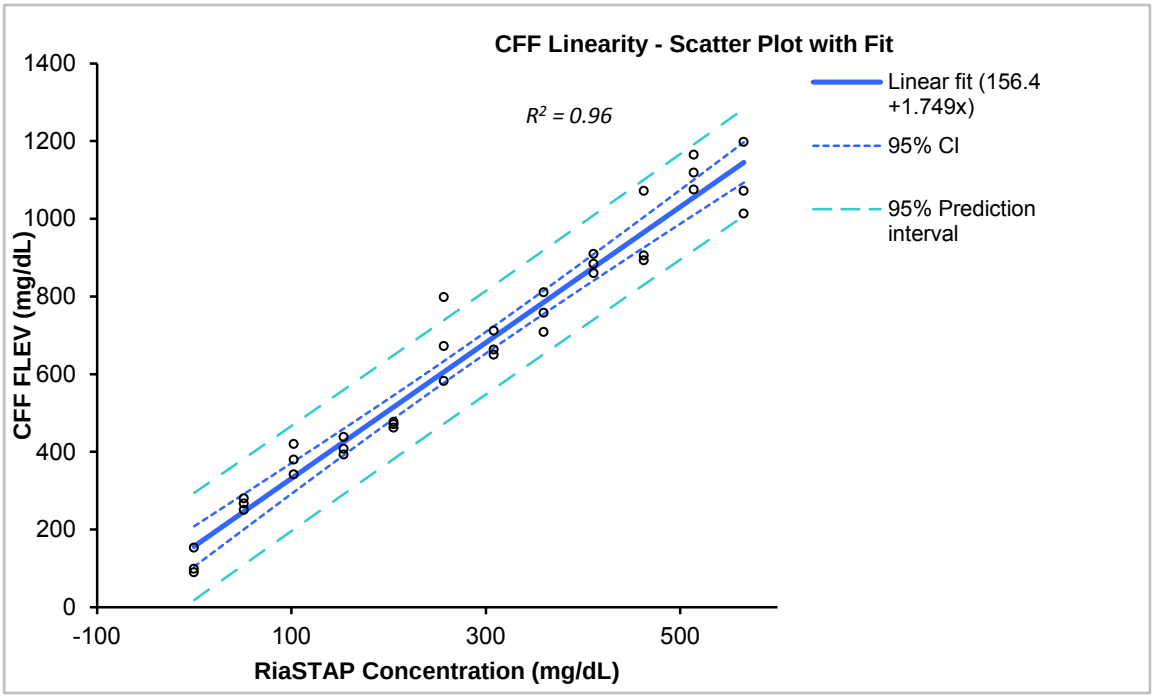
The precision of the CORA Functional Fibrinogen test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the Functional Fibrinogen Assay was CV less than 10% for the MA and FLEV parameters.

CFF Linearity

The Function Fibrinogen assay was tested for linearity according to CLSI EP6-A. Linearity with respect to Fibrinogen concentration levels is shown below.

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Clinical Performance - Method Comparison and Reader Studies

Method Comparison studies were conducted at three clinical sites on patient samples following CLSI EP09-A3 Guideline. The subjects enrolled were patients undergoing cardiovascular surgery or cardiology procedures, with blood samples drawn pre- and post-surgery and in the ICU. In order to broaden the range of comparison, up to 10% contrived samples were added. Summary statistics are presented below.

Method Comparison Statistics Summary – All Clinical Sites					
Parameter	**R**	**Intercept**	**95% CI**	**Slope**	**95% CI**
CK – R (min)	0.868	-0.325	-0.425	1.069	1.034
			-0.225		1.103
CK – K (min)	0.740	-0.097	-0.292	0.906	0.769
			0.098		1.042
CK – Alpha (deg)	0.680	7.305	-13.160	0.940	0.640
			27.769		1.240
CK – MA (mm)	0.924	2.351	0.166	0.948	0.912
			4.536		0.983
CKH – R (min)	0.812	-0.329	-0.393	1.057	1.026
			-0.265		1.089
CRT|CK – MA (mm)	0.929	-0.126	-1.909	0.978	0.948
			1.656		1.007
CFF – MA (mm)	0.938	-0.774	-1.836	1.126	1.072
			0.289		1.180
CFF – FLEV (mg/dl)	0.928	-12.495	-36.810	1.127	1.059
			11.819		1.194

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In addition, a Reader Study was conducted to assess the comparison of CORA System and TEG 5000 results based on reading printed test outcomes. The study was performed at three sites, using three experienced TEG 5000 doctors as readers at each site, for a total of nine readers. 30 test outcomes were compared for each of the reagent test categories, for a total of 270 reading comparisons per reader. Excellent agreement between the two devices was demonstrated.

In both the Method Comparison Study and Reader Study, the CORA RapidTEG (CRT) MA parameter was compared to the TEG 5000 Kaolin (CK) MA parameter, to demonstrate that the CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

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Name and Place of Business of Manufacturer:

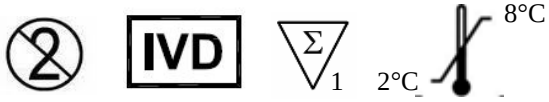


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Date of Issuance of Last Labeling Revision: June 3, 2015

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REF CRT-CC-0L2

Rx Only

CONTROL

Proprietary Name and Established Name

Proprietary Name: Abnormal WQC Material to be used with the CORA® (Coagulation Resonance Analysis) System

Established Name: Whole Blood Hemostasis System

Intended Use

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The CORA System records the kinetic changes in a sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The Abnormal WQC (Wet Quality Control) Material is to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Summary and Explanation of the Test

The CORA System is used to test the hemostasis properties of blood samples. The CORA analyzer performs internal QC checks during a pretest when the cartridge is inserted. This verifies that all electromechanical and pneumatic functions of the analyzer-cartridge combination are operating satisfactorily. Laboratories should perform QC testing as required in accordance with their laboratory policies and procedures.

Principles of the Procedure

The CORA Hemostasis System whole blood coagulation Abnormal Wet Quality Control contains a preparation of animal citrated plasma. It has been formulated specifically as a quality control for the CORA System, representing an "abnormally low" level of coagulation. This control contains no human material. It is for in vitro diagnostic use and professional use only.

Reagents

Abnormal Wet Quality Control Material

The Abnormal WQC Material consists of one 1 mL vial of lyophilized bovine citrated plasma and one 1 mL vial of diluent water for reconstituting the lyophilized material.

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Warnings and Precautions:

For In-Vitro Diagnostic Use

Hazards

The Abnormal WQC Material is potentially hazardous in case of ingestion, inhalation, skin contact and eye contact. It contains animal source material; therefore, it should be treated as potentially infectious. Use universal precautions for handling potentially bio-hazardous material. It may cause adverse effects for the environment if discarded improperly.

Sources of Reagent Error

- Do not freeze the controls.

Sources of Procedural Error

- Carefully follow the instructions for the preparation of the Abnormal WQC Material. For correct reconstitution, the full vial of diluent water must be poured into the vial of lyophilized control. Failure to do so may result in inaccurate results.
- Timing - Do not use controls if they have been reconstituted for more than 2 hours

Instructions for reconstitution, mixing, dilution, etc.

The entire contents of the diluent water vial must be placed into the Abnormal WQC vial for proper concentration, and thoroughly mixed.

Storage instructions

Abnormal WQC Materials are for single use only and should be stored refrigerated at 2°C to 8°C prior to removal from storage for use.

Analyzer

Refer to CORA System User's Manual

Specimen Collection and Preparation for Analysis

No specimen collection is required for running this quality control test. No additives or preservatives are necessary to maintain the integrity of the material, but reconstituted Abnormal WQC Material must be used within 2 hours of reconstitution.

Procedure

Materials Provided

One (1) Abnormal WQC vial and one (1) Water vial.

Materials Required (but not supplied)

CORA® Analyzer (Coramed Technologies)
Transfer pipette(s) (Samco Scientific #212 or equivalent)

Test Procedure (used in conjunction with Citrated Multichannel cartridges)

1. Remove the cartridge from refrigerated storage.
2. Tear open the pouch, remove the cartridge and discard the pouch and desiccant pack.
3. From the main menu on the CORA analyzer, select "new qc".
4. Insert the cartridge into the slot as indicated on the screen with the bar code on the left side.
5. After the cartridge pretest is completed and you have verified that the assay is what you intended to run, press "next". If the cartridge is not the desired assay, press "stop" and start over.
6. Prepare the Abnormal WQC sample according to the following instructions:
   a) Allow the control and the diluent water vial(s) to sit for approximately 10 minutes to equilibrate to room temperature.
   b) Make sure the control is on the bottom of the vial. You may need to tap the vial a few times.

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c) Remove the seal and stopper of the lyophilized control, taking care to avoid sharp metal edges.
d) Into each vial of lyophilized control, slowly pour 1 vial of 1 mL of diluent water, provided. Make sure no water drips out.
e) Re-insert the stopper into the control vial.
f) Hold the stopper in place, vigorously shake the vial until fully reconstituted, and then let it stand for 5 minutes at room temperature.
g) Shake the vial vigorously again and let stand 5 more minutes.

7. Using the transfer pipette, deliver the Abnormal WQC material to the cartridge sample port to above the level indicated on the cartridge.
8. After loading the sample press "next".
9. The test will run and results will be displayed as they become available.
10. When the test is completed, the analyzer will prompt to remove the cartridge and will return to the table of results.
11. Remove the used cartridge from the slot as demonstrated on the LCD display, and discard the cartridge.
12. Press "done" from the results screen to return to the home page.

Results

No calculations are necessary to obtain test results; these are displayed on the CORA analyzer display, and may be printed if a printer is attached.

Limitations of the Procedure

Use of Results

- Results outside of the normal ranges listed below may be caused by improperly prepared control material or product deterioration. It is recommended that any failed Abnormal WQC test should be repeated. Repeated failures should be reported to the supervisor.
- Do not report any patient results until the control parameters are within their appropriate ranges.

Expected Values

Expected values for test results are within the Reference Ranges that were established based on testing by Coramed, following Clinical and Laboratory Standards Institute (CLSI) publication C28-A3c, Defining, Establishing and Verifying Reference Intervals. Each laboratory may establish its own level of performance to monitor quality assurance. Follow your institution's policy to establish mean target values and ranges for the quality controls.

Reference Ranges for Abnormal WQC and Citrated Multichannel Reagents

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (degrees)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563 - 873

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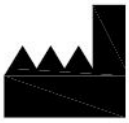
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Specific Performance Characteristics

Precision

The precision of the CORA Abnormal WQC Material was evaluated according to CLSI EP5-A2. Testing was performed in Coramed' laboratory for within-device (20-day tests using Abnormal WQC with citrated reagents), and multi-site reproducibility tests were performed across three sites, three lots, three operators and three analyzers. Results included Coefficient of Variance (CV) values for all tests completed. For these precision tests, the precision for the Abnormal WQC Material was CV less than 10% for all parameters.

Name and Place of Business of Manufacturer:



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6225 W Howard St
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Date of Issuance of Last Labeling Revision: June 4, 2015

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*
K150041

Device Name
CORA Hemostasis System - Abnormal Wet Quality Control (WQC) Material

Indications for Use *(Describe)*

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample.

The Abnormal Wet Quality Control Material is to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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K150041/A003

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Silver Spring, MD 20993-0002

June 23, 2015

RE: 510(k) #K150041 Amendment: Additional Information

The enclosed documentation and eCopy (on CD) is being submitted as an amendment to 510(k) #K150041 for Coramed's CORA® System. The eCopy is an exact duplicate of the paper copy.

This supplement provides formal documentation of information already sent to FDA via email over the period 6/22/2015 – 6/23/2015. It includes the following.

(b)(4) [redacted]

We believe that this amendment contains all the information requested by FDA, and look forward to your favorable response. Please let us know if anything needs further clarification or if more information is required

Sincerely,

Norman E. Brunner
Director of RA/QA
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(847) 647-8800 ext. 16

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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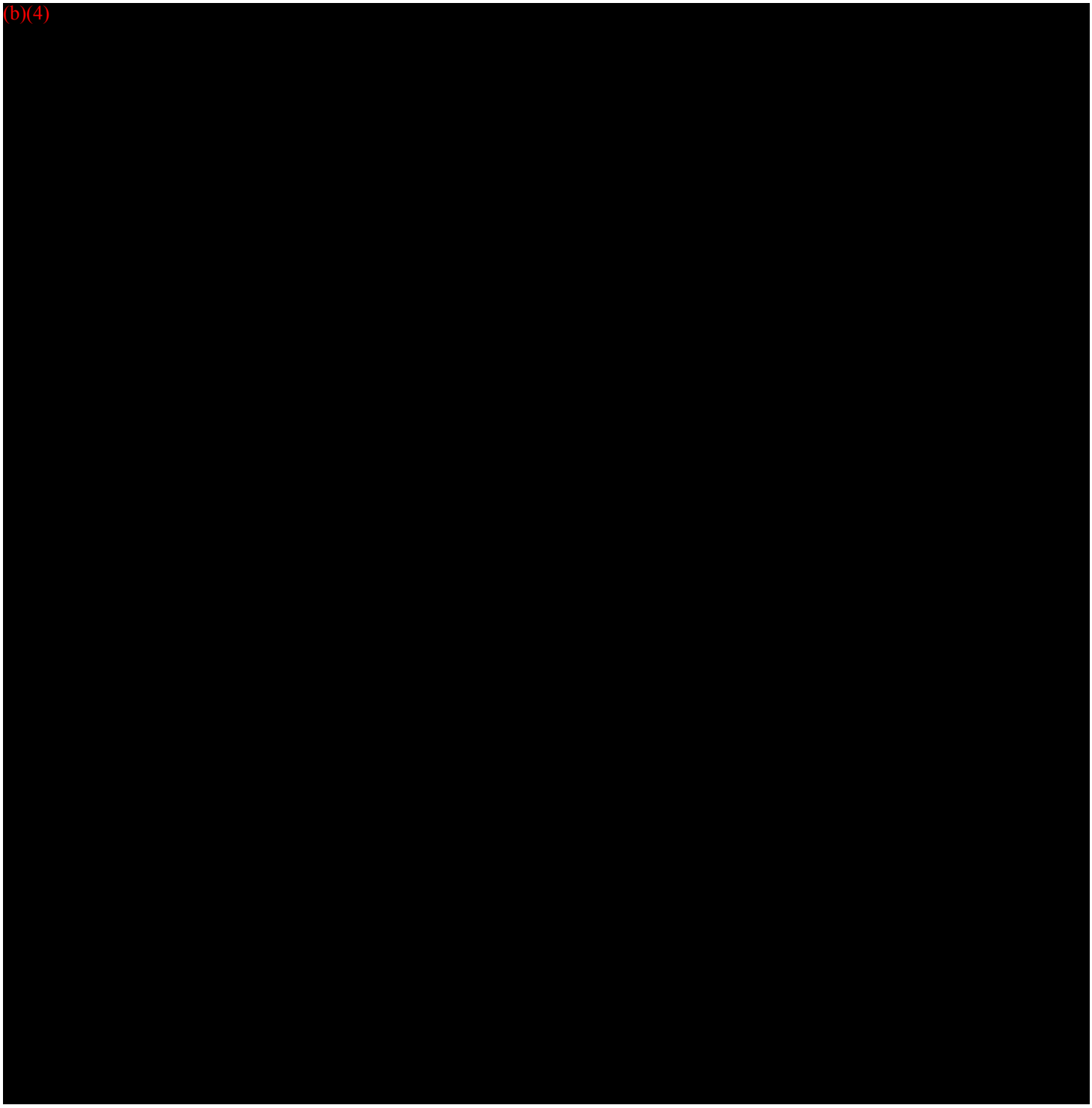
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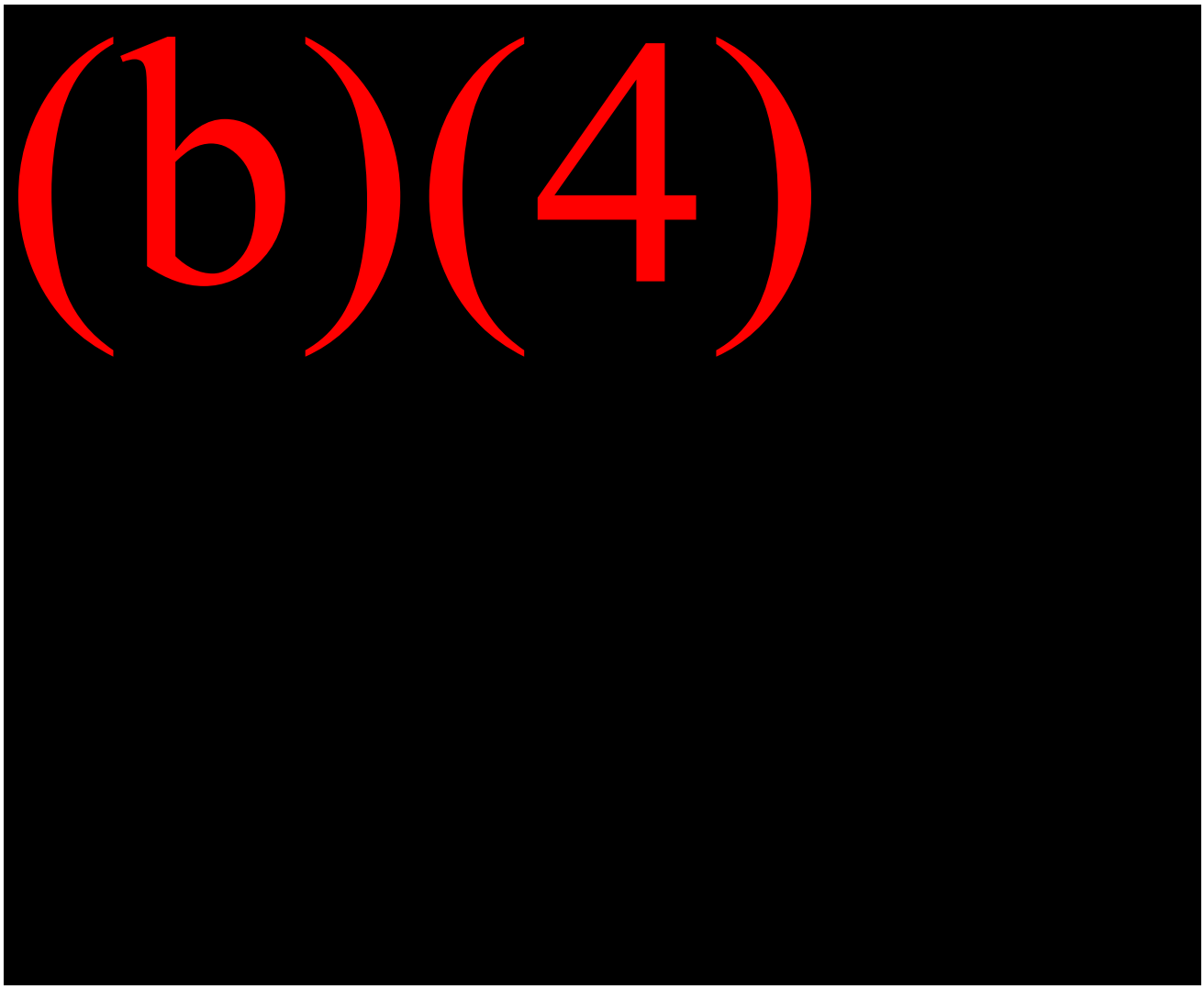
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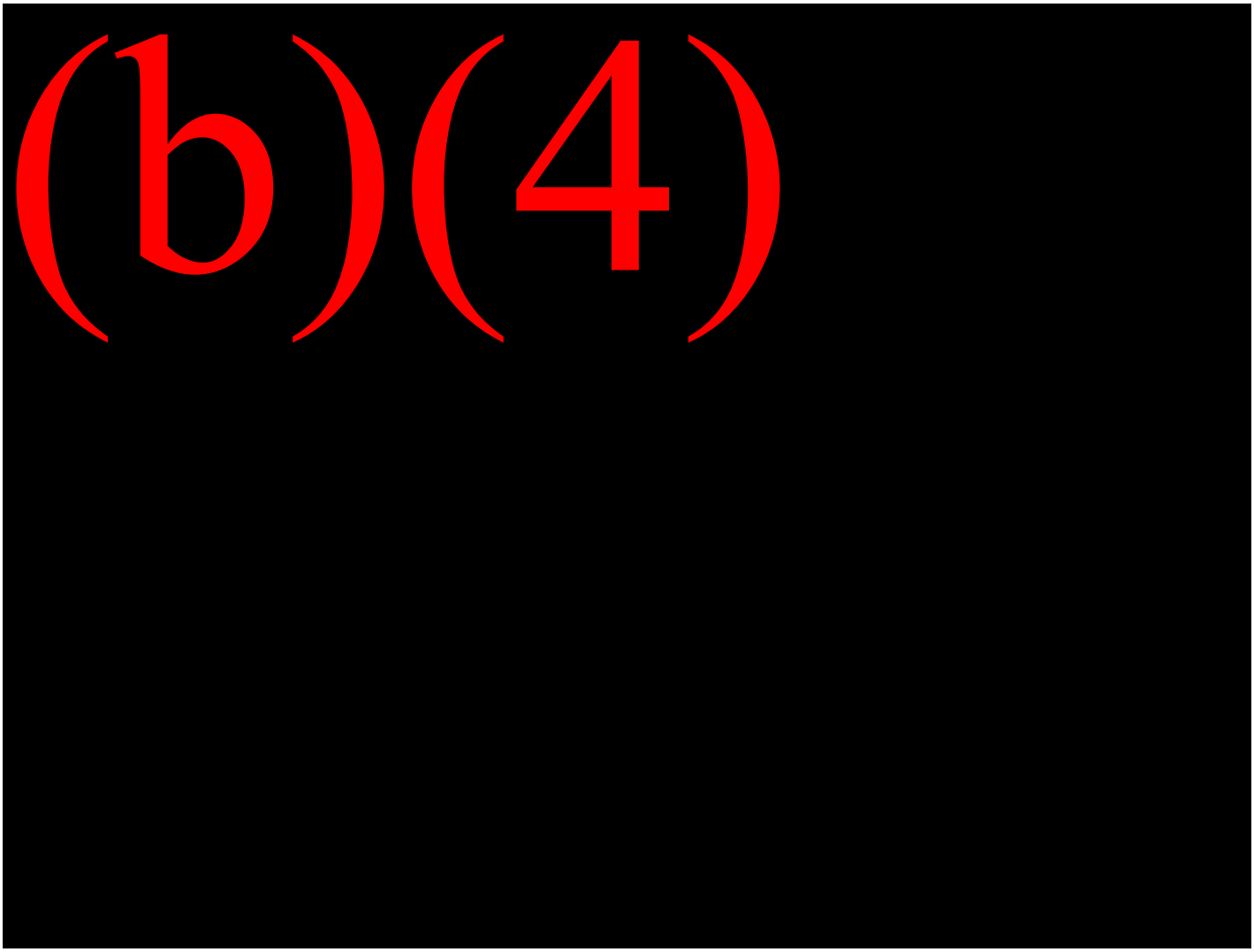
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CORA® System 510(k) Summary

APPLICANT INFORMATION

Name of Manufacturer: Coramed Technologies, LLC

Manufacturer Street Address: 6225 W. Howard St.

City, State, Zip: Niles, IL 60714

Phone Number: (847) 647-8800

FAX Number: (847) 510-0502

Contact person for all communications: Norman E. Brunner

Email for contact person: nbrunner@coramedtech.com

Date that Summary was prepared: June 23, 2015

DEVICE INFORMATION

Trade name (proprietary name): CORA® (Coagulation Resonance Analysis) System and the following assays and reagents

- Citrated Assays and Reagents
  - CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
  - CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
  - CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
  - CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent

Common name (usual name): Whole Blood Hemostasis System

Classification Name: 21CFR 864.5425 Multipurpose System for *in vitro* Coagulation Studies

PREDICATE DEVICE

- Thrombelastograph® Coagulation Analyzer (TEG®) – 5000 Series, K002177, Product Code JPA (System, Multipurpose, for In Vitro Coagulation Studies), Haemoscope Corporation

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DESCRIPTION OF THE DEVICE

System Description

The CORA System consists of a four-channel diagnostic analyzer with integrated computer module, system reagents (CK, CRT, CKH, and CFF), and Abnormal Quality Control material and microfluidic test cartridges. See below for a description of system reagents. Reagents are dried-in-place within the cartridges during manufacturing. Abnormal Quality Control material is lyophilized and can be reconstituted with water as needed for WQC testing with reagent cartridges.

To perform a test, a disposable CORA Cartridge is inserted into the analyzer. Blood or WQC material is added to an entry port on the cartridge and drawn into the cartridge under analyzer control. The amount of the sample drawn into the cartridge is automatically determined by the volume of the blood chambers in the cartridge. Once in the disposable, the sample is metered into as many as four separate analysis channels, depending upon the assays being performed. Reconstitution of reagents dried within the cartridge is accomplished by moving the sample back and forth through reagent chambers, under the control of microfluidic valves and bellows (pumps) within the cartridge. After each sample has been mixed with reagent, it is delivered to a test cell where it is monitored for visco-elastic changes due to coagulation. Excess sample material is moved under microfluidic control into an enclosed waste chamber within the cartridge.

The CORA Measurement Technique

The CORA technology is based on a disposable containing up to four independent measurement cells. Each cell consists of a short vertically-oriented injection molded tube (ring) with a diameter of 2.5mm and a length of 4.5mm. Detection of clotting in the CORA System is performed optically. Under control of the analyzer, approximately 20µl of prepared sample is delivered to the tube, where a meniscus naturally forms at each end of the tube. The tube is positioned so that the lower meniscus partially blocks light traveling from a collimated source toward a photodiode.

During testing, a piezoelectric actuator drives the measurement cell(s) through a motion profile composed of summed sinusoids at different frequencies. The profile has a maximum amplitude of under 10µm and contains frequencies from 10-500Hz. Some, but not all, of the measurement cell motion will induce motion in the sample meniscus, which will be detected by the photodiode. The resulting motion of the meniscus is monitored optically and recorded by the analyzer to calculate the resonant frequency and modulus of elasticity (stiffness) of the sample. By performing a Fast Fourier Transform (FFT) on meniscus motion data, it is possible to determine the frequencies of input motion that caused the greatest deflection of the sample (these are called the resonant frequencies).

Resonance is the tendency of a material or structure to oscillate with greater amplitude at some frequencies than others. The exact frequencies at which resonance occurs will depend on the stiffness and mass of the sample. Stiffness, in turn, is a function of a material's modulus of elasticity and the boundary conditions to which the material is exposed, such as the geometry and materials of a test cell. By holding these boundary conditions and sample mass constant from run to run, the CORA System allows direct comparison of elasticity between samples.

In a typical test, blood that has been delivered to the measurement cell will not clot for several minutes. During this time the sample has no inherent stiffness except that provided by surface tension, and since this remains constant the measured resonant frequencies will not change. Once clotting begins, however, the elastic modulus and thus the resonant frequencies increase rapidly. During fibrinolysis, the process is reversed, with elastic modulus and resonant frequencies decreasing. In tests where clotting does not occur, the resonant frequency of the sample will not change. During coagulation, however, a clot will bind to the test tube (ring) and the resonant frequency will rise with increasing firmness of the clot. The

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CORA Analyzer collects meniscus motion data, tracks changing resonant frequencies and analyzes the frequency data to provide semi-quantitative parameters describing the clot. Results are presented in a format similar to the TEG 5000.

Both the TEG 5000 and CORA System monitor the elastic modulus of clots. Method Comparison testing has been performed, yielding data from approximately 300 patients from three sites (Mayo Clinic, University of Pittsburgh Medical Center, and Sinai Hospital, Baltimore). These data include all applicable parameters from the four citrated tests (CK, CKH, CRT and CFF). The TEG 5000 measures the changes of the linkage forces of the clot between the cup and pin over time, while the CORA System measures the changes of the resonant frequency of the clot over time. Despite the difference in the way the two analyzers measure the changes in the modulus of elasticity of the clot over time, they measure the same physical phenomenon and produce the same result when converted from their specific units of measurement (forces for the TEG5000 and frequency for the CORA System) to millimeters. The fact that these results are similar across all reagents used in both technologies is demonstration that the two technologies measure the same phenomenon, the changes in elastic modulus.

The following definitions apply to calculated parameters in the CORA System:

CORA Parameter	Definition	Parameter Relation to Hemostasis
R	R is the time from the start of the test until initial fibrin formation. This represents the enzymatic portion of coagulation.	Normal / reduced / increased speed of coagulation initiation
K	K is the time after R needed to reach a certain level of clot strength. This represents clot kinetics.	Normal / reduced / increased speed of coagulation amplification and propagation
Alpha α (angle)	Alpha is the angle representing the rate increase in the clot strength and the rapidity of fibrin build-up and cross-linking.	Normal / reduced / increased speed of coagulation amplification and propagation
MA	MA, or Maximum Amplitude, represents the maximum firmness of the clot during the test.	Normal / reduced / increased clot elasticity/strength
FLEV	FLEV is an estimate of the fibrinogen level in the blood sample.	Estimated Functional Fibrinogen Level

Citrated Assays

The CK assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle), and Maximum Clot Strength (MA). K and Alpha are complementary parameters and should be used in conjunction with Clotting Time (R) and Maximum Clot Strength (MA).

The CRT assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via both the intrinsic and extrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CFF assay is a semi-quantitative *in vitro* diagnostic assay for monitoring hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. CFF is used in conjunction with CK and clotting characteristics are described by the functional parameter Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

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The CKH assay is a semi-quantitative *in vitro* diagnostic assay used in conjunction with the CORA System to monitor the effects of heparin in the blood stream of a patient. CKH is used in conjunction with CK and heparin influence is determined by comparing Clotting Times (R) between the two tests.

Wet Quality Control (WQC)

Abnormal Wet Quality Control (WQC) material consists of bovine plasma with buffers and stabilizers, and is used instead of hypocoagulable blood, in conjunction with the Citrated Multichannel system cartridge. When used with the Citrated Multichannel cartridge, this material provides consistent and repeatable values for CORA parameters to confirm reagent quality and viability.

Abnormal WQC Intended Use

The Abnormal WQC (Wet Quality Control) Material is intended to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

INTENDED USE AND INDICATIONS FOR USE

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The CORA System records the kinetic changes in a sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARING THE CORA SYSTEM TO THE TEG 5000 PREDICATE DEVICE

Table of Similarities

Item	TEG® 5000 Predicate	CORA® System
Analyzer		
Technological Purpose	Monitoring the response of a clot to low levels of applied strain	Monitoring the response of a clot to low levels of applied strain
What is measured	Changes in clot elasticity over time	Changes in clot elasticity over time
Initial Warm Up Time	5 min	5 min
Time to Complete a Test	Varies with assay	Same as TEG 5000
Assays and Reagents		
Intrinsic Contact Activation Reagent (CK)	Kaolin and $CaCl_2$	Kaolin and $CaCl_2$, same materials as TEG 5000

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Item	TEG® 5000 Predicate	CORA® System
Intrinsic Contact Activation Reagent with Heparinase for heparin reversal (CKH)	Kaolin and $CaCl_2$ with Heparinase	Kaolin, Heparinase and $CaCl_2$, same materials as TEG 5000
Citrated RapidTEG (CRT) (Tissue Factor and Kaolin Activation)	Tissue Factor (TF), Kaolin and $CaCl_2$	Tissue Factor (TF), Kaolin and $CaCl_2$, same materials as TEG5000
Citrated Functional Fibrinogen (CFF) / Platelet-Blocked (Tissue Factor Activation)	ReoPro®, Tissue Factor and $CaCl_2$, same materials as CORA	ReoPro®, Tissue Factor and $CaCl_2$, same materials as TEG 5000
Calcium Chloride Reagent (CC) (for re-calcification)	$CaCl_2$ reagent	$CaCl_2$ same materials as TEG 5000
Quality Control Material (WQC Abnormal Control)	TEG coagulation control – Level II	TEG coagulation control – Abnormal, same materials as TEG 5000

Table of Differences

Item	TEG® 5000 Predicate	CORA® System
Analyzer	Thrombelastography analyzer, separate computer and software	Fully integrated Thrombelastography analyzer
Measuring Technique	Direct-contact measurement of shear elasticity of a coagulating sample	Non-contact measurement of shear elasticity of a coagulating sample
Measuring Channels	Two, each independent and interchangeable (can be used with any approved reagent)	Four, each independent and interchangeable (can be used with any approved reagent)
Signal Transducer	Electromechanical detection (rotary variable inductive transformer) of rotary motion of a pin suspended in the sample	Optical detection (silicon photodiode) of the motion of a free surface of the sample
Temperature Control	20° to 40°C	20° to 50°C
Sample Volume (per channel)	360-380 µl	63 µl
Total Reaction Volume (single channel)	360-380 µl	20 µl
Mains Supply Voltage	120V, 60Hz and 220V, 50Hz model available	100-240V, 50-60Hz (international power supply)
Analyzer Input Voltage	24 volts AC, 30 watts max	12 volts DC, 60 watts max
Environment	Level and vibration free position, no solar radiation Operating temperature: 10° to 35 °C Storage Temperature: -30° to +50 °C (analyzer only) Relative humidity 20-80% (non-condensing)	Stable and level surface. Operating Temperature 10° to 32°C Storage Temperature: -20° to 50°C (analyzer only) Relative humidity 20 to 80% (non-condensing)

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Item	TEG® 5000 Predicate	CORA® System
Sample Preparation	Performed by the operator using pipettes to reconstitute reagents and mix reagents with the sample	Performed under analyzer control within the disposable cartridge
Pipetting	Manual accurate pipettes (10, 20, 50, 100, 340, 360, 500, 1000µl)	Unmetered transfer pipette or syringe; blood sample is added until it fills to a level above the line marked on the blood intake well of the cartridge
Consumables	Cups & Pins (acrylic plastic)	Carrier (acrylic plastic) with microfluidics laminate and test rings (acrylic plastic)

SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Analytical Precision

Testing was performed in Coramed's laboratory for precision, using CLSI EP5-A2 as guidance. Acceptance criteria for all reagents are: CV ≤ 15% for the R parameter, CV ≤ 25% for the K parameter, and CV ≤ 10% for the Alpha and MA parameters. Three types of donor citrated whole blood (CWB) were used in this precision testing:

- Hypo (donors with natural coagulation levels of R parameter near the upper limit of the reference range and MA parameter near the lower limit of the reference range);
- Normal (donors with natural coagulation levels of R and MA parameters near the center of the reference ranges):
- Hyper (donors with natural coagulation levels of R parameter near the lower limit of the reference range and MA parameter near the upper limit of the reference range

Testing was performed with blood draws from three donors (one Hypo, one Normal, and one Hyper) on each of five days (non-consecutive). Testing was performed by two operators using three reagent lots and twelve analyzers, two replicates. The structure of this precision test is shown below.

Sample Type (Hypo, Normal or Hyper)												
	Day 1 (Total of 5 days)											
Operator	Operator 1						Operator 2					
Reagent lot	1		2		3		1		2		3	
Analyzer	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2

Structure of Precision Testing

Precision test estimates by test, parameter and donor sample test level are shown in the table on the following page. All acceptance criteria were met.

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Test	Parameter	Level	n	Mean	Reagent Lot		Operator*		Analyzer (within Operator, Reagent Lot)		Day (within Analyzer, Operator, Reagent Lot)		Repeatability		Total		Total without Day (Within Day)	
					SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
CFF	FLEV	Hypo	120	269.8	2.36	0.9%	0	0.0%	0	0.0%	5.32	2.0%	5.87	2.2%	8.27	3.1%	6.33	2.3%
CFF	FLEV	Normal	120	376.8	0	0.0%	2.25	0.6%	0	0.0%	5.49	1.5%	3.98	1.1%	7.15	1.9%	4.57	1.2%
CFF	FLEV	Hyper	120	597.4	0	0.0%	0	0.0%	0	0.0%	49.38	8.3%	9.62	1.6%	50.31	8.4%	9.62	1.6%
CFF	MA	Hypo	120	14.8	0.11	0.8%	0	0.0%	0	0.0%	0.29	2.0%	0.33	2.2%	0.45	3.0%	0.35	2.3%
CFF	MA	Normal	120	20.6	0	0.0%	0.13	0.6%	0	0.0%	0.3	1.5%	0.22	1.1%	0.39	1.9%	0.25	1.2%
CFF	MA	Hyper	120	32.7	0	0.0%	0	0.0%	0	0.0%	2.71	8.3%	0.53	1.6%	2.76	8.4%	0.53	1.6%
CKH	R	Hypo	120	8.2	0	0.0%	0	0.0%	0.18	2.2%	0.36	4.3%	0.76	9.2%	0.86	10.0%	0.78	9.5%
CKH	R	Normal	120	6.0	0	0.0%	0.05	0.9%	0.09	1.6%	0.14	2.3%	0.42	7.1%	0.46	7.7%	0.44	7.3%
CKH	R	Hyper	120	4.9	0	0.0%	0.05	1.1%	0	0.0%	0.28	5.7%	0.5	10.0%	0.58	12.0%	0.5	10.0%
CK	Angle	Hypo	120	68.7	0	0.0%	1.09	1.6%	0	0.0%	1.61	2.3%	3.01	4.4%	3.59	5.2%	3.2	4.7%
CK	Angle	Normal	120	72.1	0	0.0%	0	0.0%	0	0.0%	1.14	1.6%	1.73	2.4%	2.07	2.9%	1.73	2.4%
CK	Angle	Hyper	120	76.7	0	0.0%	0	0.0%	0	0.0%	1.84	2.4%	1.77	2.3%	2.56	3.3%	1.77	2.3%
CK	K	Hypo	120	1.8	0.03	1.9%	0.06	3.6%	0	0.0%	0.13	7.2%	0.18	10.0%	0.23	13.0%	0.19	11.0%
CK	K	Normal	120	1.4	0	0.0%	0	0.0%	0	0.0%	0.09	6.7%	0.16	12.0%	0.19	13.0%	0.16	12.0%
CK	K	Hyper	120	0.9	0	0.0%	0	0.0%	0	0.0%	0.12	12.0%	0.18	20.0%	0.22	23.0%	0.18	20.0%
CK	MA	Hypo	120	52.4	0.33	0.6%	0.55	1.0%	0.26	0.5%	0.83	1.6%	0.77	1.5%	1.33	2.5%	1.03	2.0%
CK	MA	Normal	120	59.4	0	0.0%	0.5	0.8%	0.48	0.8%	0.57	1.0%	0.86	1.4%	1.24	2.1%	1.1	1.9%
CK	MA	Hyper	120	68.0	0	0.0%	0.2	0.3%	0	0.0%	0.9	1.3%	0.52	0.8%	1.06	1.6%	0.56	0.8%
CK	R	Hypo	120	8.9	0	0.0%	0.29	3.3%	0	0.0%	0.64	7.1%	0.85	9.5%	1.1	12.0%	0.9	10.0%
CK	R	Normal	120	6.5	0	0.0%	0	0.0%	0	0.0%	0.28	4.3%	0.49	7.6%	0.56	8.7%	0.49	7.6%
CK	R	Hyper	120	5.2	0.13	2.5%	0	0.0%	0	0.0%	0.31	5.8%	0.66	13.0%	0.74	14.0%	0.67	13.0%
CRT	MA	Hypo	120	52.4	0.39	0.7%	0.22	0.4%	0	0.0%	0.92	1.8%	0.59	1.1%	1.18	2.3%	0.74	1.4%
CRT	MA	Normal	120	62.7	0	0.0%	0.15	0.2%	0.14	0.2%	0.37	0.6%	0.31	0.5%	0.52	0.8%	0.37	0.6%
CRT	MA	Hyper	120	69.4	0	0.0%	0	0.0%	0	0.0%	0.91	1.3%	0.2	0.3%	0.93	1.3%	0.2	0.3%

*Operator = Operator + operator-by-reagent lot interaction

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In addition, Coramed's Citrated Reagent Precision Protocol Rev. 02 was written to supplement precision data originally provided to FDA in 510(k) K150041. This protocol specifies testing to be performed outside of reference range values but within the Analytical Measurement Range (AMR) limits. This report presents data and statistics resulting from the execution of this protocol.

The following pages contain tables of precision statistics. Table 1 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from normal donors but spiked to achieve hypocoagulable (hypo) and hypercoagulable (hyper) results. Three donors for each reagent-parameter and spiking type were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each donor-reagent-parameter-hypo/hyper type, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B
Sample	Hypercoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

The focus of this study was on achieving values for the primary coagulation parameters R, MA and FLEV outside the reference ranges but within AMR limits, and taking the resulting K and Alpha (angle) values as is. Total Precision %CV values were all within pre-established limits, except for one CFF MA hypo outcome (11.6% for a limit of 10%) and 2 outcomes for Angle. The K and Angle parameters indicate the kinetics of the clotting process, and are not clinically significant as the main parameters representing coagulation, platelet and fibrinogen activities and abnormalities. The CFF MA CV% is higher because the MA value is small (mean of 6.5 mm) and although the Standard Deviation is very small (0.8mm) the resulting CV% is just over the limit. When the SD is so small there is no clinical significance for the differences making this CV% acceptable.

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Table 2 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from patients taking anticoagulants Dabigatran and Warfarin. Four Dabigatran patients and two Warfarin patients for each reagent-parameter were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each patient-reagent-parameter, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1		2		3		4		5		6	
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

Results for this testing were generally within limits, except for a few minor exceptions. As the data shows, all the MAs, for CK, CRT, and CFF, are within the specified expected CV% across the board while for the R parameter, there are no significant differences between lots, operators and devices and the only CVs (for CK and CKH – R parameter) somewhat exceeding 15% come from repeatability (16.9% for MH-DB003 for CK and 15.9% for MH-DB004 for CKH). Even though the, K and Angle are not parameters that are considered clinically significant the raw data indicates that the single angle CV% that is above the limit was due to an outlier while the K parameter has high CVs due to the fact that elongated coagulation results in higher CVs for that parameter.

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Test	Param	Spiking	Patient ID	N	Mean	Lot		Operator		Instrument		Repetition		Total	
						StDev	CV	StDev	CV	StDev	CV	StDev	CV	StDev	CV
CK	R	hyper	D101	12	2.1	0	0	0	0	0.1	4.5	0.1	3.1	0.1	5.5
CK	R	hyper	D108	12	2.7	0	0	0	1	0.1	3.5	0.1	2.4	0.1	4.3
CK	R	hyper	D169	12	2.2	0.1	2.8	0	0	0.1	3.1	0.1	2.5	0.1	4.6
CK	R	hypo	D141	12	16.1	0	0	1.1	6.9	1.3	8	0.7	4.3	1.7	10.8
CK	R	hypo	D169	12	15.3	0.8	5.3	0	0	1.6	10.2	1.1	7.1	2	13.2
CK	R	hypo	D108	12	12.1	0.1	1	0.1	0.9	0.9	7.2	0.7	5.6	1.1	9.3
CK	K	hyper	D101	12	0.5	0	0	0	0	0	3.9	0	4.1	0	5.7
CK	K	hyper	D108	12	0.4	0	3.8	0	3.8	0	7.2	0	6.5	0	10.7
CK	K	hyper	D169	12	0.5	0	0	0	0	0	8.2	0	8.2	0.1	11.6
CK	K	hypo	D141	12	3	0.2	5.2	0.2	6	0.3	9.9	0.2	8.2	0.4	14.6
CK	K	hypo	D169	12	3.1	0.5	16.4	0	0	0.5	14.8	0.3	10	0.7	22.7
CK	K	hypo	D108	12	2.2	0	0	0.1	6.4	0.3	12	0.1	6.2	0.3	14.6
CK	Angle	hyper	D101	12	80	0.8	1.1	1.5	1.8	7.2	9	6.9	8.7	10.1	12.6
CK	Angle	hyper	D108	12	85.1	0.1	0.2	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hyper	D169	12	84.3	0.1	0.1	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hypo	D141	12	54.7	0	0	0	0	8.4	15.4	5.4	9.9	10	18.3
CK	Angle	hypo	D169	12	42.7	1	2.4	1.9	4.5	1.8	4.3	1.6	3.7	3.1	7.2
CK	Angle	hypo	D108	12	66.7	3	4.4	0	0	4.8	7.2	3.3	5	6.3	9.5
CK	MA	hyper	D108	12	71.6	0	0	0.5	0.7	0.3	0.4	0.3	0.4	0.5	0.8
CK	MA	hyper	D169	12	70	0	0	0.1	0.1	0.2	0.2	0.1	0.2	0.2	0.3
CK	MA	hyper	D121	12	71.1	0	0	0	0	0.9	1.3	0.6	0.8	1.1	1.5
CK	MA	hypo	D141	12	42	0.2	0.6	0	0	1.5	3.5	0.9	2.1	1.7	4.1
CK	MA	hypo	D169	12	46.6	0	0	0	0	0.8	1.8	0.5	1.1	1	2.1
CK	MA	hypo	D108	12	45.4	0	0	0.8	1.8	1.2	2.7	0.9	2	1.7	3.7
CKH	R	hyper	D101	12	2	0.1	4.8	0	0	0	2.4	0.1	2.8	0.1	5.5
CKH	R	hyper	D108	12	2.6	0	0	0	0	0.1	2.6	0	1.6	0.1	3.1
CKH	R	hyper	D169	12	2.2	0	0	0	0	0	1.5	0	1	0	1.8
CKH	R	hypo	D141	12	15.7	0	0	1	6.4	0.7	4.5	0.6	4.1	1.3	8.2
CKH	R	hypo	D169	12	14.5	0	0	0.8	5.2	0.8	5.7	0.5	3.2	1.1	7.9
CKH	R	hypo	D108	12	12.3	0.6	5	0	0	0.8	6.3	0.5	4.4	1.1	8.8
CRT	MA	hyper	D108	12	70.8	0.2	0.3	0	0	0.1	0.2	0.1	0.2	0.2	0.3
CRT	MA	hyper	D121	12	72.5	0.2	0.3	0	0	0.4	0.5	0.4	0.5	0.5	0.8
CRT	MA	hyper	D145	12	73	0.2	0.2	0	0	0.2	0.3	0.2	0.2	0.3	0.4
CRT	MA	hypo	D141	12	41.3	0	0	0	0	0.7	1.8	0.5	1.2	0.9	2.2
CRT	MA	hypo	D169	12	44.4	0	0	0.3	0.7	0.6	1.3	0.4	0.9	0.8	1.7
CRT	MA	hypo	D108	12	45.5	0	0	0.4	0.9	1	2.1	0.5	1.1	1.1	2.5
CFF	MA	hyper	D101	12	49.9	0.1	0.1	0	0	0.5	0.9	0.3	0.5	0.5	1.1
CFF	MA	hyper	D141	12	44.3	0	0	0	0	0.5	1.2	0.3	0.6	0.6	1.3
CFF	MA	hyper	D145	12	47	0	0	0	0	0.7	1.4	0.5	1	0.8	1.7
CFF	MA	hypo	D101	12	10.2	0.2	1.5	0	0	0.3	3	0.2	1.7	0.4	3.6
CFF	MA	hypo	D125	12	9.5	0	0	0.2	1.8	0.4	4	0.3	2.7	0.5	5
CFF	MA	hypo	D169	12	6.5	0	0	0.7	10.1	0.3	4.9	0.4	6	0.8	11.6
CFF	FLEV	hyper	D101	12	910.7	1.2	0.1	0	0	8.6	0.9	5	0.5	10	1.1
CFF	FLEV	hyper	D141	12	809	0	0	0	0	9.6	1.2	5.2	0.6	10.9	1.3
CFF	FLEV	hyper	D145	12	858.1	0	0	0	0	11.9	1.4	8.5	1	14.7	1.7
CFF	FLEV	hypo	D101	12	186.4	2.9	1.5	0	0	5.5	3	3.1	1.7	6.8	3.6
CFF	FLEV	hypo	D125	12	173.4	0	0	3.1	1.8	7	4	4.6	2.6	8.7	5
CFF	FLEV	hypo	D169	12	157.5	1.8	1.2	1.1	0.7	2	1.3	1.7	1.1	3.2	2.1

Spiked Precision – Table 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

Test	Param	PatientID	N	Mean	Lot		Operator		Instrument		Repetition		Total	
					StDev	CV	StDev	CV	StDev	CV	StDev	CV	StDev	CV
CK	R	MH-DB001	12	13	0	0	0	0	0.4	3.2	1.2	8.9	1.2	9.4
CK	R	MH-DB002	12	21.3	0	0	0	0	1	4.7	2.1	10.1	2.3	11
CK	R	MH-DB003	12	14.4	0	0	0	0	0	0	2.4	16.9	2.4	16.9
CK	R	MH-DB004	12	11.8	0.5	4	0.5	4.3	0	0	1.6	13.9	1.7	14.8
CK	R	MH-WR001	12	9.9	0.7	7	0.3	2.7	0.3	2.6	0.5	4.9	0.8	8.5
CK	R	MH-WR002	12	10.1	1	10.2	0	0	0.3	3.2	1	10	1.4	13.6
CK	K	MH-DB001	12	1.3	0	0	0	0	0	0	0.2	18.2	0.2	18.2
CK	K	MH-DB002	12	2.4	0	0	0	0	0.4	15.4	1	42	1	44.5
CK	K	MH-DB003	12	1.3	0	0	0	0	0	0	0.3	19.8	0.3	19.8
CK	K	MH-DB004	12	0.9	0.1	11.4	0	0	0	0	0.3	33	0.3	34.4
CK	K	MH-WR001	12	2.2	0	0	0	0	0	0	0.2	8.2	0.2	8.2
CK	K	MH-WR002	12	2	0	0	0	0	0	0	0.4	19.1	0.4	19.1
CK	Angle	MH-DB001	12	72.5	0	0	0	0	0	0	3.6	5	3.6	5
CK	Angle	MH-DB002	12	55.5	0	0	0	0	10.3	18.6	11.6	20.8	15.2	27.4
CK	Angle	MH-DB003	12	72.7	0	0	0	0	0	0	3.2	4.3	3.2	4.3
CK	Angle	MH-DB004	12	79.5	0	0	0	0	0	0	3.4	4.3	3.4	4.3
CK	Angle	MH-WR001	12	65	0	0	0	0	0	0	1.1	1.7	1.1	1.7
CK	Angle	MH-WR002	12	67.1	0	0	1.1	1.6	0	0	3	4.4	3.1	4.6
CK	MA	MH-DB001	12	60.2	0	0	0	0	0	0	0.9	1.5	0.9	1.5
CK	MA	MH-DB002	12	64.5	0	0	0.2	0.4	0	0	0.6	1	0.7	1
CK	MA	MH-DB003	12	64.1	0	0	0.4	0.7	0	0	0.5	0.8	0.7	1
CK	MA	MH-DB004	12	71.9	0.1	0.1	0.5	0.6	0	0	0.5	0.7	0.7	0.9
CK	MA	MH-WR001	12	60.6	0	0	0	0	0	0	0.9	1.4	0.9	1.4
CK	MA	MH-WR002	12	59.7	0	0	0	0	1	1.6	0.8	1.3	1.2	2
CKH	R	MH-DB001	12	12.2	0.8	6.8	0	0	0	0	0.7	5.8	1	8.2
CKH	R	MH-DB002	12	19.3	0	0	1.6	8.4	0	0	2.2	11.4	2.6	13.5
CKH	R	MH-DB003	12	13.5	0	0	0.5	4	0	0	1.4	10.6	1.5	11.1
CKH	R	MH-DB004	12	11.3	0	0	0	0	0	0	1.8	15.9	1.8	15.9
CKH	R	MH-WR001	12	8.4	0	0	0.1	0.8	0	0	0.8	9.7	0.8	9.8
CKH	R	MH-WR002	12	9.1	0.5	5.1	0	0	0	0	0.7	7.4	0.8	8.6
CRT	MA	MH-DB001	12	64.9	0.1	0.1	0	0	0.1	0.1	0.1	0.2	0.1	0.2
CRT	MA	MH-DB002	12	67.7	0.1	0.1	0	0	0	0	0.2	0.2	0.2	0.2
CRT	MA	MH-DB003	12	66	0	0	0	0	0	0	0.1	0.2	0.1	0.2
CRT	MA	MH-DB004	12	73.8	0.1	0.1	0	0	0.1	0.1	0.2	0.2	0.2	0.3
CRT	MA	MH-WR001	12	64	0.1	0.1	0	0	0	0	0.2	0.3	0.2	0.3
CRT	MA	MH-WR002	12	64.7	0	0	0	0	0	0	0.3	0.4	0.3	0.4
CFF	MA	MH-DB001	12	20.7	0.1	0.4	0	0	0.3	1.3	0.1	0.6	0.3	1.4
CFF	MA	MH-DB002	12	23.7	0.3	1.3	0.3	1.4	0	0	0.2	0.7	0.4	1.6
CFF	MA	MH-DB003	12	23.4	0.2	1	0	0	0	0	0.3	1.5	0.4	1.7
CFF	MA	MH-DB004	12	51.9	1.1	2.2	0	0	0	0	0.4	0.8	1.1	2
CFF	MA	MH-WR001	12	20.7	0	0	0	0	0	0	0.4	1.7	0.4	1.7
CFF	MA	MH-WR002	12	24.7	0.1	0.4	0.3	1.2	0	0	0.3	1.3	0.4	1.7
CFF	FLEV	MH-DB001	12	377.3	1.4	0.4	0	0	4.8	1.3	2.4	0.6	5.3	1.4
CFF	FLEV	MH-DB002	12	432.2	5.8	1.3	6.2	1.4	0	0	3	0.7	6.8	1.6
CFF	FLEV	MH-DB003	12	426.5	4.5	1	0	0	0	0	6.2	1.5	7.3	1.7
CFF	FLEV	MH-DB004	12	947.1	20.9	2.2	0	0	0	0	7.5	0.8	19.3	2
CFF	FLEV	MH-WR001	12	377.4	0	0	0	0	0	0	6.5	1.7	6.5	1.7
CFF	FLEV	MH-WR002	12	450	1.6	0.4	5.2	1.2	0	0	6	1.3	7.7	1.7

Patient-Derived Hypo Samples (Dabigatran and Warfarin) – Table 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Interference

Testing was performed in Coramed's laboratory for interference, using CLSI EP7-A2 as guidance.

For CK, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Only Hemolysis and Hemodilution were found to be interferents.

For CRT, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Short Draw, Hemolysis and Hemodilution were found to be interferents.

For CKH, Protamine was tested for interference. Protamine was found to be an interferent for CKH at concentrations above 0.062 mg/ml.

For CFF, potential interferents tested were Na Heparin and Hemodilution. Heparin was found to be an interferent for CFF above Heparin concentrations of 1 IU/ml, and Hemodilution was found to be an interferent above hemodilution levels of 30%.

Linearity

Testing was performed in Coramed's laboratory for linearity, using CLSI EP6-A as guidance.

CFF was tested and found to be linear with varying concentrations of Fibrinogen (RiaSTAP) added. These concentrations ranged from 0 mg/dl to 565.5 mg/dl, over an FLEV range of 156 mg/dl to 1145 mg/dl. This corresponds to an MA range of 8.5 mm to 62.7 mm.

Sensitivity and Specificity

CK was tested for Sensitivity and Specificity with respect to Na Heparin, comparing R parameters of five blood samples with different clinically relevant concentrations of Heparin to five samples without heparin. Both Sensitivity and Specificity were found to be 100%.

Heparin Neutralization

Heparin Neutralization of CKH was tested using blood samples spiked with Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) and comparing these results to data obtained from testing CK with un-spiked blood samples. CKH was found to completely neutralize UFH levels of 5 IU/ml blood and LMWH levels of 0.013 mg/ml blood.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SUMMARY OF CLINICAL PERFORMANCE DATA

Testing was performed at three clinical sites for Reference Ranges and Method Comparison.

Reference Ranges

Reference Ranges for the CORA assays were estimated using the CLSI C28-A3c Guideline on three reference sample groups. Blood samples from up to 55 normal volunteer subjects were taken at each of the three sites, for a total of 157 samples. There were at least 151 valid results for every parameter for all reagents. Samples were excluded on a per-parameter basis using standard outlier criteria. An alternative method would have been to exclude all parameters for any tests where one or more parameter results were determined to be outliers. However, it was decided to retain all valid parameter results in calculating reference ranges because a larger number of samples adds statistical credibility. Also, it does not appear that using the alternative approach would have any significant effect on the reference ranges. Subjects were chosen representing demographic populations of the three areas, regarding age, race and gender. These reference ranges are shown below.

Reagent ↓	N	R (min)	N	K (min)	N	Angle (deg)	N	MA (mm)	N	FLEV (mg/dl)
CK	157	4.6-9.1	157	0.8-2.1	155	63 - 78	151	52 - 69		
CRT							152	52 - 70		
CKH	155	4.3-8.3								
CFF							151	15 - 32	152	278-581

Reference Ranges for CKH are shown but not usually required because the only purpose is to neutralize the heparin in a patient's blood, regardless of the patient's hemostasis condition. Comparing results from the CK and CKH tests for the R parameter can assist in determining whether or not there is heparin in the blood sample.

Reference Ranges for Wet Quality Control (WQC) Abnormal material when used in CORA assay cartridges were estimated. Using three lots of Abnormal Quality Control and three citrated reagent lots, a total of over 135 test results were obtained.

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (deg)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563-873

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Method Comparison

Method Comparison studies were conducted at three clinical sites on patient samples following CLSI EP09-A3 Guideline. The subjects enrolled were patients undergoing cardiovascular surgery or cardiology procedures, with blood samples drawn pre- and post-surgery and in the ICU. In order to broaden the range of comparison, up to 10% contrived samples were added. Summary statistics are presented below.

Method Comparison Statistics Summary – All Clinical Sites					
Parameter	**R**	**Intercept**	**95% CI**	**Slope**	**95% CI**
CK – R (min)	0.868	-0.325	-0.425	1.069	1.034
			-0.225		1.103
CK – K (min)	0.740	-0.097	-0.292	0.906	0.769
			0.098		1.042
CK – Alpha (deg)	0.680	7.305	-13.160	0.940	0.640
			27.769		1.240
CK – MA (mm)	0.924	2.351	0.166	0.948	0.912
			4.536		0.983
CKH – R (min)	0.812	-0.329	-0.393	1.057	1.026
			-0.265		1.089
CRT|CK – MA (mm)	0.929	-0.126	-1.909	0.978	0.948
			1.656		1.007
CFF – MA (mm)	0.938	-0.774	-1.836	1.126	1.072
			0.289		1.180
CFF – FLEV (mg/dl)	0.928	-12.495	-36.810	1.127	1.059
			11.819		1.194

In addition, a Reader Study was conducted to assess the comparison of CORA System and TEG 5000 results based on reading printed test outcomes. The study was performed at three sites, using three experienced TEG 5000 doctors as readers at each site, for a total of nine readers. 30 test outcomes were compared for each of the reagent test categories, for a total of 270 reading comparisons per reader. Excellent agreement between the two devices was demonstrated.

In both the Method Comparison Study and Reader Study, the CORA RapidTEG (CRT) MA parameter was compared to the TEG 5000 Kaolin (CK) MA parameter, to demonstrate that the CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTING

The data and information provided in this submission support a substantial equivalence determination for the CORA System and the TEG 5000 predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Heparin Neutralization Test Protocol

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

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K150041/A001

Coramed Technologies, LLC
6225 W. Howard Street, Niles, Illinois 60714
847-647-8800 | 847-510-0502 FAX

CORA|MED

FDA CDRH DMC
JUL 08 2015
Received

July 6, 2015

United States Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: K150041 – CORA (Coagulation Resonance Analysis) System

Dear Sir or Madam:

I am the official contact on the above referenced 510(k). This letter is to notify you that Coramed Technologies has transferred the above referenced premarket notification to Haemonetics Corporation. Therefore, effective July 6, 2015, Paige Sweeney of Haemonetics Corporation will become the official contact for the above-referenced premarket notification file and will be responsible for all regulatory requirements related to this 510(k). Below is Paige Sweeney's contact information:

Paige Sweeney
Senior Manager, Regulatory Affairs
Haemonetics Corporation
400 Wood Road
Braintree, MA 02184
(Ph) 781-348-7295
(Fax) 781-356-3558
paige.sweeney@haemonetics.com

In the future, all correspondence and communication should be sent to Paige Sweeney.

Sincerely,

Norman E. Brunner
Director, RA/QA

Cc: Paige Sweeney
Haemonetics Corporation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K150041

FDA/CDRH/DCC
JAN 09 2015
RECEIVED

Coramed Technologies, LLC
6225 W. Howard Street, Niles, Illinois 60714
847-647-8800 | 847-510-0502 FAX

CORA|MED

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 8, 2015

RE: 510(k) Notification

The enclosed documentation and eCopy (on CD) is being submitted as a 510(k) Notification for Coramed's CORA® System. The eCopy is an exact duplicate of the paper copy.

The following information is relevant to this submission.

Administrative Information

- Type of Submission: Traditional
- Device Type (Common Name): Whole Blood Hemostasis System
- 510(k) Submitter: Coramed Technologies LLC, 6225 Howard St., Niles, IL 60714
- Contact Person: Norman E. Brunner, Director of RA/QA, 847-647-8800 x-16
- Confidentiality Preference: Coramed requests that the information in this 510(k) Notification be kept confidential until clearance is granted.
- Recommended Classification Regulation: 21CFR 864.5425 Multipurpose System for *in vitro* Coagulation Studies
- Device Class II
- Hematology Panel
- Product Code: JPA
- FDA Document numbers associated with prior formal correspondence with FDA: Pre-IDEs I090972, I090972/S001 and I090972/S002; Pre-Submissions Q130017, Q130017/S001, Q130017/A001 and K140421.

The reason for this submission is that the CORA System is a new IVD device for which 510(k) marketing clearance is requested. It consists of the CORA Hemostasis Analyzer and an associated Citrated Multichannel cartridge and reagents for the analysis of citrated whole blood samples. The submission also includes Abnormal Quality Control material to be used with the system.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

This submission is presented following the format recommended in "Guidance for Industry and FDA Staff – Format for Traditional and Abbreviated 510(k)s". It is structured based on the 21sections listed in Chapter 1 of this Guidance. Sections that do not apply are included but are annotated "This section does not apply".

Design and Use of the Device (from FDA Guidance "Format for Traditional and Abbreviated 510(k)s" Appendix A - see Table below)

Question	Yes/No
Is the device intended for prescription use (21CFR 801 Subpart D)?	Yes
Is the device intended for over-the-counter use (21CFR 807 Subpart C)?	No
Does the device contain components from a tissue or other biologic source?	Yes - QC material only
Is the device provided sterile?	No
Is the device intended for single use?	Yes – cartridges only
Does the device contain a drug?	No
Does the device contain a biologic?	No
Does the device contain software?	Yes
Does the submission include clinical information?	Yes
Is the device implanted?	No

We believe that this submission contains all the information required to reach a "Substantially Equivalent" decision for the CORA System, and look forward to your favorable response. Please let us know if anything needs further clarification or if more information is required.

Sincerely,



Norman E. Brunner
Director of RA/QA
Coramed Technologies, LLC
nbrunner@coramedtech.com
(847) 647-8800 ext. 16

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

Coramed Technologies CORA® System 510(k)

Table of Contents

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Section 6: Truthful and Accuracy Statement

Section 7: Class III Summary and Certification

Section 8: FDA Form 3454 Financial Certification Statement
FDA Form 3674 Certificate of Compliance – ClinicalTrials.gov Data Bank

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Section 11: Device Description

Section 12: Substantial Equivalence Discussion

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Service-Maintenance-Settings (SMS) User Guide
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Abnormal QC Material Insert

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

Section 16: Software
(Software Documentation in Separate Binders)

- Volume 1: CORA Instrument Software Documentation
  - Document (b)(4) Software Hazard Analysis (FMECA)
  - Document (b)(4) Software Requirements Specification (SRS)
  - Document (b)(4) (b)(4)
  - Document (b)(4) Software Architecture Description
  - Document (b)(4) (b)(4) Software Interface Control Description
  - Document (b)(4) (b)(4) Software Design Description
  - Document (b)(4) (b)(4) Software Design Description
  - Document (b)(4) SRS Traceability Matrix
  - Document (b)(4) (b)(4) SRS Traceability Matrix
  - Coramed Document (b)(4) Software Configuration Management and Development Environment Description
  - Coramed CORA System Software Revision Level History and Unresolved Anomalies
- Volume 2: CORA Instrument Software Test Procedures / Reports
- Volume 3: CORA System Service-Maintenance-Settings (SMS) Software Documentation
  - Document (b)(4) SMS Software Hazard Analysis (FMECA)
  - Documen (b)(4) SMS Software Requirements Specification
  - Document (b)(4) SMS Software Architecture Description
  - Document (b)(4) SMS Software Design Description
  - Document (b)(4) SMS Software Verification Traceability Matrix
  - Document (b)(4) SMS Software Development Environment Description
  - Document (b)(4) SMS Software Test Protocol and Test Cases (including test cases and reports)
  - Document (b)(4) SMS Software Verification and Validation Plan
  - Document (b)(4) SMS Test Report

Section 17: Electromagnetic Compatibility / Electrical Safety

- Certificate of Compliance IEC 60601-1-2
- Certificate of Compliance EN 61326
- Certificate of Compliance UL 20130205-E359802
- UL Test Report and Procedure E359802-A1-UL
- CB Test Certificate US-20815-UL

Section 18: Performance Testing - Bench

Section 19: Performance Testing - Animal

Section 20: Performance Testing – Clinical

Section 21: Other

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
CORAMED TECHNOLOGIES, LLC 6225 W. HOWARD STREET NILES IL 60714 US	Norman Brunner 2.1 E-MAIL ADDRESS nbrunner@coramedtech.com 2.2 TELEPHONE NUMBER (include Area code) 847-6478800 16 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 847-5100502
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD158312

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 09-Dec-2014

FormFDA3601(01/2007)

"Close Window" Print Cover sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
01/08/2015	(b)(4)	N/A

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Coramed Technologies, LLC	N/A		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	(847) 647-8800 x-16		
Street Address	**FAX Number *(including area code)***		
6225 W. Howard St.	(847) 510-0502		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Niles	IL	60714	USA
Contact Name			
Norman E Brunner			
Contact Title	**Contact E-mail Address**		
Director of RA/QA	nbrunner@coramedtech.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

PSC Publishing Services (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	JPA	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K002177	TEG 5000	Haemoscope Corporation
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Whole Blood Hemostasis System

	Trade or Proprietary or Model Name for This Device	Model Number
1	CORA (Coagulation Resonance Analysis) System	CORA01
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 I090972	2 I090972/S001	3 I090972/S002	4 Q130017	5 Q130017/S001	6 Q130017/A001
7 K140421	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☒ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
JPA	21CFR 864.5425	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Hematology

Indications *(from labeling)*

Too long for form - see attached Intended Use / Indications for Use page

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)* N/A

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: N/A	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Coramed Technologies, LLC	N/A
Division Name *(if applicable)*	Phone Number *(including area code)*: 847-647-8800
Street Address: 6225 W. Howard St.	FAX Number *(including area code)*: 847-510-0502

City	State / Province	ZIP Code	Country
Niles	IL	60714	USA

Contact Name	Contact Title	Contact E-mail Address
Norman E. Brunner	Director of RA/QA	nbrunner@coramedtech.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	Phone Number *(including area code)*
Street Address	FAX Number *(including area code)*

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	Phone Number *(including area code)*
Street Address	FAX Number *(including area code)*

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

SECTION I **UTILIZATION OF STANDARDS**

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1-2	IEC	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests	Edition 3	'2007
2	61010-1	IEC	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use. Pt. I, General Requirements	Edition 2	04/01/2003
3	61010-2-010	IEC	Particular requirements for laboratory equipment for the heating of materials	Second Edition	06/2003
4	61010-2-081	IEC	Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes	Edition 1.1	08/2009
5	61010-2-101	IEC	Particular requirements for in vitro diagnostic (IVD) medical equipment	First Edition	01/2002
6	61326-1	EN/IEC	EN61326-1:2006 (IEC 61326-1:2005 Ed 1) Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements. Part 1: General Requirements	Edition 1	'2005
7	61010-1	UL	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements	Edition 2	10/28/2008

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

SECTION I **UTILIZATION OF STANDARDS**

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	C28-A3c (Now EP28-A3c: 2010)	CLSI	Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline	Third Edition (corrected version)	October 2010
2	EP05-A2	CLSI	Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline	Second Edition	August, 2004
3	EP6-A	CLSI	Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline	April, 2003	April, 2003
4	EP07-A2	CLSI	Interference Testing in Clinical Chemistry; Approved Guideline	Second Edition	November, 2005
5	EP09-A3	CLSI	Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline	Third Edition	August, 2013
6	EP25-A	CLSI	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline	September, 2009	September, 2009
7	C22.2 NO. 61010-1	CSA	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use. Pt. 1, General Requirements	Edition 2	10/01/2008

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

Coramed Technologies, LLC
6225 W. Howard Street, Niles, Illinois 60714
847-647-8800 | 847-510-0502 fax

CORA|MED

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 8, 2015

RE: 510(k) Notification

The enclosed documentation and eCopy (on CD) is being submitted as a 510(k) Notification for Coramed's CORA® System. The eCopy is an exact duplicate of the paper copy.

The following information is relevant to this submission.

Administrative Information

- Type of Submission: Traditional
- Device Type (Common Name): Whole Blood Hemostasis System
- 510(k) Submitter: Coramed Technologies LLC, 6225 Howard St., Niles, IL 60714
- Contact Person: Norman E. Brunner, Director of RA/QA, 847-647-8800 x-16
- Confidentiality Preference: Coramed requests that the information in this 510(k) Notification be kept confidential until clearance is granted.
- Recommended Classification Regulation: 21CFR 864.5425 Multipurpose System for *in vitro* Coagulation Studies
- Device Class II
- Hematology Panel
- Product Code: JPA
- FDA Document numbers associated with prior formal correspondence with FDA: Pre-IDEs I090972, I090972/S001 and I090972/S002; Pre-Submissions Q130017, Q130017/S001, Q130017/A001 and K140421.

The reason for this submission is that the CORA System is a new IVD device for which 510(k) marketing clearance is requested. It consists of the CORA Hemostasis Analyzer and an associated Citrated Multichannel cartridge and reagents for the analysis of citrated whole blood samples. The submission also includes Abnormal Quality Control material to be used with the system.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

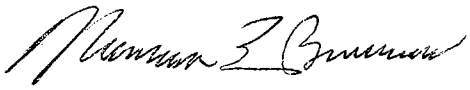
This submission is presented following the format recommended in "Guidance for Industry and FDA Staff – Format for Traditional and Abbreviated 510(k)s". It is structured based on the 21sections listed in Chapter 1 of this Guidance. Sections that do not apply are included but are annotated "This section does not apply".

Design and Use of the Device (from FDA Guidance "Format for Traditional and Abbreviated 510(k)s" Appendix A - see Table below)

Question	Yes/No
Is the device intended for prescription use (21CFR 801 Subpart D)?	Yes
Is the device intended for over-the-counter use (21CFR 807 Subpart C)?	No
Does the device contain components from a tissue or other biologic source?	Yes - QC material only
Is the device provided sterile?	No
Is the device intended for single use?	Yes – cartridges only
Does the device contain a drug?	No
Does the device contain a biologic?	No
Does the device contain software?	Yes
Does the submission include clinical information?	Yes
Is the device implanted?	No

We believe that this submission contains all the information required to reach a "Substantially Equivalent" decision for the CORA System, and look forward to your favorable response. Please let us know if anything needs further clarification or if more information is required.

Sincerely,



Norman E. Brunner
Director of RA/QA
Coramed Technologies, LLC
nbrunner@coramedtech.com
(847) 647-8800 ext. 16

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*
Not known

Device Name
CORA Hemostasis System

Indications for Use *(Describe)*
The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The CORA System records the kinetic changes in a sample of citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*
Not known

Device Name
CORA Hemostasis System - Citrated Multichannel Cartridge

Indications for Use *(Describe)*
The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The Citrated Multichannel Cartridge, to be used with the CORA System instrument, contains four independent assays (CK, CRT, CKH and CFF), described below.

The CK assay monitors the hemostasis process via the intrinsic pathway in citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).
The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA).
The CKH assay monitors the effects of heparin in citrated whole blood specimens on the CORA System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests.
The CFF assay monitors hemostasis of citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*
Not known

Device Name
CORA Hemostasis System - Abnormal Quality Control Material

Indications for Use *(Describe)*
The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample.

The Abnormal QC Material is to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

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CORA® System 510(k) Summary

APPLICANT INFORMATION

Name of Manufacturer: Coramed Technologies, LLC

Manufacturer Street Address: 6225 W. Howard St.

City, State, Zip: Niles, IL 60714

Phone Number: (847) 647-8800

FAX Number: (847) 510-0502

Contact person for all communications: Norman E. Brunner

Email for contact person: nbrunner@coramedtech.com

Date that Summary was prepared: January 8, 2015

DEVICE INFORMATION

Trade name (proprietary name): CORA® (Coagulation Resonance Analysis) System and the following assays and reagents

- Citrated Assays and Reagents
  - CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
  - CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
  - CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
  - CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent

Common name (usual name): Whole Blood Hemostasis System

Classification Name: 21CFR 864.5425 Multipurpose System for *in vitro* Coagulation Studies

PREDICATE DEVICE

- Thrombelastograph® Coagulation Analyzer (TEG®) – 5000 Series, K002177, Product Code JPA (System, Multipurpose, for In Vitro Coagulation Studies), Haemoscope Corporation

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DESCRIPTION OF THE DEVICE

System Description

The CORA System consists of a four-channel diagnostic analyzer with integrated computer module, system reagents (CK, CRT, CKH, and CFF), and Abnormal Quality Control material and microfluidic test cartridges. See below for a description of system reagents. Reagents are dried-in-place within the cartridges during manufacturing. Abnormal Quality Control material is lyophilized and can be reconstituted with water as needed for WQC testing with reagent cartridges.

To perform a test, a disposable CORA Cartridge is inserted into the analyzer. Blood or WQC material is added to an entry port on the cartridge and drawn into the cartridge under analyzer control. The amount of the sample drawn into the cartridge is automatically determined by the volume of the blood chambers in the cartridge. Once in the disposable, the sample is metered into as many as four separate analysis channels, depending upon the assays being performed. Reconstitution of reagents dried within the cartridge is accomplished by moving the sample back and forth through reagent chambers, under the control of microfluidic valves and bellows (pumps) within the cartridge. After each sample has been mixed with reagent, it is delivered to a test cell where it is monitored for visco-elastic changes due to coagulation. Excess sample material is moved under microfluidic control into an enclosed waste chamber within the cartridge.

The CORA Measurement Technique

The CORA technology is based on a disposable containing up to four independent measurement cells. Each cell consists of a short vertically-oriented injection molded tube (ring) with a diameter of 2.5mm and a length of 4.5mm. Detection of clotting in the CORA System is performed optically. Under control of the analyzer, approximately 20µl of prepared sample is delivered to the tube, where a meniscus naturally forms at each end of the tube. The tube is positioned so that the lower meniscus partially blocks light traveling from a collimated source toward a photodiode.

During testing, a piezoelectric actuator drives the measurement cell(s) through a motion profile composed of summed sinusoids at different frequencies. The profile has a maximum amplitude of under 10µm and contains frequencies from 10-500Hz. Some, but not all, of the measurement cell motion will induce motion in the sample meniscus, which will be detected by the photodiode. The resulting motion of the meniscus is monitored optically and recorded by the analyzer to calculate the resonant frequency and modulus of elasticity (stiffness) of the sample. By performing a Fast Fourier Transform (FFT) on meniscus motion data, it is possible to determine the frequencies of input motion that caused the greatest deflection of the sample (these are called the resonant frequencies).

Resonance is the tendency of a material or structure to oscillate with greater amplitude at some frequencies than others. The exact frequencies at which resonance occurs will depend on the stiffness and mass of the sample. Stiffness, in turn, is a function of a material's modulus of elasticity and the boundary conditions to which the material is exposed, such as the geometry and materials of a test cell. By holding these boundary conditions and sample mass constant from run to run, the CORA System allows direct comparison of elasticity between samples.

In a typical test, blood that has been delivered to the measurement cell will not clot for several minutes. During this time the sample has no inherent stiffness except that provided by surface tension, and since this remains constant the measured resonant frequencies will not change. Once clotting begins, however, the elastic modulus and thus the resonant frequencies increase rapidly. During fibrinolysis, the process is reversed, with elastic modulus and resonant frequencies decreasing. In tests where clotting does not occur, the resonant frequency of the sample will not change. During coagulation, however, a clot will bind to the test tube (ring) and the resonant frequency will rise with increasing firmness of the clot. The

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CORA Analyzer collects meniscus motion data, tracks changing resonant frequencies and analyzes the frequency data to provide semi-quantitative parameters describing the clot. Results are presented in a format similar to the TEG 5000.

Both the TEG 5000 and CORA System monitor the elastic modulus of clots. Method Comparison testing has been performed, yielding data from approximately 300 patients from three sites (Mayo Clinic, University of Pittsburgh Medical Center, and Sinai Hospital, Baltimore). These data include all applicable parameters from the four citrated tests (CK, CKH, CRT and CFF). The TEG 5000 measures the changes of the linkage forces of the clot between the cup and pin over time, while the CORA System measures the changes of the resonant frequency of the clot over time. Despite the difference in the way the two analyzers measure the changes in the modulus of elasticity of the clot over time, they measure the same physical phenomenon and produce the same result when converted from their specific units of measurement (forces for the TEG5000 and frequency for the CORA System) to millimeters. The fact that these results are similar across all reagents used in both technologies is demonstration that the two technologies measure the same phenomenon, the changes in elastic modulus.

The following definitions apply to calculated parameters in the CORA System:

CORA Parameter	Definition	Parameter Relation to Hemostasis
R	R is the time from the start of the test until initial fibrin formation. This represents the enzymatic portion of coagulation.	Normal / reduced / increased speed of coagulation initiation
K	K is the time after R needed to reach a certain level of clot strength. This represents clot kinetics.	Normal / reduced / increased speed of coagulation amplification and propagation
Alpha α (angle)	Alpha is the angle representing the rate increase in the clot strength and the rapidity of fibrin build-up and cross-linking.	Normal / reduced / increased speed of coagulation amplification and propagation
MA	MA, or Maximum Amplitude, represents the maximum firmness of the clot during the test.	Normal / reduced / increased clot elasticity/strength
FLEV	FLEV is an estimate of the fibrinogen level in the blood sample.	Estimated Functional Fibrinogen Level

Citrated Assays

The CK assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via the intrinsic pathway in citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle), and Maximum Clot Strength (MA). K and Alpha are complementary parameters and should be used in conjunction with Clotting Time (R) and Maximum Clot Strength (MA).

The CRT assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via both the intrinsic and extrinsic pathway in citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA).

The CFF assay is a semi-quantitative *in vitro* diagnostic assay for monitoring hemostasis of citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. CFF is used in conjunction with CK and clotting characteristics are described by the functional parameter Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

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The CKH assay is a semi-quantitative *in vitro* diagnostic assay used in conjunction with the CORA System to monitor the effects of heparin in the blood stream of a patient. CKH is used in conjunction with CK and heparin influence is determined by comparing Clotting Times (R) between the two tests.

Wet Quality Control (WQC)

Abnormal Wet Quality Control (WQC) material consists of bovine plasma with buffers and stabilizers, and is used instead of hypocoagulable blood, in conjunction with the Citrated Multichannel system cartridge. When used with the Citrated Multichannel cartridge, this material provides consistent and repeatable values for CORA parameters to confirm reagent quality and viability.

INTENDED USE AND INDICATIONS FOR USE`

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The CORA System records the kinetic changes in a sample of citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

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The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARING THE CORA SYSTEM TO THE TEG 5000 PREDICATE DEVICE

Table of Similarities

Item	TEG® 5000 Predicate	CORA® System
Analyzer		
Technological Purpose	Monitoring the response of a clot to low levels of applied strain	Monitoring the response of a clot to low levels of applied strain
What is measured	Changes in clot elasticity over time	Changes in clot elasticity over time
Initial Warm Up Time	5 min	5 min
Time to Complete a Test	Varies with assay	Same as TEG 5000
Assays and Reagents		
Intrinsic Contact Activation Reagent (CK)	Kaolin and $CaCl_2$	Kaolin and $CaCl_2$, same materials as TEG 5000
Intrinsic Contact Activation Reagent with Heparinase for heparin reversal (CKH)	Kaolin and $CaCl_2$ with Heparinase	Kaolin, Heparinase and $CaCl_2$, same materials as TEG 5000
Citrated RapidTEG (CRT) (Tissue Factor and Kaolin Activation)	Tissue Factor (TF), Kaolin and $CaCl_2$	Tissue Factor (TF), Kaolin and $CaCl_2$, same materials as TEG5000

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Item	TEG® 5000 Predicate	CORA® System
Citrated Functional Fibrinogen (CFF) / Platelet-Blocked (Tissue Factor Activation)	ReoPro® ,Tissue Factor and $CaCl_2$, same materials as CORA	ReoPro®, Tissue Factor and $CaCl_2$, same materials as TEG 5000
Calcium Chloride Reagent (CC) (for re-calcification)	$CaCl_2$ reagent	$CaCl_2$ same materials as TEG 5000
Quality Control Material (WQC Abnormal Control)	TEG coagulation control – Level II	TEG coagulation control – Abnormal, same materials as TEG 5000

Table of Differences

Item	TEG® 5000 Predicate	CORA® System
Analyzer	Thrombelastography analyzer, separate computer and software	Fully integrated Thrombelastography analyzer
Measuring Technique	Direct-contact measurement of shear elasticity of a coagulating sample	Non-contact measurement of shear elasticity of a coagulating sample
Measuring Channels	Two, each independent and interchangeable (can be used with any approved reagent)	Four, each independent and interchangeable (can be used with any approved reagent)
Signal Transducer	Electromechanical detection (rotary variable inductive transformer) of rotary motion of a pin suspended in the sample	Optical detection (silicon photodiode) of the motion of a free surface of the sample
Temperature Control	20° to 40°C	20° to 50°C
Sample Volume (per channel)	360-380 µl	63 µl
Total Reaction Volume (single channel)	360-380 µl	20 µl
Mains Supply Voltage	120V, 60Hz and 220V, 50Hz model available	100-240V, 50-60Hz (international power supply)
Analyzer Input Voltage	24 volts AC, 30 watts max	12 volts DC, 60 watts max
Environment	Level and vibration free position, no solar radiation Operating temperature: 10° to 35 °C Storage Temperature: -30° to +50 °C (analyzer only) Relative humidity 20-80% (non-condensing)	Stable and level surface. Operating Temperature 10° to 32°C Storage Temperature: -20° to 50°C (analyzer only) Relative humidity 20 to 80% (non-condensing)
Sample Preparation	Performed by the operator using pipettes to reconstitute reagents and mix reagents with the sample	Performed under analyzer control within the disposable cartridge

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Item	TEG® 5000 Predicate	CORA® System
Pipetting	Manual accurate pipettes (10, 20, 50, 100, 340, 360, 500, 1000µl)	Unmetered transfer pipette or syringe; blood sample is added until it fills to a level above the line marked on the blood intake well of the cartridge
Consumables	Cups & Pins (acrylic plastic)	Carrier (acrylic plastic) with microfluidics laminate and test rings (acrylic plastic)

SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Analytical Precision

Testing was performed in Coramed's laboratory for precision, using CLSI EP5-A2 as guidance. Acceptance criteria for all reagents are: CV ≤ 15% for the R parameter, CV ≤ 25% for the K parameter, and CV ≤ 10% for the Alpha and MA parameters. Three types of donor citrated whole blood (CWB) were used in this precision testing:

- Hypo (donors with natural coagulation levels of R parameter near the upper limit of the reference range and MA parameter near the lower limit of the reference range);
- Normal (donors with natural coagulation levels of R and MA parameters near the center of the reference ranges):
- Hyper (donors with natural coagulation levels of R parameter near the lower limit of the reference range and MA parameter near the upper limit of the reference range

Testing was performed with blood draws from three donors (one Hypo, one Normal, and one Hyper) on each of five days (non-consecutive). Testing was performed by two operators using three reagent lots and twelve analyzers, two replicates. The structure of this precision test is shown below.

Sample Type (Hypo, Normal or Hyper)												
	Day 1 (Total of 5 days)											
Operator	Operator 1						Operator 2					
Reagent lot	1		2		3		1		2		3	
Analyzer	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2

Structure of Precision Testing

Precision test estimates by test, parameter and donor sample test level are shown in the table on the following page. All acceptance criteria were met.

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Test	Parameter	Level	n	Mean	Reagent Lot		Operator*		Analyzer (within Operator, Reagent Lot)		Day (within Analyzer, Operator, Reagent Lot)		Repeatability		Total		Total without Day (Within Day)	
					SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
CFF	FLEV	Hypo	120	269.8	2.36	0.9%	0	0.0%	0	0.0%	5.32	2.0%	5.87	2.2%	8.27	3.1%	6.33	2.3%
CFF	FLEV	Normal	120	376.8	0	0.0%	2.25	0.6%	0	0.0%	5.49	1.5%	3.98	1.1%	7.15	1.9%	4.57	1.2%
CFF	FLEV	Hyper	120	597.4	0	0.0%	0	0.0%	0	0.0%	49.38	8.3%	9.62	1.6%	50.31	8.4%	9.62	1.6%
CFF	MA	Hypo	120	14.8	0.11	0.8%	0	0.0%	0	0.0%	0.29	2.0%	0.33	2.2%	0.45	3.0%	0.35	2.3%
CFF	MA	Normal	120	20.6	0	0.0%	0.13	0.6%	0	0.0%	0.3	1.5%	0.22	1.1%	0.39	1.9%	0.25	1.2%
CFF	MA	Hyper	120	32.7	0	0.0%	0	0.0%	0	0.0%	2.71	8.3%	0.53	1.6%	2.76	8.4%	0.53	1.6%
CKH	R	Hypo	120	8.2	0	0.0%	0	0.0%	0.18	2.2%	0.36	4.3%	0.76	9.2%	0.86	10.0%	0.78	9.5%
CKH	R	Normal	120	6.0	0	0.0%	0.05	0.9%	0.09	1.6%	0.14	2.3%	0.42	7.1%	0.46	7.7%	0.44	7.3%
CKH	R	Hyper	120	4.9	0	0.0%	0.05	1.1%	0	0.0%	0.28	5.7%	0.5	10.0%	0.58	12.0%	0.5	10.0%
CK	Angle	Hypo	120	68.7	0	0.0%	1.09	1.6%	0	0.0%	1.61	2.3%	3.01	4.4%	3.59	5.2%	3.2	4.7%
CK	Angle	Normal	120	72.1	0	0.0%	0	0.0%	0	0.0%	1.14	1.6%	1.73	2.4%	2.07	2.9%	1.73	2.4%
CK	Angle	Hyper	120	76.7	0	0.0%	0	0.0%	0	0.0%	1.84	2.4%	1.77	2.3%	2.56	3.3%	1.77	2.3%
CK	K	Hypo	120	1.8	0.03	1.9%	0.06	3.6%	0	0.0%	0.13	7.2%	0.18	10.0%	0.23	13.0%	0.19	11.0%
CK	K	Normal	120	1.4	0	0.0%	0	0.0%	0	0.0%	0.09	6.7%	0.16	12.0%	0.19	13.0%	0.16	12.0%
CK	K	Hyper	120	0.9	0	0.0%	0	0.0%	0	0.0%	0.12	12.0%	0.18	20.0%	0.22	23.0%	0.18	20.0%
CK	MA	Hypo	120	52.4	0.33	0.6%	0.55	1.0%	0.26	0.5%	0.83	1.6%	0.77	1.5%	1.33	2.5%	1.03	2.0%
CK	MA	Normal	120	59.4	0	0.0%	0.5	0.8%	0.48	0.8%	0.57	1.0%	0.86	1.4%	1.24	2.1%	1.1	1.9%
CK	MA	Hyper	120	68.0	0	0.0%	0.2	0.3%	0	0.0%	0.9	1.3%	0.52	0.8%	1.06	1.6%	0.56	0.8%
CK	R	Hypo	120	8.9	0	0.0%	0.29	3.3%	0	0.0%	0.64	7.1%	0.85	9.5%	1.1	12.0%	0.9	10.0%
CK	R	Normal	120	6.5	0	0.0%	0	0.0%	0	0.0%	0.28	4.3%	0.49	7.6%	0.56	8.7%	0.49	7.6%
CK	R	Hyper	120	5.2	0.13	2.5%	0	0.0%	0	0.0%	0.31	5.8%	0.66	13.0%	0.74	14.0%	0.67	13.0%
CRT	MA	Hypo	120	52.4	0.39	0.7%	0.22	0.4%	0	0.0%	0.92	1.8%	0.59	1.1%	1.18	2.3%	0.74	1.4%
CRT	MA	Normal	120	62.7	0	0.0%	0.15	0.2%	0.14	0.2%	0.37	0.6%	0.31	0.5%	0.52	0.8%	0.37	0.6%
CRT	MA	Hyper	120	69.4	0	0.0%	0	0.0%	0	0.0%	0.91	1.3%	0.2	0.3%	0.93	1.3%	0.2	0.3%

*Operator = Operator + operator-by-reagent lot interaction

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Interference

Testing was performed in Coramed's laboratory for interference, using CLSI EP7-A2 as guidance.

For CK, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Only Hemolysis and Hemodilution were found to be interferents.

For CRT, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Short Draw, Hemolysis and Hemodilution were found to be interferents.

For CKH, Protamine was tested for interference. Protamine was found to be an interferent for CKH at concentrations above 0.062 mg/ml.

For CFF, potential interferents tested were Na Heparin and Hemodilution. Heparin was found to be an interferent for CFF above Heparin concentrations of 1 IU/ml, and Hemodilution was found to be an interferent above hemodilution levels of 30%.

Linearity

Testing was performed in Coramed's laboratory for linearity, using CLSI EP6-A as guidance.

CFF was tested and found to be linear with varying concentrations of Fibrinogen.

Sensitivity and Specificity

CK was tested for Sensitivity and Specificity with respect to Na Heparin, comparing R parameters of five blood samples with different clinically relevant concentrations of Heparin to five samples without heparin. Both Sensitivity and Specificity were found to be 100%.

Heparin Neutralization

Heparin Neutralization of CKH was tested using blood samples spiked with Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) and comparing these results to data obtained from testing CK with un-spiked blood samples. CKH was found to completely neutralize UFH levels of 6 IU/ml blood and LMWH levels of 0.016 mg/ml blood.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SUMMARY OF CLINICAL PERFORMANCE DATA

Testing was performed at three clinical sites for Reference Ranges and Method Comparison.

Reference Ranges

Reference Ranges for the CORA assays were estimated using the CLSI C28-A3c Guideline on three reference sample groups. Blood samples from up to 55 normal volunteer subjects were taken at each of the three sites, for a total of 157 samples. There were at least 151 valid results for every parameter for all reagents. Samples were excluded on a per-parameter basis using standard outlier criteria. An alternative method would have been to exclude all parameters for any tests where one or more parameter results were determined to be outliers. However, it was decided to retain all valid parameter results in calculating reference ranges because a larger number of samples adds statistical credibility. Also, it does not appear that using the alternative approach would have any significant effect on the reference ranges. Subjects were chosen representing demographic populations of the three areas, regarding age, race and gender. These reference ranges are shown below.

Reagent ↓	N	R (min)	N	K (min)	N	Angle (deg)	N	MA (mm)	N	FLEV (mg/dl)
CK	157	4.6-9.1	157	0.8-2.1	155	63 - 78	151	52 - 69		
CRT							152	52 - 70		
CKH	155	4.3-8.3								
CFF							151	15 - 32	152	278-581

Reference Ranges for CKH are shown but not usually required because the only purpose is to neutralize the heparin in a patient's blood, regardless of the patient's hemostasis condition. Comparing results from the CK and CKH tests for the R parameter can assist in determining whether or not there is heparin in the blood sample.

Reference Ranges for Wet Quality Control (WQC) Abnormal material when used in CORA assay cartridges were estimated. Using three lots of Abnormal Quality Control and three citrated reagent lots, a total of over 135 test results were obtained.

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (deg)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563-873

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Method Comparison

Method Comparison studies were conducted at three clinical sites on patient samples following CLSI EP09-A3 Guideline. The subjects enrolled were patients undergoing cardiovascular surgery or cardiology procedures, with blood samples drawn pre- and post-surgery and in the ICU. In order to broaden the range of comparison, up to 10% contrived samples were added. Summary statistics are presented below.

Method Comparison Statistics Summary – All Clinical Sites					
Parameter	**R**	**Intercept**	**95% CI**	**Slope**	**95% CI**
CK – R (min)	0.868	-0.325	-0.425	1.069	1.034
			-0.225		1.103
CK – K (min)	0.740	-0.097	-0.292	0.906	0.769
			0.098		1.042
CK – Alpha (deg)	0.680	7.305	-13.160	0.940	0.640
			27.769		1.240
CK – MA (mm)	0.924	2.351	0.166	0.948	0.912
			4.536		0.983
CKH – R (min)	0.812	-0.329	-0.393	1.057	1.026
			-0.265		1.089
CRT|CK – MA (mm)	0.929	-0.126	-1.909	0.978	0.948
			1.656		1.007
CFF – MA (mm)	0.938	-0.774	-1.836	1.126	1.072
			0.289		1.180
CFF – FLEV (mg/dl)	0.928	-12.495	-36.810	1.127	1.059
			11.819		1.194

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTING

The data and information provided in this submission support a substantial equivalence determination for the CORA System and the TEG 5000 predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Coramed Technologies, LLC
6225 W Howard Street, Niles, Illinois 60714
847-647-8800 | 847-510-0502 fax

CORA|MED

Premarket Notification Truthful And Accuracy Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as the Director of RA/QA of Coramed Technologies, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Norman E Brunner
(Typed Name)

December 22, 2014
(Date)

*(Premarket Notification [510(k)] Number)
*For a new submission, leave the 510(k) number blank.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 7: Class III Summary and Certification

This section does not apply to the CORA System 510(k) because the CORA System is a Class II device

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: December 31, 2015

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable check box.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

(b) (6)

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Gabriel Raviv, PhD	President
FIRM/ORGANIZATION	
Coramed Technologies, LLC, 6225 Howard St., Niles, IL 60714	
SIGNATURE	**DATE** *(mm/dd/yyyy)*
	12/16/2013

This section applies only to the requirements of the Paperwork Reduction Act of 1995.

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Do NOT send your completed form to the PRA Staff email address below.

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Food and Drug Administration
Office of Chief Information Officer
PRAStaff@fda.hhs.gov

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Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2015. See PRA Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
Coramed Technologies, LLC

2. Date of the Application/Submission Which This Certification Accompanies
01/08/2015

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
6225 W Howard St.

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City
Niles

State/Province/Region
IL

Country
USA

ZIP or Postal Code
60714

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 847-647-8800

(Fax): 847-510-0502

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Common Name: Whole Blood Hemostasis System; Classification Name: 21CFR 864.5425 Multipurpose System for In Vitro Coagulation Studies; Proprietary Name: CORA® (COagulation Resonance Analysis) System Model CORA01

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☒ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): NCT01790386

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Norman E. Brunner	Director of RA/QA

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	
6225 W. Howard St.	
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City: Niles	State/Province/Region: IL
Country: USA	ZIP or Postal Code: 60714

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 847-647-8800 x-16

(Fax): 847-510-0502

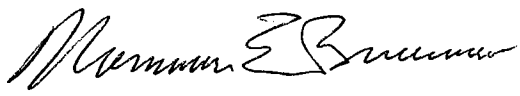
14. Date of Certification

01/08/2015

[redacted]

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign



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PRAStaff@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 9: Declarations of Conformity and Summary Reports

The following standards are referenced as part of demonstration of substantial equivalence for this Traditional 510(k). A Form 3654 has been provided for each referenced standard.

- CLSI C28-A3c (Now EP28-A3c: 2010) Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition (2008)
- CLSI EP05-A2 Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition (2004)
- CLSI EP6-A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2003)
- CLSI EP07-A2 Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition (2005)
- CLSI EP09-A3 Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition (2013)
- CLSI EP25-A Evaluation of Stability of *In Vitro* Diagnostic Reagents; Approved Guideline (2009)
- CSA C22.2 NO. 61010-1 – Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use. Pt. 1, General Requirements - Edition 2 - Revision Date 2008-10-01
- IEC60601-1-2:2007 Ed 3: Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- IEC61010-1 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use. Pt. 1, General Requirements - Edition 2 - Revision Date 2003-04-01
- IEC61010-2-010 : Particular requirements for laboratory equipment for the heating of materials, Second Edition, 2003-06
- IEC 61010-2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes, Edition 1.1 2009-08
- IEC 61010-2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment, First Edition, 2002-01
- EN61326-1:2006 (IEC 61326-1:2005 Ed 1) Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements. Part 1: General Requirements
- UL 61010-1 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements - Edition 2 - Revision Date 2008-10-28

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

CLSI C28-A3c (Now EP28-A3c: 2010) Defining, Establishing, Verifying Reference Ranges; Approved Guideline - 3rd Ed. (2008)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#7-224	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U S C 360d], http://www fda gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default htm

[3] http://www accessdata fda gov/scripts/cdrh/cfdocs/cfStandards/search cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard The summary report includes information on all standards utilized during the development of the device

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard Found at http://www accessdata fda gov/scripts/cdrh/cfdocs/cfStandards/search cfm

[6] The online search for CDRH Guidance Documents can be found at http://www fda gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default htm

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
CLSI C28-A3c (Now EP28-A3c: 2010) Defining, Establishing, Verifying Reference Ranges; Approved Guideline - 3rd Ed. (2008)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

CLSI EP05-A2 Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - 2nd Ed. (2004)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#7-110	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U S C 360d], http://www fda gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default htm

[3] http://www accessdata fda gov/scripts/cdrh/cfdocs/cfStandards/search cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard The summary report includes information on all standards utilized during the development of the device

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard Found at http://www accessdata fda gov/scripts/cdrh/cfdocs/cfStandards/search cfm

[6] The online search for CDRH Guidance Documents can be found at http://www fda gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default htm

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
CLSI EP05-A2 Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - 2nd Ed. (2004)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

CLSI EP6-A Evaluation of Linearity of Quantitative Measurement Procedures; A Statistical Approach; Approved Guideline (2003)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#7-193	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U S C 360d], http://www fda gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default htm

[3] http://www accessdata fda gov/scripts/cdrh/cfdocs/cfStandards/search cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
CLSI EP6-A Evaluation of Linearity of Quantitative Measurement Procedures; A Statistical Approach; Approved Guideline (2003)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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DESCRIPTION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

CLSI EP07-A2 Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition (2005)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#7-127	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
CLSI EP07-A2 Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition (2005)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

CLSI EP09-A3 Measurement Procedure Comparison, Bias Estimation Using Patient Samples; Approved Guideline - 3rd Ed. (2013)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#7-245	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
CLSI EP09-A3 Measurement Procedure Comparison, Bias Estimation Using Patient Samples; Approved Guideline - 3rd Ed. (2013)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

CLSI EP25-A Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline (2009)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#7-235	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
CLSI EP25-A Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline (2009)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

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DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

CSA C22.2 NO. 61010-1 - Safety Requirements for Electrical Laboratory Equipment - Part 1: Edition 2 (2008)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
CSA C22.2 NO. 61010-1 - Safety Requirements for Electrical Laboratory Equipment - Part 1: Edition 2 (2008)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC60601-1-2:2007 Ed 3: Medical Electrical Equipment – Part 1-2: Electromagnetic Compatibility - Requirements and Tests (2007)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-53	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U S C 360d], http://www fda gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-1-2:2007 Ed 3: Medical Electrical Equipment – Part 1-2: Electromagnetic Compatibility - Requirements and Tests (2007)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 61010-1 - Safety Requirements for Electrical Equipment for ... Laboratory Use. Pt. 1, General Requirements - Edition 2 (2003)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
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If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 61010-1 - Safety Requirements for Electrical Equipment for ... Laboratory Use. Pt. 1, General Requirements - Edition 2 (2003)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 61010-2-010 : Particular requirements for laboratory equipment for the heating of materials, Second Edition (2003)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 61010-2-010 : Particular requirements for laboratory equipment for the heating of materials, Second Edition (2003)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 61010-2-081: Particular requirements for automatic and semi-automatic lab equip. for analysis, other purposes, Ed. 1.1 (2009)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 61010-2-081: Particular requirements for automatic and semi-automatic lab equip. for analysis, other purposes, Ed. 1.1 (2009)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 61010-2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment, First Edition (2002)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 61010-2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment, First Edition (2002)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 61326-1:2005 Ed 1 Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
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Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U S C 360d], http://www fda gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default htm

[3] http://www accessdata fda gov/scripts/cdrh/cfdocs/cfStandards/search cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard The summary report includes information on all standards utilized during the development of the device

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 61326-1:2005 Ed 1 Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

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DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

UL 61010-1 - Safety Requirements for Electrical Laboratory Equipment. - Part 1: General Requirements - Edition 2 - (2008)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
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If yes, was the guidance document followed in preparation of this 510k?	☐	☐

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DESCRIPTION

JUSTIFICATION

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CORA® System 510(k) Executive Summary

DESCRIPTION OF THE DEVICE

Intended Use / Indications for Use

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The CORA System records the kinetic changes in a sample of citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

System Description

The CORA System consists of a four-channel diagnostic instrument with integrated computer module, system reagents, quality controls and microfluidic test cartridges. Reagents are dried-in-place within the cartridges during manufacturing. Abnormal Quality Control material is lyophilized and can be reconstituted with water as needed for WQC testing with reagent cartridges.

To perform a test, a disposable CORA Cartridge is inserted into the instrument. Blood or WQC material is added to an entry port on the cartridge and drawn into the cartridge under instrument microfluidic control. The amount of the sample drawn into the cartridge is automatically determined by the volume of the blood chambers in the cartridge. Once in the disposable, the sample is moved into as many as four separate analysis channels, depending upon the assays being performed. Reconstitution of reagents dried within the cartridge is accomplished by moving the sample back and forth through reagent chambers, under the control of microfluidic valves and bellows within the cartridge. After each sample has been mixed with reagent, it is delivered to a test cell wherein a sample is suspended and optically monitored for changes in the sample due to coagulation.

CORA Technology

The CORA technology employs a non-contact coagulation measurement method, whereby the blood sample is vibrated and the frequency of peak amplitude (resonant frequency) of the sample is optically measured. A piezoelectric actuator vibrates the measurement cell(s) through a motion profile composed of summed sinusoids at different frequencies from 10-500Hz. Some of the measurement cell motion will induce motion in the sample meniscus, which will be detected by a photodiode. The resulting motion of the meniscus is monitored optically and analyzed by the instrument to calculate the resonant frequency and modulus of elasticity (stiffness) of the sample. By performing a Fast Fourier Transform (FFT) on meniscus motion data, it is possible to determine the frequencies of input motion that caused the greatest deflection of the sample (these are called the resonant frequencies).

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Resonance is the tendency of a material or structure to oscillate with greater amplitude at some frequencies than others. The exact frequencies at which resonance occurs will depend on the stiffness and mass of the sample. Stiffness, in turn, is a function of a material's modulus of elasticity and the boundary conditions to which the material is exposed, such as the geometry and materials of a test cell. By holding these boundary conditions and sample mass constant from run to run, the CORA System allows direct comparison of elasticity between samples.

The CORA System works using a disposable cartridge containing up to four independent measurement cells. Each cell consists of a short vertically-oriented injection molded tube (ring) with a diameter of 2.5mm and a length of 4.5mm. Detection of clotting in the CORA System is performed optically. Under control of the instrument, approximately 20µl of prepared sample is delivered to the tube, where a meniscus naturally forms at each end of the tube. The tube is positioned so that the lower meniscus partially blocks light traveling from a collimated source toward a photodiode. In a typical test, blood that has been delivered to the measurement cell will not clot for several minutes. During this time the sample has no inherent stiffness except that provided by surface tension, and since this remains constant the measured resonant frequencies will not change. Once clotting begins, however, the elastic modulus and thus the resonant frequencies increase rapidly. During fibrinolysis, the process is reversed, with elastic modulus and resonant frequencies decreasing. In tests where clotting does not occur, the resonant frequency of the sample will not change. During coagulation, however, a clot will bind to the test tube (ring) and the resonant frequency will rise with increasing firmness of the clot. The CORA Instrument collects meniscus motion data, tracks changing resonant frequencies and analyzes the frequency data to provide semi-quantitative parameters describing the clot. Results are presented in a format identical to the TEG 5000 predicate device.

DEVICE COMPARISON TABLE

The following table demonstrates that the CORA and TEG 5000 systems are substantially equivalent. Both instruments monitor the same physical properties of the coagulation process, providing test results using disposables, reagents and WQC of the same materials. Environmental conditions, test times and power requirements are similar. The CORA system is more automated and much simpler to operate, resulting in the reduced chance of operator error. The CORA system provides for 4 independent test channels, whereas the TEG 5000 has 2 independent test channels.

Item	TEG® 5000 Predicate	CORA® System
Instrument		
Technological Purpose	Monitoring the response of a clot to low levels of applied strain	Monitoring the response of a clot to low levels of applied strain
What is measured	Changes in clot elasticity over time	Changes in clot elasticity over time
Initial Warm Up Time	5 min	5 min
Time to Complete a Test	Varies with assay	Same as TEG 5000
Instrument	Thrombelastography instrument, separate computer and software	Fully integrated Thrombelastography instrument
Measuring Technique	Direct-contact measurement of shear elasticity of a coagulating sample	Non-contact measurement of shear elasticity of a coagulating sample
Measuring Channels	Two, each independent and interchangeable (can be used with any approved reagent)	Four, each independent and interchangeable (can be used with any approved reagent)

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Item	TEG® 5000 Predicate	CORA® System
Signal Transducer	Electromechanical detection (rotary variable inductive transformer) of rotary motion of a pin suspended in the sample	Optical detection (silicon photodiode) of the motion of a free surface of the sample
Temperature Control	20° to 40°C	20° to 50°C
Sample & Total Reaction Volumes (per channel)	360 – 380 µl; 360 – 380 µl	63 µl; 20 µl
Mains Supply Voltage & Instrument Input Voltage	120V, 60Hz or 220V, 50Hz Mains; Input 24 volts AC, 30 watts max	100-240V, 50-60Hz Mains; Input 12 volts DC, 60 watts max
Environment Conditions	Level and vibration free position, no solar radiation Operating temperature: 10° to 35 °C Storage Temperature: -30° to +50 °C (instrument only) Relative humidity 20 - 80% (non-condensing)	Stable and level surface. Operating Temperature 10° to 32°C Storage Temperature: -20° to +50°C (instrument only) Relative humidity 20 - 80% (non-condensing)
Sample Preparation	Performed by the operator using pipettes to reconstitute reagents and mix reagents with the sample	Performed under instrument control within the disposable cartridge
Pipetting	Manual accurate pipettes (10, 20, 50, 100, 340, 360, 500, 1000µl)	Unmetered transfer pipette or syringe; blood sample added to a level above the line marked on the cartridge blood intake well
Consumables	Cups & Pins (acrylic plastic)	Carrier (acrylic plastic) with microfluidics laminate and test rings (acrylic plastic)
Assays and Reagents		
CK: Intrinsic Contact Activation Reagent	Kaolin and $CaCl_2$	Kaolin and $CaCl_2$, same materials as TEG 5000
CRT: Citrated RapidTEG (Tissue Factor and Kaolin Activation)	Tissue Factor, Kaolin and $CaCl_2$	Tissue Factor (TF), Kaolin and $CaCl_2$, same materials as TEG5000
CFF: Citrated Functional Fibrinogen, Platelet-Blocked, Tissue Factor Activation	ReoPro®, Tissue Factor and $CaCl_2$, same materials as CORA	ReoPro®, Tissue Factor and $CaCl_2$, same materials as TEG 5000
CKH: Intrinsic Contact Activation Reagent with Heparinase	Kaolin, $CaCl_2$ and Heparinase, for neutralizing heparin	Kaolin, $CaCl_2$ and Heparinase, same materials as used with TEG 5000
Abnormal Quality Control Material	TEG coagulation control – Level 2	CORA Abnormal coagulation control –same material as TEG 5000 Level 2

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SUMMARY OF PERFORMANCE TESTING

Non-Clinical Performance Testing

Analytical Precision

Testing was performed in Coramed's laboratory for precision, using CLSI EP5-A2 as guidance. Blood samples from three different subjects were used for these tests, one with normal coagulation levels, one with lower levels of coagulation (hypo) and one with higher levels of coagulation (hyper). All three samples were run in duplicate for five days over an 8 day period. Each day two (2) operators ran six (6) CORA instruments in parallel and in duplicate, with two instruments running one reagent lot. A total of three (3) reagent lots were evaluated each day. This resulted in 12 observations per sample per operator each day. Each channel in the cartridge contained reagents for each of the four assays. Statistics were calculated for repeatability, between-day, between-operator, between lot, between-instrument, and Total. Coefficients of Variance (CV) for these tests were within product specifications.

Interference

Testing was performed in Coramed's laboratory for interference, using CLSI EP7-A2 as guidance. For CK and CRT, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). For CK, only Hemolysis and Hemodilution were found to be interferents. For CRT Short Draw, Hemolysis and Hemodilution were found to be interferents. For CKH, Protamine was tested for interference and found to be an interferent at concentrations above 0.062 mg/ml. For CFF, Heparin was found to be an interferent above concentrations of 1 IU/ml and Hemodilution was found to be an interferent above hemodilution levels of 30%.

Linearity

Testing was performed in Coramed's laboratory for linearity, using CLSI EP6-A as guidance. CFF was found to be linear with varying concentrations of Fibrinogen.

Sensitivity and Specificity

CK was tested for Sensitivity and Specificity with respect to Heparin, comparing R parameters of multiple blood samples with different clinically relevant concentrations of Heparin to multiple samples without heparin. Both Sensitivity and Specificity were found to be 100%.

Heparin Neutralization

Heparin Neutralization of CKH was tested using blood samples spiked with Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) and comparing these results to data obtained from testing CK with un-spiked blood samples. CKH was found to completely neutralize UFH levels of 6 IU/ml blood and LMWH levels of 0.016 mg/ml blood.

Clinical Testing

Testing was performed at three clinical sites for Reference Ranges and Method Comparison.

Reference Ranges

Reference Ranges for the CORA assays were estimated using the CLSI C28-A3c Guideline on three reference sample groups. Blood samples from up to 55 normal volunteer subjects were taken at each of the three sites, for a total of 157 samples. Subjects were chosen representing demographic populations of the three areas, regarding age, race and gender. For CK, ranges were established for the R, K, Angle and MA. For CRT, the reference range for the MA parameter was established. For CFF, the ranges for the MA and

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FLEV parameters were established. Reference Ranges for CKH were established for the R parameter but are not required because the only purpose is to neutralize the heparin in a patient's blood, regardless of the patient's hemostasis condition. Comparing the CKH results with CK results for the R parameter can be used to determine if there is any heparin present in a patient sample.

Reference Ranges for Abnormal Wet Quality Control (WQC) material when used in CORA Multichannel Citrated cartridges were estimated. Using three lots of Abnormal Quality Control material and three Multichannel Citrated cartridge lots, a total of 135 test results were obtained. For CK with Abnormal WQC, ranges were established for the R, K, Angle and MA. For CRT with Abnormal WQC, the reference range for MA was established. For CKH with Abnormal WQC, the range was established for R, and for CFF with WQC, the ranges for MA and FLEV were established.

Method Comparison

Method Comparison studies were conducted at three clinical sites on patient samples. Over 100 patients per site were enrolled, totaling over 300 patients each tested at two time points using both the CORA System and the TEG 5000. The subjects were patients undergoing heart surgery or PCI procedures, with blood samples drawn pre- and post-surgery and/or in the ICU. In order to broaden the range of comparison, up to 10% additional contrived samples were taken at each clinical site. In this submission, regression plots and statistics are presented comparing the CORA System with the TEG 5000, demonstrating excellent equivalence between the two systems for all assays and relevant parameters.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTING

The data and information provided in this submission support a substantial equivalence determination for the CORA System and the TEG 5000 predicate device. Therefore, clearance of this 510(k) premarket notification for the CORA instrument, assays and reagents should be granted.

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General Description of CORA System

CORA SYSTEM COMPONENTS AND ACCESSORIES

Instrument: CORA® (Coagulation Resonance Analysis) System

Assays and Reagents:

- Citrated Assays and Reagents
  - CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
  - CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
  - CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
  - CFF (Citrated Functional Fibrinogen) (Tissue Factor + $CaCl_2$ + ReoPro® for citrated blood) reagent
- Abnormal WQC material

Cartridge

- 4-Channel Citrated Cartridge (CK/CRT/CKH/CFF)

CORA SYSTEM PARAMETERS

Both the TEG 5000 and CORA System monitor the elastic modulus of clots. As a result, even though CORA measurements are frequency-based, they are readily converted to TEG 5000 equivalents. The following definitions apply to calculated parameters in the CORA System:

CORA Parameter	Definition	Parameter Relation to Hemostasis
R	R is the time from the start of the test until initial fibrin formation. This represents the enzymatic portion of coagulation.	Clotting time - Normal / reduced / increased speed of coagulation initiation
K	K is the time after R needed to reach a certain level of clot strength. This represents clot kinetics.	Normal / reduced / increased speed of coagulation amplification and propagation
Alpha α (angle)	Alpha is the angle representing the rate of increase in the clot strength and the rapidity of fibrin build-up and cross-linking.	Normal / reduced / increased speed of coagulation amplification and propagation
MA	MA, or Maximum Amplitude, represents the maximum firmness of the clot during the test.	Normal / reduced / increased clot elasticity/strength
FLEV	FLEV is an estimate of the fibrinogen level in the blood sample.	Estimated Functional Fibrinogen Level

DETAILED DESCRIPTION OF ASSAYS AND REAGENTS

Citrated Assays

The CK assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via the intrinsic pathway in citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle), and Maximum Clot Strength (MA). K and Alpha are complementary parameters and should be used in conjunction with Clotting Time (R) and Maximum Clot Strength (MA).

The CRT assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via both the intrinsic and extrinsic pathway in citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA).

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The CFF assay is a semi-quantitative *in vitro* diagnostic assay for monitoring hemostasis of citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. CFF is used in conjunction with CK and clotting characteristics are described by the functional parameter Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

The CKH assay is a semi-quantitative *in vitro* diagnostic assay used in conjunction with the CORA System to monitor the effects of heparin in the blood stream of a patient. CKH is used in conjunction with CK and heparin influence is determined by comparing Clotting Times (R) between the two tests.

Wet Quality Control (WQC)

Abnormal Wet Quality Control (WQC) material consists of bovine plasma with buffers and stabilizers, and is used instead of hypocoagulable blood, in conjunction with the Citrated Multichannel system cartridge. When used with the Citrated Multichannel cartridge, this material provides consistent and repeatable values for CORA parameters to confirm reagent quality and viability.

CORA INSTRUMENT DEVICE DESCRIPTION

Summary

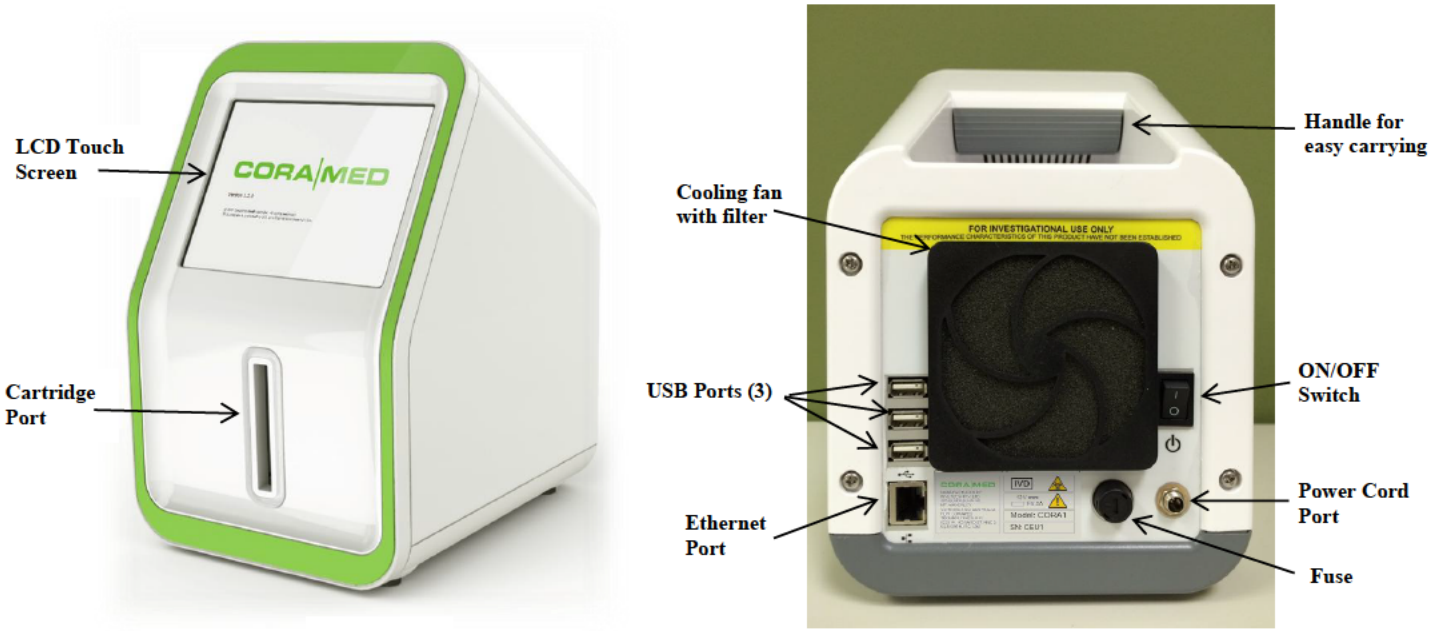
The Haemoscope Thrombelastograph® Coagulation Analyzer TEG® 5000 instrument is based on classical thrombelastography, developed by Hartert in 1948. The technique allows continuous measurement of clot elasticity in the presence of coagulation factors and inhibitors during clot initiation, formation, retraction and subsequent fibrinolysis.

Like the TEG 5000, the CORA System uses thrombelastography to provide continuous measurement of clot elasticity. Although the two systems differ in their test cell geometries and excitation and detection methods, they deliver the same semi-quantitative clinical parameters related to clot formation and dissolution. As with the TEG 5000, the CORA System has no patient-contacting components.

The CORA System consists of a four-channel diagnostic instrument with integrated computer module, display touch screen for operator interaction, and a slot for inserting one of the CORA cartridges. To perform a test, a disposable CORA Cartridge is inserted into the instrument. The instrument reads the bar code on the cartridge and identifies the type of cartridge for operator confirmation. Then, the operator adds a blood or WQC sample to the entry port on the cartridge and uses the touch screen to issue the command to the instrument to proceed with the test. The sample is then drawn into the cartridge under instrument control. The amount of the sample drawn into the cartridge is automatically determined by the volume of the blood chambers in the cartridge. Once in the disposable, the sample is metered into as many as four separate analysis channels, depending upon the assays being performed. Reconstitution of reagents dried within the cartridge is accomplished by moving the sample back and forth through reagent chambers, under the control of microfluidic valves and bellows within the cartridge. (See cartridge description below.) After each sample has been mixed with reagent, it is delivered to a test cell where it is monitored for changes due to coagulation. Excess sample material is moved under microfluidic control into a waste chamber within the cartridge.

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The CORA Instrument

Instrument Quality Control Features

The CORA instrument is designed with internal Quality Control (QC) features that test all instrument functionality. At power on, a Power-On-Self-Test (POST) QC program checks for all instrument performance that is possible without a cartridge being present. Then when a cartridge is inserted into the slot, the instrument performs a Pre-Test QC to verify the bar code reader's ability to identify the cartridge and the integrity of the cartridge-instrument interface. When the test begins, In-Use QC programs continuously monitor the instrument performance throughout the test. Through the incorporation of these three levels of QC, all essential functions of the instrument are checked and verified without the need for external QC materials. The following details are provided to support this statement.

Power-On-Self-Test (POST) QC Functions Performed

When the power switch at the rear of the unit is moved to the "ON" position, the instrument initiates the POST sequence. This performs QC tests on all instrument functions that can be tested without a cartridge present, including valves and valve controls, pneumatics (compressor, accumulators, regulators and sensors), optics, heaters and temperature sensors, instrument internal temperature, processor self-tests, display screen test pattern, touch screen and Ethernet port. Any test failure will report as an error on the display screen and prevent the instrument from further operation.

Pre-Test QC Functions Performed

When a cartridge is fully inserted fully into the slot, the card-present switch is activated and the instrument closes the clamp and starts the Pre-Test QC process. This performs QC tests on the bar code reader, LED/Photo detector modules, piezoelectric actuator, heater/RTD sensor modules, pneumatics integrity at the cartridge-instrument interface, valve and valve controls, and internal temperature monitor. Any test failure will report as an error on the display screen and prevent the instrument from further operation. The bar code reader reads the bar code on the cartridge and identifies the cartridge type to the operator via the display screen. The operator is required to confirm that this is the intended cartridge, so if the bar code reader reads incorrectly (or not at all), the test will not be allowed to proceed.

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In-Use QC Functions Performed

After the operator confirms the identity of the cartridge, the instrument prompts the operator to add the blood sample to the input well of the cartridge and proceed with the test. This initiates a sequence of microfluidics actions (steps) performed by the instrument, drawing the required blood sample or WQC material based on the inserted cartridge, into the cartridge, mixing the sample with the reagents dried within the internal chambers of the cartridge, then delivering the sample to the test rings. During this microfluidics phase, the instrument internal QC functions monitor critical operational parameters (temperature, pressure, vacuum and valve state) at each step, for any out-of-range condition that would invalidate the test. Also, sample volume delivered to the rings is measured and must be within specific limits, as well as the absence of air bubbles in the sample, or the test will be invalidated. The data acquisition phase of instrument operation initiates after delivery of the test sample to the rings, and records all operational parameters continuously every 5-second cycle. At every cycle, any critical operational parameter (temperature, pressure, vacuum, photo detector voltage level, and resonant frequency amplitude) found to be out of range will be reported and the test will be invalidated.

Internal Instrument Logging of QC Functions Performed

Throughout all Internal QC operations, monitored parameters are recorded into an internal QC log file. This can be used by service personnel to assist in troubleshooting and repair operations, and may also serve to provide an audit trail to confirm correct instrument operation.

Instrument Functional Description

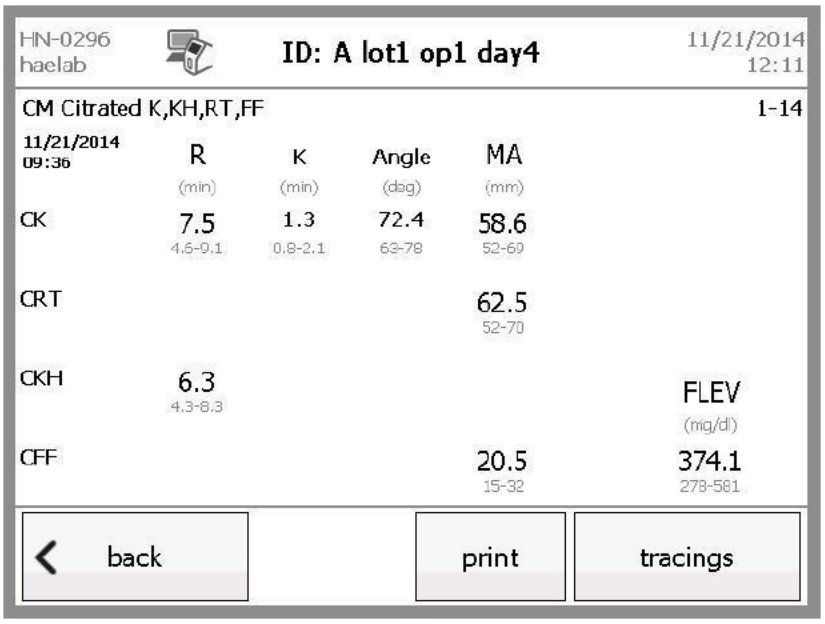
During testing, a piezoelectric actuator drives the measurement cell(s) through a motion profile composed of summed sinusoids at different frequencies. The profile has a maximum amplitude of under 10µm and contains frequencies from 10-500Hz. Some, but not all, of the measurement cell motion will induce higher amplitude motion in the sample meniscus, which will be detected by the photodiode. The resulting motion of the meniscus is monitored optically and analyzed by the instrument to calculate the resonant frequency and modulus of elasticity (stiffness) of the sample. By performing a Fast Fourier Transform (FFT) on meniscus motion data, it is possible to determine the frequencies of input motion that caused the greatest deflection of the sample (these are called the resonant frequencies).

Resonance is the tendency of a material or structure to oscillate with greater amplitude at some frequencies than others. The exact frequencies at which resonance occurs will depend on the stiffness and mass of the sample. Stiffness, in turn, is a function of a material's modulus of elasticity and the boundary conditions to which the material is exposed, such as the geometry and materials of a test cell. By holding these boundary conditions and sample mass constant from run to run, the CORA System allows direct comparison of elasticity between samples.

In a typical test, blood that has been delivered to the measurement cell will not clot for several minutes. During this time the sample has no inherent stiffness except that provided by surface tension, and since this remains constant the measured resonant frequencies will not change. Once clotting begins, however, the elastic modulus and thus the resonant frequencies increase rapidly. During fibrinolysis, the process is reversed, with elastic modulus and resonant frequencies decreasing. In tests where clotting does not occur, the resonant frequency of the sample will not change. During coagulation, however, a clot will bind to the test tube (ring) and the resonant frequency will rise with increasing firmness of the clot. The CORA Instrument collects meniscus motion data, tracks changing resonant frequencies and analyzes the frequency data to provide semi-quantitative parameters describing the clot. Results are presented using parameters same as the TEG 5000; examples of a screen shot and printout are shown below.

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Typical Example of CORA Results Screen

Typical Example of the Printout →

```
Results Printed: 07/17/2014 4:22 PM
Patient ID: ct-125-po
Note:
Date/Time of Test Run: 07/17/2014 2:10 PM
User: Admin
Instrument Name: CEU3
Location: CMT
-----------------------------------------
        CM Citrated K, KH, RT, FF
-----------------------------------------

                    CK
                Patient      Reference
Parameter        Value        Ranges
-----------------------------------------
R (min)           3.5         4.6- 9.1
K (min)           1.5         0.8- 2.1
Ang(deg)         63.4        63.0-78.0
MA (mm)          66.9        52.0-69.0
Reference Ranges: Manufacturer Defined
-----------------------------------------
                    CRT
                Patient      Reference
Parameter        Value        Ranges
-----------------------------------------
MA (mm)          69.9        52.0-70.0
Reference Ranges: Manufacturer Defined
-----------------------------------------
                    CKH
                Patient      Reference
Parameter        Value        Ranges
-----------------------------------------
R (min)           3.9         4.3- 8.3
Reference Ranges: Manufacturer Defined
-----------------------------------------
                    CFF
                Patient      Reference
Parameter        Value        Ranges
-----------------------------------------
MA (mm)          35.8        15.0-32.0
FLEV(mg/dL)     623.1         278-581
Reference Ranges: Manufacturer Defined
-----------------------------------------
Cartridge Lot# 131119-1
Cartridge expiration date;  11/30/2015
Instrument SN:  CEU3
Firmware:  0.1.1417.45734
```

CORA CARTRIDGE DEVICE DESCRIPTION

The CORA System consists of a four-channel diagnostic instrument with integrated computer module, system reagents (CK, CRT, CKH, CFF and CC), quality controls (Level I and Level II) and microfluidic test cartridges. The cartridge channels are equivalent and fully independent, so any reagent can be spotted in any channel or may be eliminated altogether from a cartridge, and any combination of reagents may be spotted in any order. Reagents are dried-in-place within the cartridges during manufacturing. Quality control materials are lyophilized and can be reconstituted with water as needed for WQC testing with reagent cartridges and in cartridges spotted with $CaCl_2$.



Blood or Wet QC Material added here

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The CORA Measurement Technique

The CORA technology is based on a disposable containing up to four independent measurement cells. Each cell consists of a short vertically-oriented injection molded tube (ring) with a diameter of 2.5mm and a length of 4.5mm. Detection of clotting in the CORA System is performed optically. Under control of the instrument, approximately 20µl of prepared sample is delivered to the tube, where a meniscus naturally forms at each end of the tube. The tube is positioned so that the lower meniscus partially blocks light traveling from a collimated source toward a photodiode. The following graphic explains the cartridge structure and microfluidics actions.

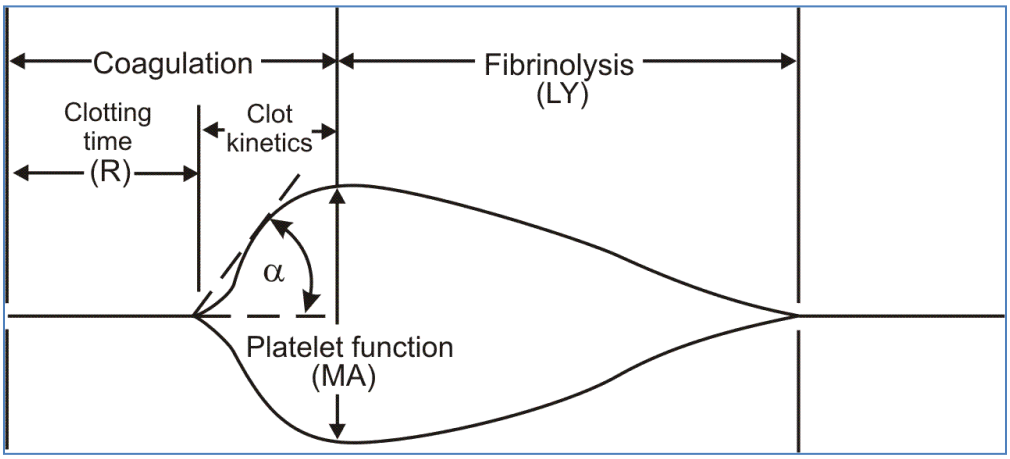
(b)(4)



Cartridge Structure and Microfluidics Actions

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The following tracing is representative of tracings from both the CORA System and the TEG 5000. However, due to size limitations of the CORA display, the CORA tracing is not intended to be used for interpretation of patient test results. It is useful for monitoring test progress because the numeric results (parameters) are not displayed on the screen until each is finalized.



Typical Graphical Representation (Tracing) of the Clotting Process

Hazard / Risk Analysis Summary

Coramed has a documented Risk Management Procedure which was used to develop a Risk Management Plan for the CORA System, including the instrument, reagents, cartridges and accessories. A high-level hazard table was developed, with severities assigned to each hazard, followed by fault tree analyses of each hazard and mitigation strategies as appropriate, all summarized in the Risk Management Summary table. Then, Design and Process Failure Mode and Effects Analysis (DFMEA and PFMEA) were conducted.

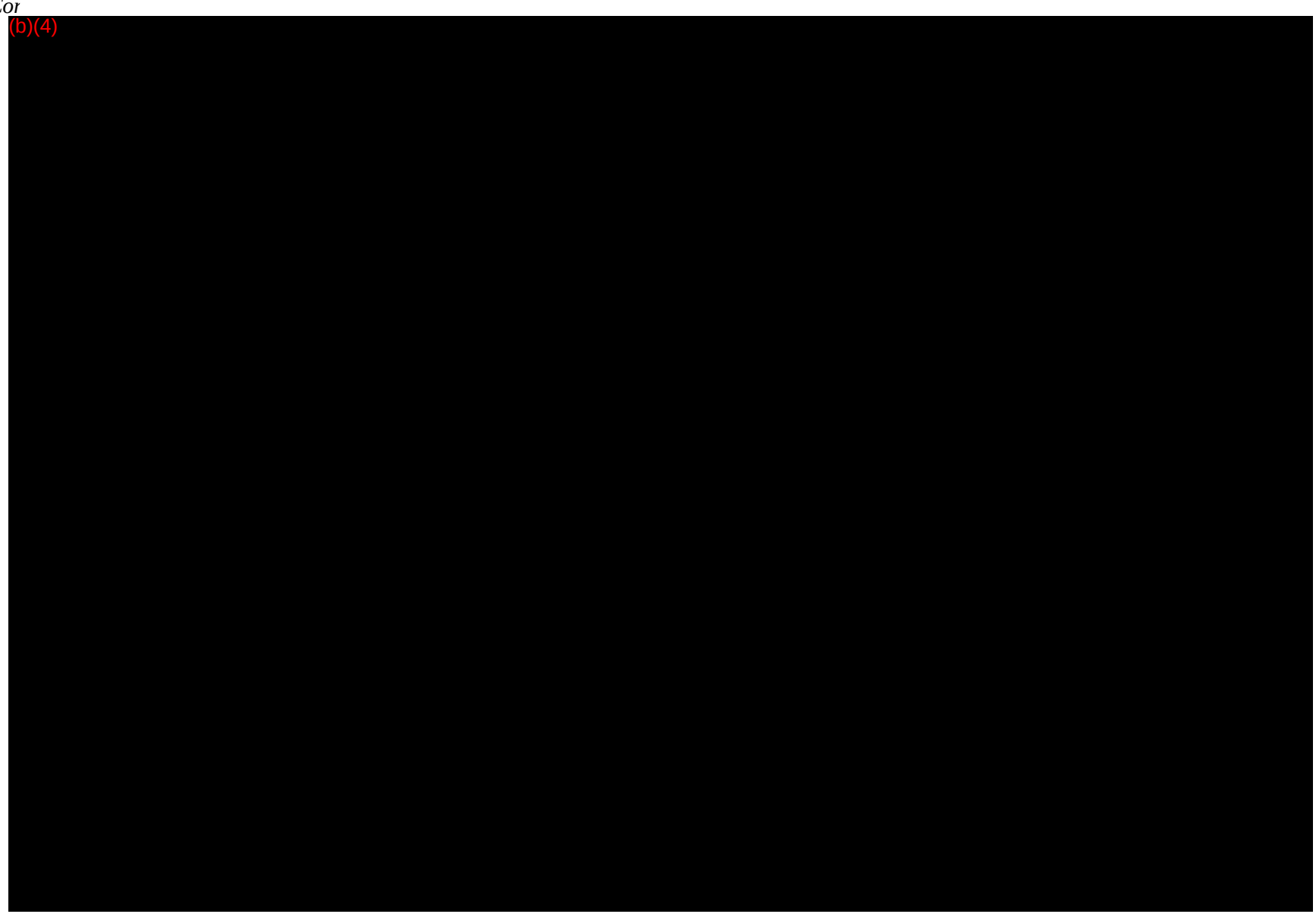
The following page shows a functional block diagram for the CORA instrument. This was used as the high-level basis for a DFMEA and a PFMEA encompassing the examination of all functional aspects of the instrument, including software. Similarly, an extensive DFMEA and corresponding PFMEA were performed for the cartridge and reagents. These were conducted and documented in accordance with the ISO 14971 standard: *Medical Devices – Application of risk management to medical devices.*

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(b)(4)



System Block Diagram

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SECTION 12: SUBSTANTIAL EQUIVALENCE DISCUSSION

PREDICATE DEVICE

- Thrombelastograph® Coagulation Analyzer (TEG®) – 5000 Series, K002177, Product Code JPA (System, Multipurpose, for In Vitro Coagulation Studies), Haemoscope Corporation

Summary of Technological Characteristics

Similarities
Intended Use / Indications for Use

TEG® 5000 Predicate	CORA® System
The TEG 5000 Series Analyzer is intended to be used to provide a quantitative and qualitative indication of the coagulation state of a blood sample by monitoring, measuring, analyzing and reporting coagulation parameter information. The Thrombelastograph (TEG) Coagulation Analyzer TEG-5000 Series records the kinetic changes in a sample of whole blood, plasma or platelet-rich-plasma as the sample clots, retracts and./or lyses (breaks apart). Results from the TEG Analyzer should not be the sole basis for a patient diagnosis; TEG results should be considered along with a clinical assessment on the patient's condition and other coagulation laboratory tests. For professional use only.	The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The CORA System records the kinetic changes in a sample of citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV. The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges. Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

The above comparison shows the equivalence of Intended Use and Indications for Use between the CORA System and the TEG 5000.

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Similarities

Item	TEG® 5000 Predicate	CORA® System
Instrument		
Technological Purpose	Monitoring the response of a clot to low levels of applied strain	Monitoring the response of a clot to low levels of applied strain
What is measured	Changes in clot elasticity over time	Changes in clot elasticity over time
Initial Warm Up Time	5 min	5 min
Assays and Reagents		
Intrinsic Contact Activation Reagent (CK)	Kaolin and $CaCl_2$	Kaolin and $CaCl_2$ (CK), same materials as TEG 5000
Intrinsic Contact Activation Reagent with Heparinase for heparin reversal (CKH)	Kaolin and $CaCl_2$ with Heparinase	Kaolin, Heparinase and $CaCl_2$, same materials as TEG 5000
Citrated RapidTEG (CRT) (Tissue Factor and Kaolin Activation)	Tissue Factor (TF), Kaolin and $CaCl_2$	Tissue Factor (TF), Kaolin and $CaCl_2$, same materials as TEG5000
Citrated Functional Fibrinogen (CFF) / Platelet-Blocked (Tissue Factor Activation)	ReoPro®, Tissue Factor and $CaCl_2$, same materials as CORA	ReoPro®, Tissue Factor and $CaCl_2$, same materials as TEG 5000
Calcium Chloride Reagent (CC) (for re-calcification)	$CaCl_2$ reagent	$CaCl_2$ same materials as TEG 5000
Abnormal Quality Control Material	TEG coagulation control – Level 2	CORA coagulation control - Abnormal, same material as TEG 5000 Level 2

Differences

Item	TEG® 5000 Predicate	CORA® System
Instrument	Thrombelastography instrument, separate computer and software	Fully integrated Thrombelastography instrument
Measuring Technique	Direct-contact measurement of shear elasticity of a coagulating sample	Non-contact measurement of shear elasticity of a coagulating sample
Physical configuration used for sample measurement	Rotating cylindrical container (cup) with pin suspended inside cup; non-contact measurement of pin rotation	Vertically-oriented cylindrical container (ring or tube) containing sample with meniscus formed at bottom; non-contact measurement of meniscus amplitude of vibration

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Item	TEG® 5000 Predicate	CORA® System
Physical principle underlying measuring technique	Clotting process causes an increase in the modulus of elasticity, which increases stiffness and increases the force binding the cup and pin when the cup rotates. This increases the rotation of the pin, causing increased angular force on the torsion wire, which increases the TEG clot strength amplitude. During clot dissolution (lysis), the TEG angular force decreases, corresponding to decreasing clot strength amplitude.	Clotting process causes an increase in the modulus of elasticity, which increases stiffness and increases the force of the clot within the ring walls when moving up and down in the ring tube against the sample's own weight. This increases the resonant frequency, which increases the CORA clot strength amplitude. During clot dissolution (lysis), the CORA resonant frequency decreases, corresponding to decreasing clot strength amplitude.
Boundary conditions affecting clot stiffness measurements	Physical cup & pin dimensions define boundary conditions that are held constant, allowing comparison of one sample to the next.	Physical ring tube dimensions define boundary conditions that are held constant, allowing comparison of one sample to the next.
Measuring Channels	2	4
Signal Generation	Single-frequency harmonic oscillation of a cylindrical cuvette containing the sample around a suspended pin	Multi-frequency harmonic oscillation of a small open-ended cylinder containing the sample
Signal Transducer	Electromechanical detection (rotary variable inductive transformer) of rotary motion of a pin suspended in the sample	Optical detection (silicon photodiode) of the motion of a free surface of the sample
Sensitivity to applied strains	To be detected, strength of clot must overcome torsional stiffness forces imposed by wire suspending the pin in the cup.	Applied strains are very low, resulting in minimal interference with small changes in clot formation.
Temperature Control	20° to 40° C	20° to 50° C
Sample Volume (per channel)	360 to 380 µl	63 µl
Total Reaction Volume (single channel)	360 to 380 µl	20 µl
Mains Supply Voltage	120V, 60Hz and 220V, 50Hz model available	100-240V, 50-60Hz (international power supply)
Instrument Input Voltage	24 volts AC, 30 watts max	12 volts DC, 60 watts max
Environment	Level and vibration free position, no solar radiation Operating temperature: 10° to 35 ° C Storage Temperature: -30° to 50 ° C (instrument only) Relative humidity 20 to 80% (non-condensing)	Stable and level surface. Operating Temperature 10° to 32° C Storage Temperature: -20° to +50° C (instrument only) Relative humidity 20 to 80% (non-condensing)
Operating Position	Level (adjusted by leveling feet)	Level (adjustment not required)

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Item	TEG® 5000 Predicate	CORA® System
Sample Preparation	Performed by the operator using pipettes to reconstitute reagents and mix reagents with the sample	Performed under instrument control within the disposable cartridge
Pipetting	Manual accurate pipettes (10, 20, 50, 100, 340, 360, 500, 1000µl)	Unmetered transfer pipette or syringe; blood sample is added until it fills to a level above the line marked on the blood intake well of the cartridge
Consumables	Cups & Pins (acrylic plastic)	Carrier (acrylic plastic) with microfluidics laminate and test rings (acrylic plastic)

(b)(4) These data include all applicable parameters from the four citrated tests (CK, CKH, CRT and CFF). The TEG 5000 measures the changes of the linkage forces of the clot between the cup and pin over time, while the CORA System measures the changes of the resonant frequency of the clot over time. Despite the difference in the way the two instruments measure the changes in the modulus of elasticity of the clot over time, they measure the same physical phenomenon and produce the same result when converted from their specific units of measurement (forces for the TEG5000 and frequency for the CORA System) to millimeters. The fact that these results are similar across all reagents used in both technologies is demonstration that the two technologies measure the same phenomenon, the changes in elastic modulus.

CDRH Blue Book Memorandum #K86-3 was consulted to confirm the determination of CORA and TEG 5000 Substantial Equivalence. The detailed flowchart in this document was used as guidance. Intended Use is the same for both devices, and Indications for Use differences do not alter the intended diagnostic effect, which is the same for both devices. The CORA System has different technological characteristics compared to the TEG 5000, but new types of safety and effectiveness questions are not raised. This statement is supported by evidence presented throughout other sections of this 510(k), including using accepted scientific methods to assess the effects of the new technological characteristics. Performance data is presented to assist in this assessment, demonstrating the equivalence of the CORA and TEG 5000 devices and leading to a Substantial Equivalence determination.

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Section 13: Labeling

This section of the Coramed Technologies CORA 510(k) submission contains labeling used on the Analyzer and cartridge, copies of package insert drafts for the Citrated Multichannel cartridge and the Abnormal Quality Control, and drafts of the CORA Analyzer User Manual and SMS User Guide.

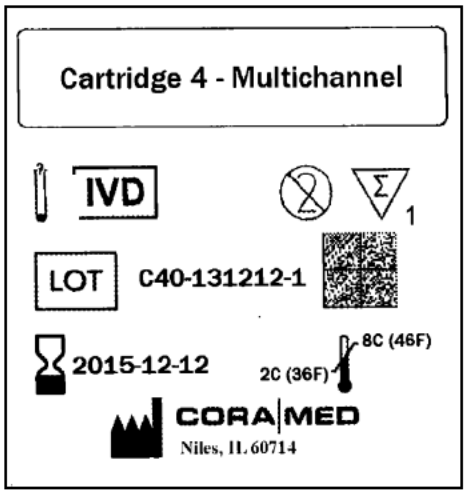
Analyzer Label on back of unit



Representative Picture of Cartridge Showing Label



Pouch Label



Citrated Multichannel Cartridge

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Instructions for Use

The following draft documents are attachments in this section:

- CORA System User Manual
- Service-Maintenance-Settings (SMS) User Guide
- Citrated Multichannel Cartridge Insert
- Abnormal Quality Control Insert

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CORA

CORA® System
USER'S MANUAL

01-124-C CORA® System User's Manual Rev. 06 Copyright © 2014 Coramed Technologies LLC

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SECTION I: ABOUT THE CORA SYSTEM

PROPRIETARY NAME AND ESTABLISHED NAME

Proprietary Name: CORA® (Coagulation Resonance Analysis) System and the following citrated assays and reagents

CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent
Abnormal WQC material to be used for QC testing of citrated reagents

Established Name: Whole Blood Hemostasis System

INTENDED USE / INDICATIONS FOR USE

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The CORA System records the kinetic changes in a sample of citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

USE OR FUNCTION

The CORA system consists of an analyzer and disposable cartridges. The following sections describe the use and function of these.

Analyzer Overview

The analyzer contains a user-friendly interface in the form of a color touch-enabled display. Through this interface, the operator can control all operations of the analyzer except turning it on and off, which is accomplished by accessing a switch at the rear of the analyzer. The system is designed to accept a disposable plastic cartridge, into which a blood sample can be placed. Once a test is started, the analyzer will process the sample and report results on the touchscreen display.

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The analyzer consists of the following features:

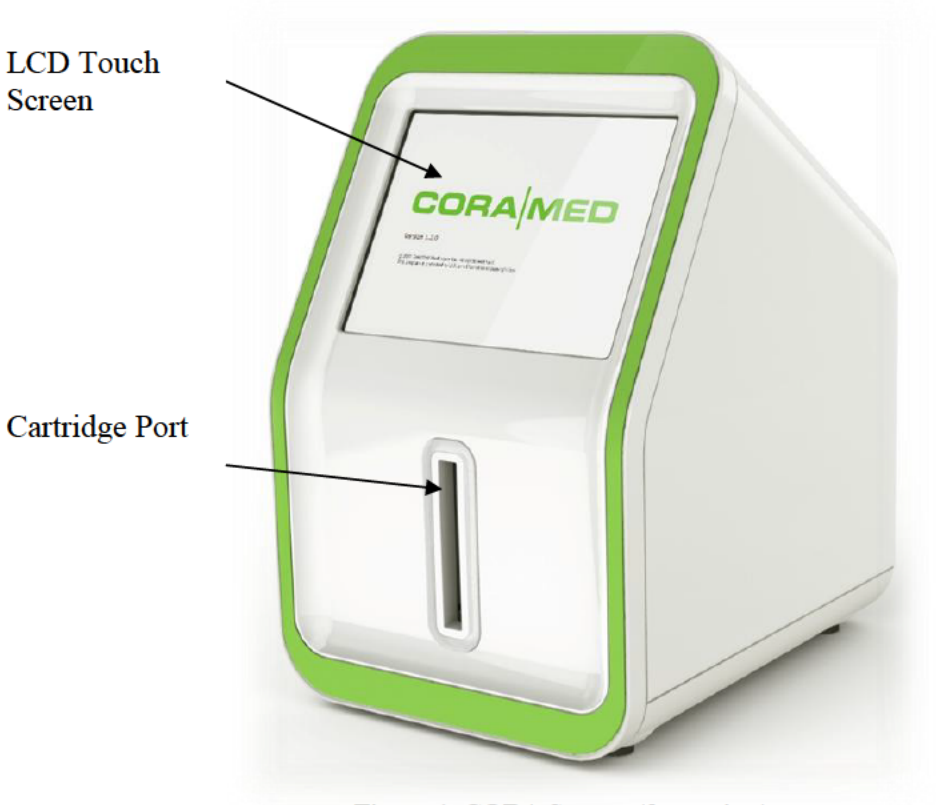


Figure 1. CORA System (front view)

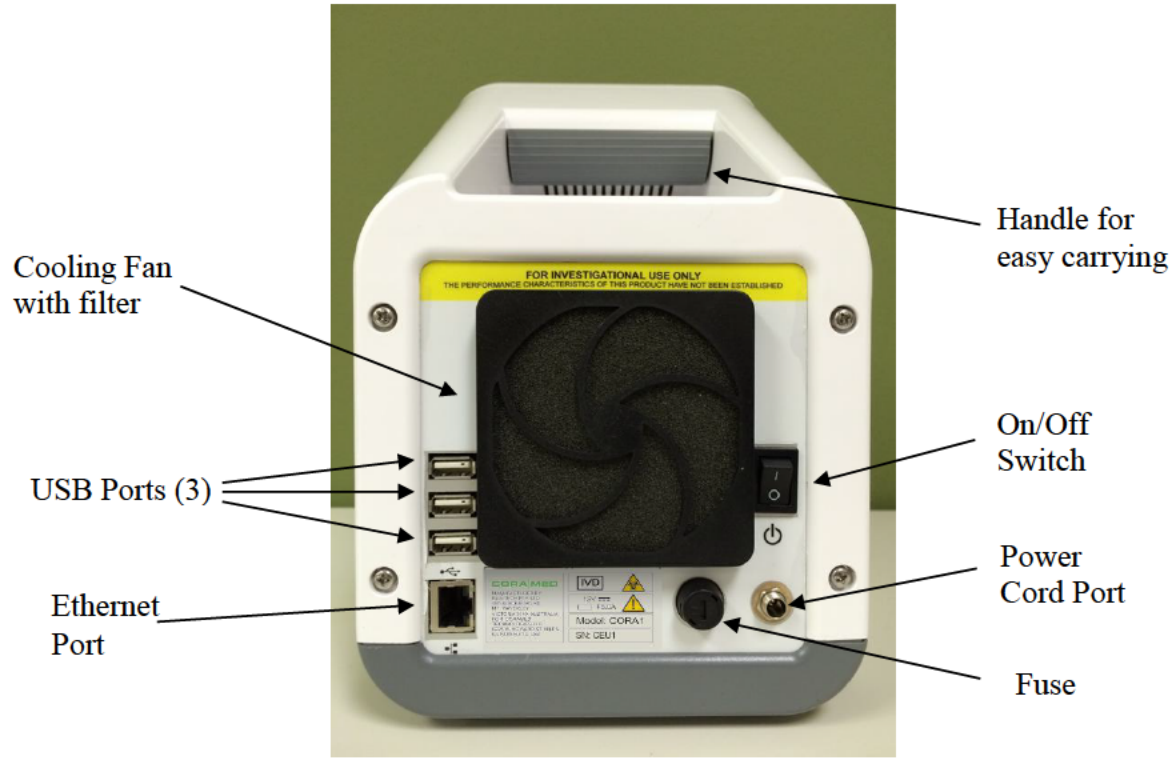


Figure 2. The CORA System (rear view)

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LCD Touch Screen: The primary user interface is a 6.5" color LCD touchscreen which displays instructions guiding the user through CORA System operations. All prompts, directions, selections, and results are displayed on this screen.

Power Input: The CORA system must be connected to a standard power outlet (100 – 240 volt 50/60 Hz) in order to function properly. Power cords appropriate for connection to local AC power mains are provided by Coramed or through distribution channels.

Ethernet Port: The device may be connected via Ethernet to a stand-alone computer (using a cross-over cable) or to an Ethernet switch or router for service, maintenance and setup, and for uploading patient data if desired. All communication through this port is encrypted.

Cooling Fan: A fan in the analyzer ensures that the internal temperature of the analyzer remains close to the ambient temperature. This allows the widest possible range of sample temperatures to be selected without requiring active cooling in the analyzer.

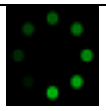
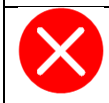
Carrying Handle: The CORA system has an integrated ergonomic carrying handle.

On/Off Switch: The power switch is located in the rear of the device, "I" indicates "on" and "O" indicates "off".

Cartridge Port: The cartridge port at the front of the analyzer accepts Coramed assay cartridges. Each cartridge contains all of the components necessary to allow the analyzer to prepare samples and perform hemostasis tests. During a test, the cartridge is locked in place. Both the unit and the cartridge are designed to prevent incorrect use.

Icons: Table 1 lists icons the user may encounter on the CORA system, along with their definitions. Figure 3 shows the location of all the icons on the display.

Table 1: CORA System user interface icons

	**Unit is Saving Data**		**Data is being collected (progress indicator)**
	**Critical Error**		**Remote User**
	**Error**		**Warning**
	**Unit is operating in Exclusive Mode**		

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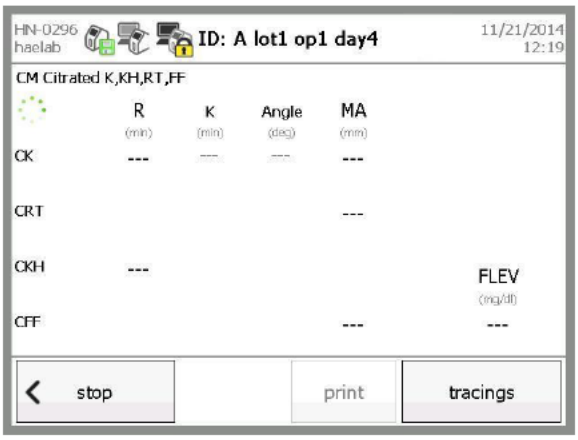


Figure 3. Locations of icons in the user interface

Icons in the top left corner of the screen indicate analyzer status (saving, locked, remote user). There is an icon below these for a progress indicator. When necessary, errors, critical errors and warnings are displayed in their own window.

Cartridge Overview

CORA disposable assay cartridges have a sample port at one end. This port is designed to accept an unmetered amount of blood, delivered by transfer pipette. Under analyzer control, the cartridge will pull this sample into up to four staging areas, mix the sample with reagents that have been dried in place, and then transfer a small amount into the test cells. Any excess blood is moved to a sealed waste area within the disposable.



Figure 4. CORA System disposable assay cartridge

Results Overview

Results of tests performed by the CORA system are designed to be easily read and understood. Up to four basic parameters are calculated during a test: R, K, Alpha, and MA. The following table describes each in more detail.

Table 2: CORA parameters and their meanings

R	The amount of time between the start of the test and the beginning of coagulation.
K	The speed of formation of the clot from R time to a specific clot strength
Alpha	The speed of clot strengthening.
MA	Maximum Amplitude is the ultimate strength of the clot.

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Test results are also plotted on a continuously-updated graph to view the progress of the test. Numerical parameters are determined over the course of a test (which can have a duration of up to 90 minutes), so at any given time there may be parameters that have not yet been finalized. In this case, those parameters are shown as dashed lines until they have been determined. Unused channels and parameters inappropriate for the assay being run will remain blank. Finalized parameters outside of the expected range will be highlighted in orange and an exclamation mark will appear next to the number. A typical results page looks similar to the following:

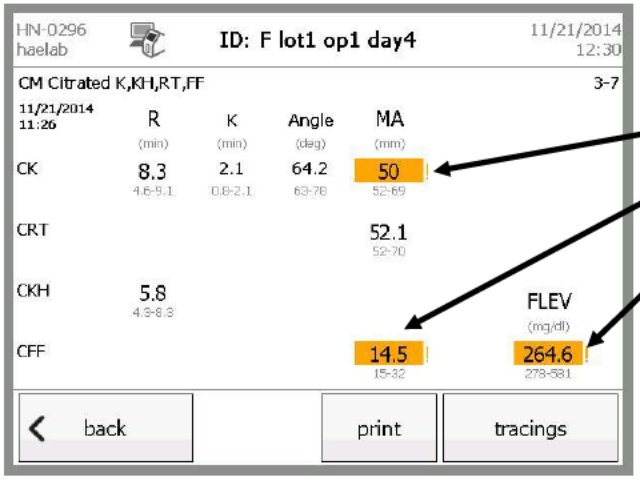


Figure 5. A typical results page for a four-channel assay. Values outside normal ranges are shown in orange with an exclamation point.

Quality Controls Overview

Wet quality control (WQC) consists of a vial with lyophilized biological material for use with the Citrated Multichannel cartridge. When a cartridge is inserted into the CORA device, it triggers a script to access the performance of the system as an Abnormal sample. WQC is described in more detail in Section V of this manual.

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SECTION II: GETTING STARTED WITH THE CORA SYSTEM

INSTALLATION PROCEDURES AND SPECIAL REQUIREMENTS

The CORA system is designed for the rigors of the hospital environment. When installing the device, try to find a location that is reasonably flat and level where the analyzer will be protected from accidental damage. Once a location has been determined, connect the unit's AC power adapter to an outlet using the supplied electrical cord. Then connect the smaller cord to the analyzer, making sure that the plug is screwed into the receptacle on the analyzer. There are no other special requirements.

PRINCIPLES OF OPERATION

Hemostasis is the physiological control of bleeding and is a complex process incorporating vasculature, platelets, coagulation factors (FI-FXIII), fibrinolytic proteins, and coagulation inhibitors. Normal hemostasis is a delicate balance between hemorrhage and thrombosis. The CORA System is an In Vitro Diagnostics (IVD) device that can be used to quantify the hemostatic function of a blood sample.

The CORA System and the Citrated Multichannel Cartridge are used to test the hemostasis properties of citrated blood samples using four different assays/reagents simultaneously, one in each of the four cartridge channels. For the CK assay, Kaolin-activated test methods are used to reduce variability and to reduce the running time of a native whole blood sample. The CRT assay maximally accelerates the clotting process by simultaneously activating the intrinsic and extrinsic coagulation pathways, allowing for the maximum clot strength to be reached more quickly. CKH is similar to CK but with the addition of heparinase, to neutralize the effects of heparin in the blood. If there is heparin present, the R time for CK will be significantly longer than the R time for CKH. The CFF assay fully inhibits all the platelets, thereby excluding their contribution to clot strength, and therefore measures only the functional fibrinogen contribution to clot strength.

PERFORMANCE CHARACTERISTICS AND SPECIFICATIONS

Analyzer Specifications

Dimensions	Width: 175mm
	Length: 257mm
	Height: 270mm
Weight	9.4 lbs (4.2 kg)
Voltage Rating	100V to 240V AC
Power Supply Output Voltage	12 volts DC

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Output Power / Current Rating	5 A, 60 W (max)
Supply Frequency	50/60 Hz
Replaceable Fuse – 5 Amp	Manufacturer: SIBA, P/N GZ179021-5A, 5mm x 20mm, Quick-Action Ceramic, UL Recognized E167295
Display	Backlit color LCD, 640x480 resolution, integrated 4-wire touch screen
Operating Temperature	10° to 32°C
Operating Pressure	0 to 2000 m above sea level
Operating Humidity	20 to 80% RH (non-condensing)
Shipping/Storage Temperature	-20° to +50°C
Shipping/Storage Humidity	20% to 80% RH (non-condensing)

Analytical Measurement Ranges

The following table gives the Analytical Measurement Ranges for the CORA System. It describes how parameter values are displayed and printed for values within the range, above the range and below the range.

Analytical Measurement Ranges (AMR)								
Reagent	Parameter	Low	High	Within AMR	Below AMR		Above AMR	
				Display & Print	Display	Print	Display	Print
CK	R (min)	0.4	17	Actual value	< 0.4 !	< 0.4 !	> 17 !	> 17 !
	K (min)	0.5	5	Actual value	< 0.5 !	< 0.5 !	> 5 !	> 5 !
	Angle (degrees)	39	83	Actual value	< 39 !	< 39 !	> 83 !	> 83 !
	MA (mm)	40	75	Actual value	< 40 !	< 40 !	> 75 !	> 75 !
CRT	MA (mm)	40	75	Actual value	< 40 !	< 40 !	> 75 !	> 75 !
CKH	R (min)	0.3	17	Actual value	< 0.3 !	< 0.3 !	> 17 !	> 17 !
CFF	MA (mm)	4	52	Actual value	< 4 !	< 4 !	> 52 !	> 52 !
	FLEV (mg/dl)	130	950	Actual value	<130 !	<130 !	> 950!	> 950!

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SECTION III: OPERATING INSTRUCTIONS

To turn on the device, move the power switch located at the lower corner of the rear of the analyzer from the "O" position to the "I" position. After a brief startup sequence, an initialization screen will appear as shown in figure 6. At this point, the device will execute a Power-On Self-Test (POST). Following a successful POST, the login screen will be presented, as shown in Figure 7. In this screen, the user can enter their username and password using the touch screen keyboard. To move from username to password, select the "return" key or touch the "password" box. When finished, pressing either the "return" key or the "login" button will complete the login.

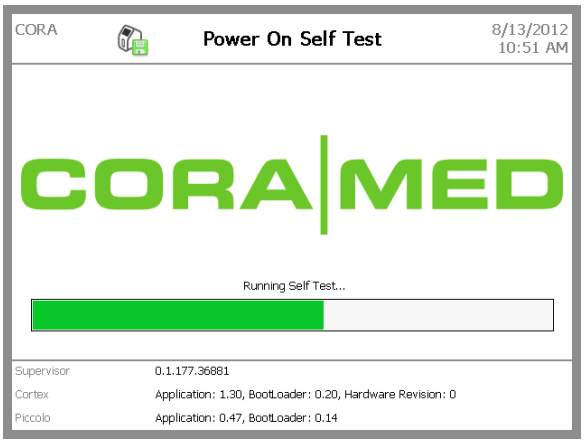


Figure 6. Initialization and POST screen



Figure 7. Login screen

Failed login attempts will result in a page similar to figure 8, requiring the user to reenter their username and password. The unit can safely be shut down from this screen by using the On/Off switch at the rear of the unit.

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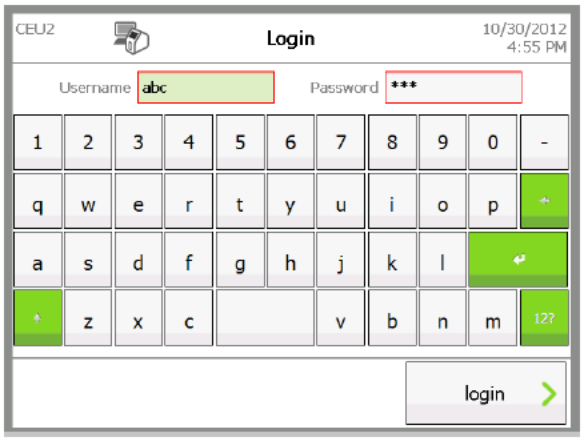


Figure 8. An incorrect login has been entered. Note the username and password fields bordered in red.

A successful login will bring up the analyzer's main menu, as shown in Figure 9.

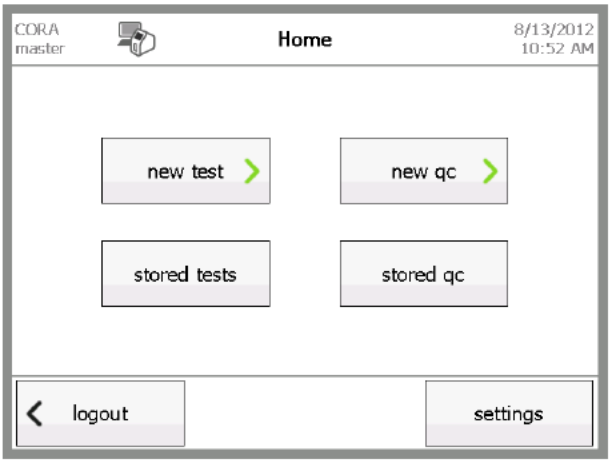


Figure 9. The main menu of the analyzer allows the operator to run new diagnostic and WQC tests or review results from earlier tests. It also provides access to analyzer settings and a method for logging out.

CORA System Operation Overview

The CORA System has been designed to be intuitive and easy to use. During all analyzer operations a button at the lower right of the screen will take the user forward to the next step of the workflow, while a button at the lower left will return to the previous step. Detailed guides for the running of assays, WQC's, and viewing results are discussed in later sections of this manual.

Settings

To change any analyzer settings from their default, select the "Settings" key from the main menu. In order to change settings, you must be logged in with Administrator credentials.

Once in the settings screen, it is possible to change the data and time along with the format used to display the date and time. To change date or time press the up or down arrow for the field you wish to change. Each press will increase or decrease the value by one. When the values are correct, press the Apply button in the bottom corner of the screen to save the changes. For the changes to take effect, the analyzer must be powered

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off and back on again. Altering the date and time has no effect on previously run tests. Always verify that the correct date and time are displayed before running new tests.

To change the date or time style, select the appropriate box and choose any of the available options from the drop-down list. An example of the currently selected date and time format is displayed to the right of the "Time Style" box.

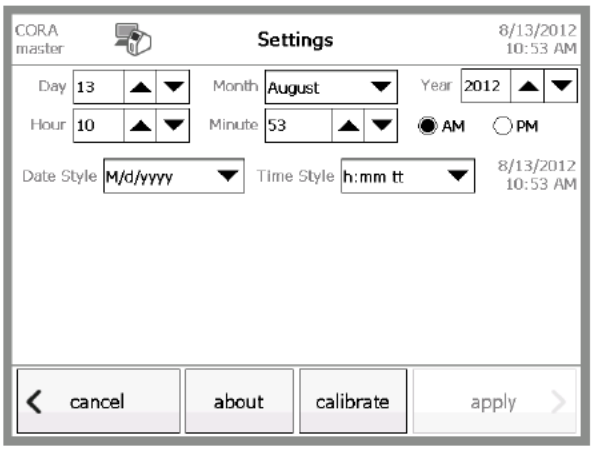


Figure 10. Settings page

To calibrate the touchscreen, select the "calibrate" button. The analyzer will prompt you to press several locations on the screen (figure 11). After completing this process, tap anywhere on the screen to move back to the settings page.

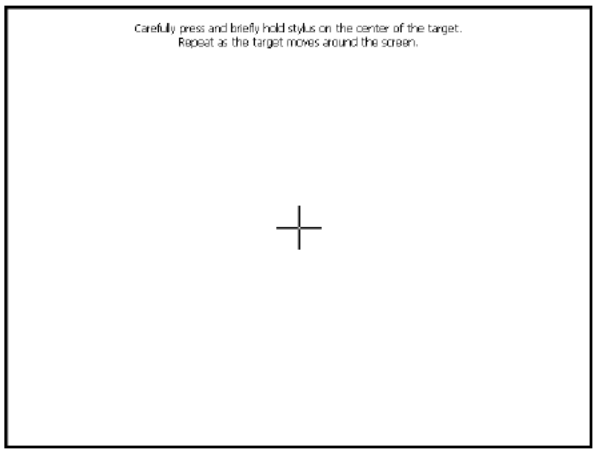


Figure 11. Calibration Screen

Information about the analyzer can be found by selecting the "about" button on the settings screen. Doing so will display a screen similar to Figure 12, where you determine which version of the analyzer software is currently installed, as well as the IP address of the analyzer. Pressing "back" will return you to the settings menu.

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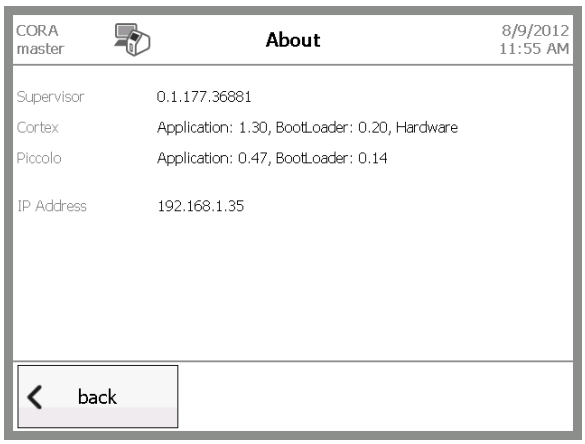


Figure 12. About Screen

Note: To save changes made to any of the settings, return to the main menu by pressing the "apply" button and cycle the analyzer power as noted above. Pressing "cancel" will discard changes and return to the main menu.

Running an Assay on the CORA system (Quick Guide)

1. From the main menu select "new test".
2. Select the patient ID you wish to use. If the patient is not listed, you may add a new patient by selecting the "+" option and entering a patient ID on the screen. Then press "next".
3. Insert the cartridge into the slot as indicated on the screen with the bar code on the left side.
4. After the cartridge pretest is completed and you have verified that the assay is what you intended to run, press "next". If the cartridge is not the desired assay, press "stop" and start over.
5. Add blood to the cartridge sample port to above the level indicated.
6. After loading the sample press "next".
7. The test will run and results will be displayed as they become available.
8. To see a graphical display of the test results thus far, press "tracings".
9. To cycle through individual channel results, press "next tracing" until the desired channel is displayed.
10. When the test is completed, the analyzer will prompt you to remove the cartridge and will return to the table of results.
11. Remove the used cartridge from the slot as shown on the LCD display.
12. Press "done" from the results screen to return to the home page.

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Performing a New Assay (Detailed Guide)

1. From the main menu select “new test,” as shown in Figure 13.

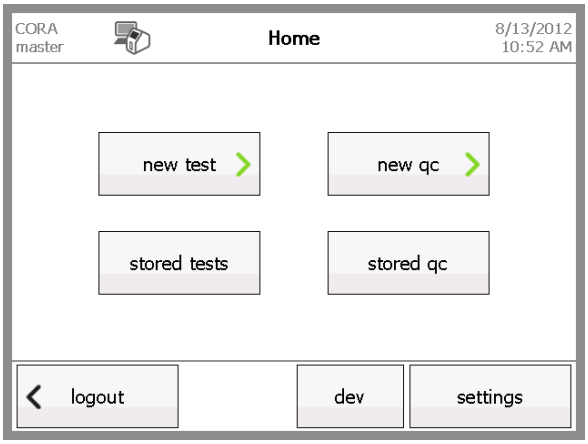


Figure 13: Main menu

2. Using the touchscreen and scroll bars as necessary, select the patient ID you wish to use (Figure 14).

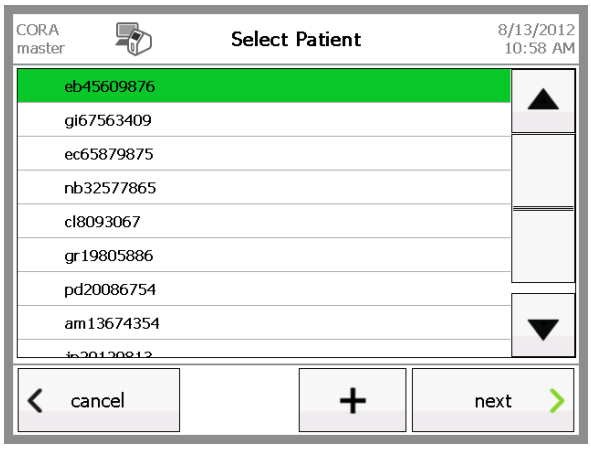


Figure 14. Patient Select screen

If the patient is not listed, a new patient ID can be added by selecting the “+” option to bring up the Add Patient screen. (Figure 15) Entering a patient ID# on this screen, followed by the “ok” or the return key, will add a new patient ID to this analyzer. To return to the main screen without entering a new patient, press “cancel”. Once you have added a patient, select them from the list as shown in Figure 14.

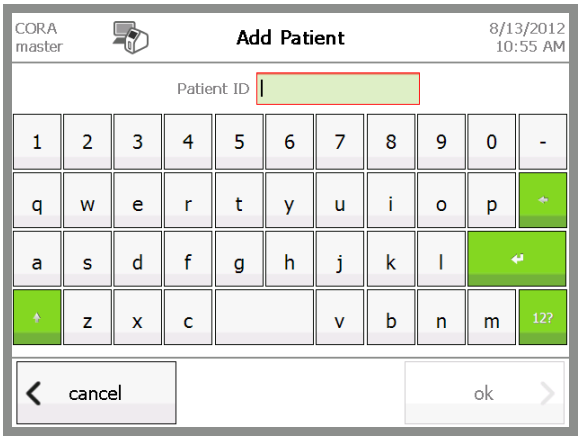


Figure 15. Add New Patient screen

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3. Insert the cartridge into the slot as indicated on the screen with the barcode on the left side, as shown in Figure 16.

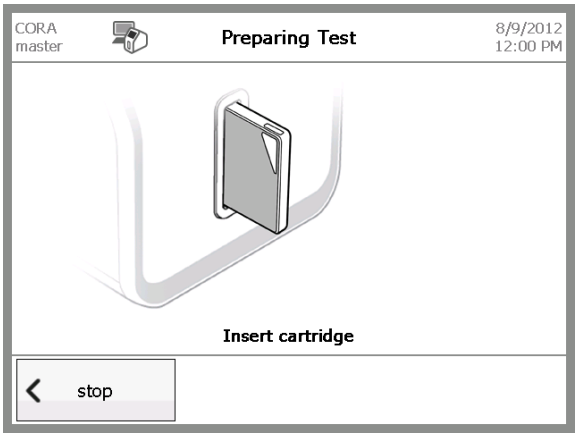


Figure 16. Insert Cartridge screen

IMPORTANT: Cartridges should be kept in their sealed pouches and in the specified storage conditions (2° to 8° C) until just before use. Cartridges can be used straight from the refrigerator – they do not have to be allowed to come to room temperature.

Before opening the cartridge pouch**,** verify that you have the proper cartridge for the assay you wish to run. Tear the pouch at the provided notch to remove the cartridge and then place the cartridge in the analyzer.

Inserting the cartridge triggers a barcode scanner and QC pretest of the cartridge. At the successful completion of the pretest, the analyzer will prompt you to verify that the assay being run is what was intended, as shown in Figure 17. If the assay is correct, press next, otherwise press stop to go back to the main menu. In the event that the cartridge pretest fails, the analyzer will prompt you to insert a new cartridge or contact service personnel if the problem persists.

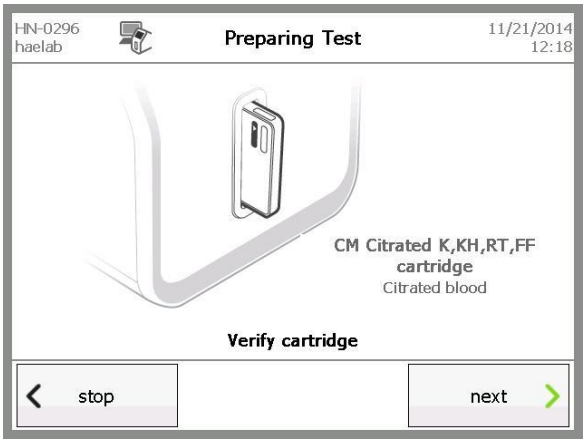


Figure 17. Verify Cartridge Screen

4. The analyzer will prompt you to load a sample of blood by transfer pipette or syringe into the cartridge sample well (Figure 18). Ensure that the blood reaches above the indicated line on the side of the cartridge. Precise measurement is unnecessary, as the analyzer will abort the test if too little blood is present.

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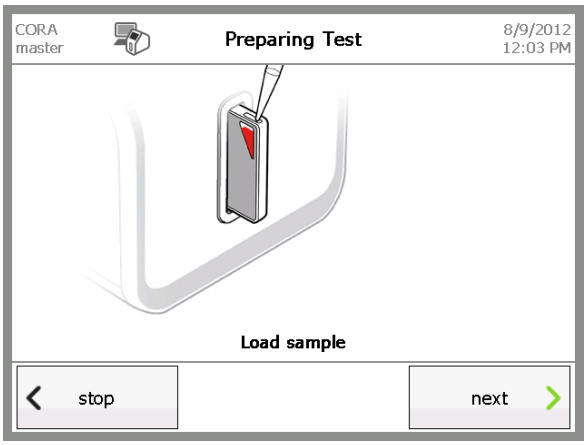


Figure 18: Load Blood Sample Screen

NOTE: Blood should be drawn by a trained phlebotomist following proper techniques and standards. For the citrated assays, citrated blood should be drawn into matching evacuated venous collection tubes. Citrated samples should be tested no earlier than fifteen minutes after being drawn.

5. Press "next" to proceed or "stop" to cancel the test.

6. The CORA analyzer then processes and runs the assay, with the display switching to a table of results. Over the course of the test, results will be updated as parameters are finalized, as shown in Figure 19.



Figure 19. Test results (in process)

The device automatically draws the blood into the active area of the cartridge, meters the exact amount required for the test, mixes it with the reagents spotted in the cartridge, and begins mapping the results as described below. DO NOT attempt to remove the cartridge during the test at any time until the completion of the assay or selecting to halt the test.

While the assay is running, you may access the graphical display of test results by pressing the "tracings" button. From the tracing screen, the user may select "next tracing" to cycle through superimposed, offset and single-tracing views, as shown in Figures 20-22. At any point you can return to the results table by selecting "results".

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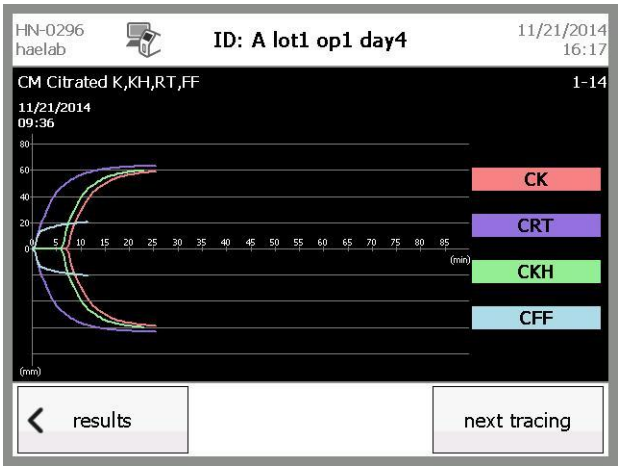


Figure 20. Superimposed Tracings screen

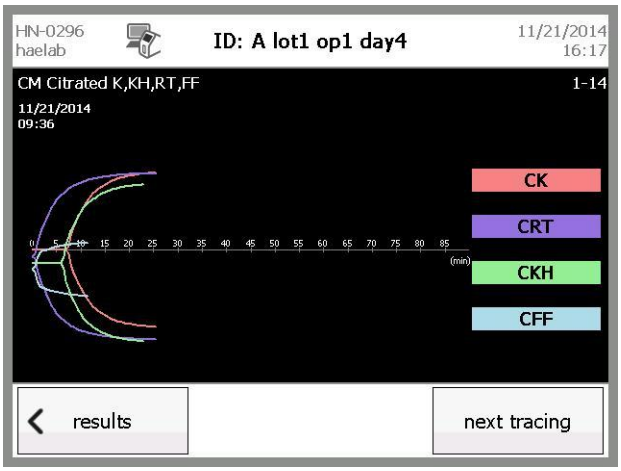


Figure 21. Offset Tracings screen

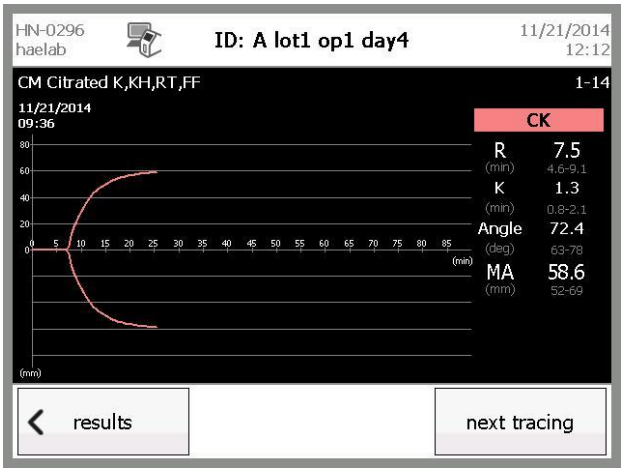


Figure 22. Single Tracing screen

If at any time you wish to discontinue the test, pressing "stop" from the Results screen will cause the system to prompt you to save the collected data. See Figure 23. Select "discard" to delete the test and return to the main menu, "save" to store the partial test and "cancel" to continue the test. If partial results are saved, the test record will show that the run was aborted by the user.

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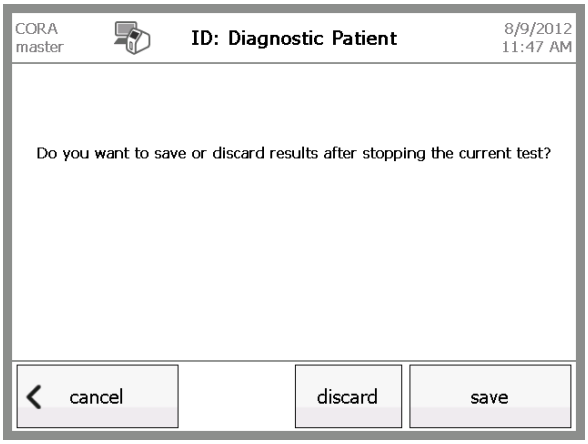


Figure 23. Stopped Test screen, showing the option of saving or discarding partial test results.

When the assay is finished the "stop" button will become a "done" button, as shown in Figure 24. The user may then view the tracings with the "tracings" button, print test results with the "print" button, or return to the main menu by pressing "done."

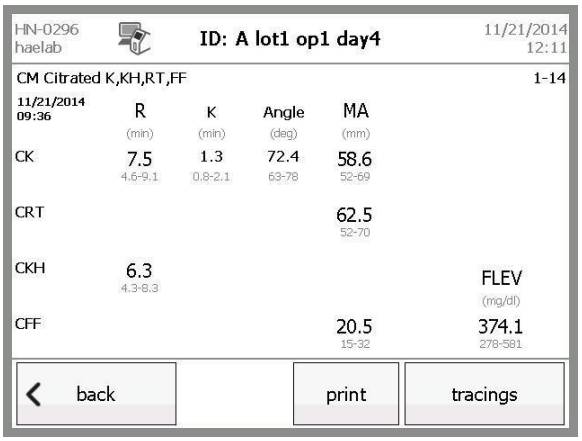


Figure 24. Complete Results screen

When a test has been completed or aborted, the analyzer will prompt you to remove the cartridge. This prompt will be in the form of an image and instructions on the touchscreen, shown in Figure 25, and a flashing light at the cartridge entry slot. Do not remove the cartridge until prompted. Immediately dispose of the cartridge properly in marked biohazard container.

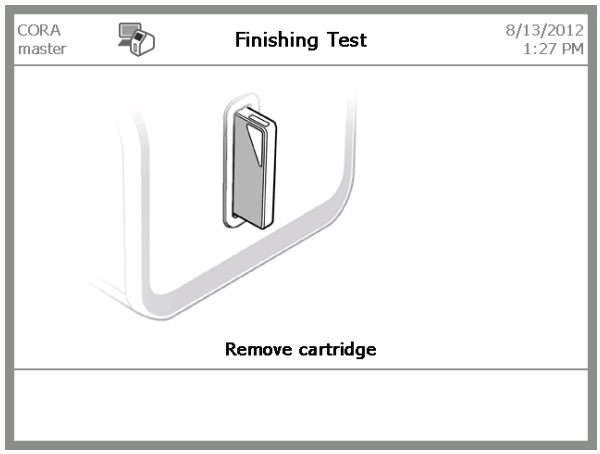


Figure 25. Remove Cartridge screen

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Recalling Patient Data (Quick Guide)

1. From the main menu select “stored tests.”
2. Highlight the desired test by selecting it then press “results” press “home” to return to the main menu.
3. To view the tracings press “tracings”.
4. To cycle through tracings from overlap to off-set to individual channels one through all collected channels select “next tracing”.
5. Return to the results page by selecting “results”.
6. Press “back” to return to the data selection page.
7. Press “home” to return to the main menu.

Recalling Patient Data (Detailed Guide)

1. From the main menu select “stored tests”.

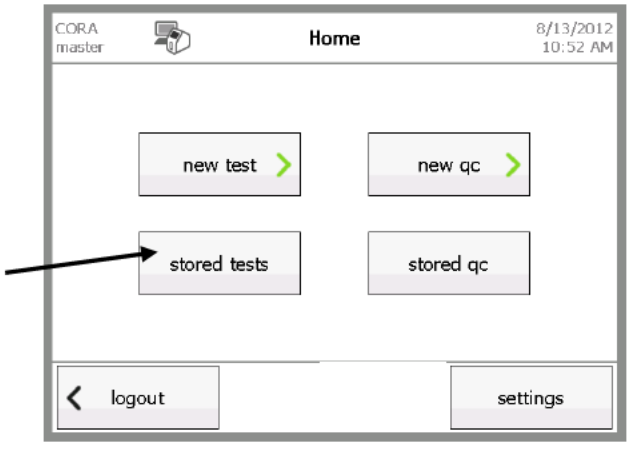


Figure 26: Main Menu

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2. Highlight the desired test by selecting it and pressing "results" (figure 27). To return to the main menu without selecting a test, press the "home" button.

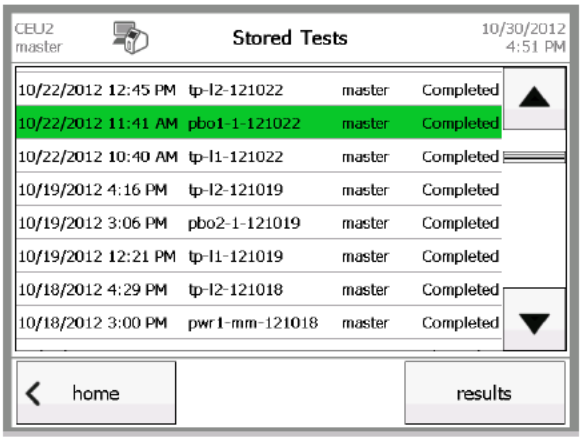


Figure 27. Stored Patient Results screen

When a record has been selected, the table of results for that record will be displayed, as shown in Figure 28.

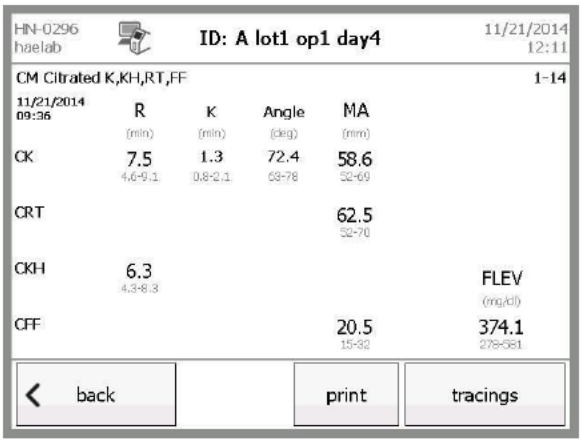


Figure 28: Results Screen

3. To view the tracings associated with a test record, press the "tracings" button.

4. To cycle through each tracing from superimposed, to offset, to each individual tracing, press "next tracing" (See Figures 20, 21, and 22).

5. To return to the list of stored tests, press "back".

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SECTION IV: QUALITY CONTROL PROCEDURES AND MATERIALS

This section contains instructions for testing wet quality control materials in the CORA System. Below is a handy **Quick Guide** to be used as a reference.

Quick Guide for Running a Wet Quality Control (WQC)

1. From the main menu select "new qc".
2. Insert the cartridge into the slot as indicated onscreen with the bar code on the left side.
3. Once the cartridge has passed pretest and you have verified it as the intended assay, press "next." If the cartridge is not the desired one, press "stop" and start over.
4. Prepare the WQC sample according to instructions on the package insert accompanying the WQC materials.
5. Deliver the WQC sample to the cartridge, filling to the line on the cartridge.
6. After loading the sample press "next."
7. The test will run and results will be displayed on the results page as they are available.
8. To see real time tracings press "tracings."
9. To cycle through superimposed, offset and single-channel tracings, repeatedly press "next tracing."
10. Press "results" to return to the results table.
11. When prompted to remove the cartridge, dispose of it properly.
12. Press "done" to return to the main menu.

Performing a WQC (Detailed Guide)

1. From the main menu select "new qc" as shown in Figure 29. Analyzer operation for WQC tests is very similar to running normal assays. As a result, figures in this section are very similar to those for patient assays.

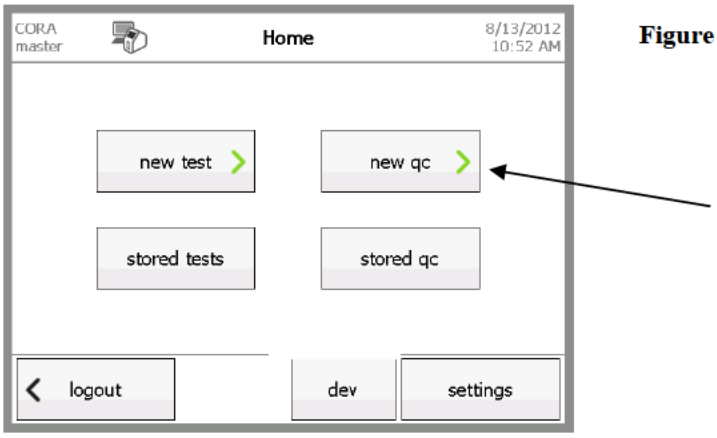


Figure 29. Main Menu

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2. Insert the cartridge into the slot as indicated on the screen with the bar code on the left side (see Figure 16).

Inserting the cartridge triggers a barcode scanner and QC pretest of the cartridge. At the successful completion of the pretest, the Analyzer will prompt you to verify that the WQC assay being run is what was intended, as shown earlier in Figure 17. If the assay is correct, press next, otherwise press stop to go back to the main menu. In the event that the cartridge pretest fails, the Analyzer will prompt you to insert a new cartridge or contact service personnel if the problem persists.

3. Press "next" if the card type is correct.

4. Prepare the WQC sample according to instructions on the package insert accompanying the WQC materials.

5. Using a transfer pipette, place the prepared WQC sample into the cartridge sample port, filling to the line marked on the cartridge. Press "next" to proceed.

NOTE: Each WQC vial, once reconstituted, contains 1ml of WQC material, which is sufficient for two WQC assays.

6. The CORA system runs the WQC, automatically drawing the WQC material into the active area of the cartridge. DO NOT remove the cartridge until prompted to do so, either after normal completion of the test or as a result of choosing to abort the test.

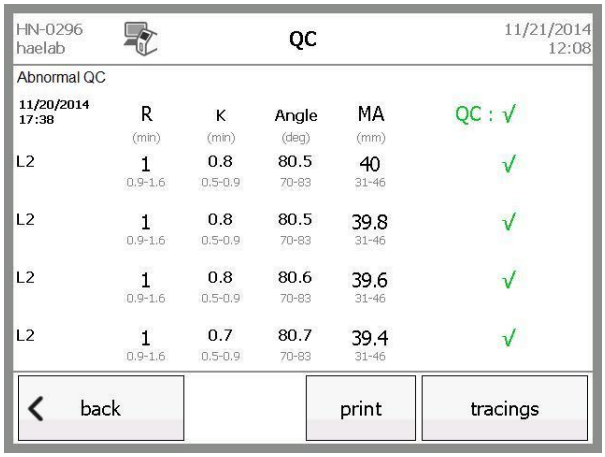


Figure 30. Running WQC

If at any time you wish to discontinue the test, pressing "stop" will cause the system to prompt you to save the collected data. Select "discard" to delete the test and return to the main menu, "save" to store the partial test and "cancel" to continue the test. If partial results are saved, the test record will show that the run was aborted by the user.

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As the WQC is running, you may access the tracings by pressing the "tracings" button. From the tracing screen, the user may select "next tracing" to cycle through superimposed, offset and individual-channel tracings (see Figures 20-22).

7. When the assay is finished the "stop" button will become a "done" button, as shown in Figure 24. You may then view the tracings with the "tracings" button or return to the main menu by pressing "done."

8. Remove the used cartridge when prompted to do so and immediately dispose of it in the proper marked biohazard waste receptacle. See notation on Page 3.

Recalling Stored WQC Data (Quick Guide)

1. From the main menu select "Stored tests".

2. Highlight the desired test by selecting it then press "results" press "home" to return to the main menu.

3. To view the tracings press "tracings".

4. To cycle through tracings from overlap to off-set to individual channels one through all collected channels select "next tracing".

5. Return to the results page by selecting "results".

6. Press "back" to return to the data selection page.

7. Press "home" to return to the main menu.

Recalling Stored WQC Data (Detailed Guide)

1. From the main menu select "stored qc."

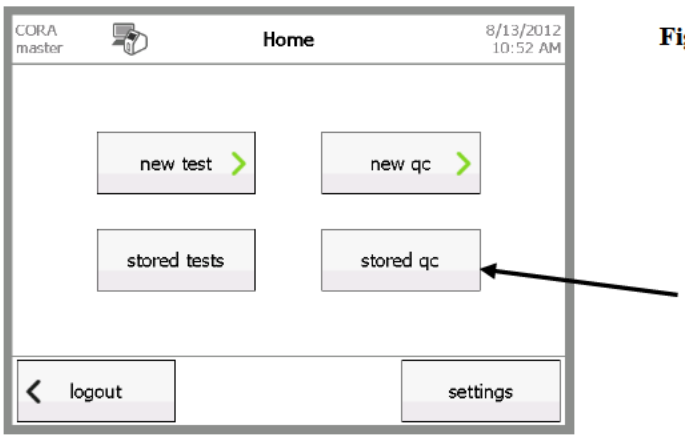


Figure 31: Main Menu

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2. Highlight the desired test by selecting it and then pressing “results.” Selecting “home” will return to the main menu (figure 32).

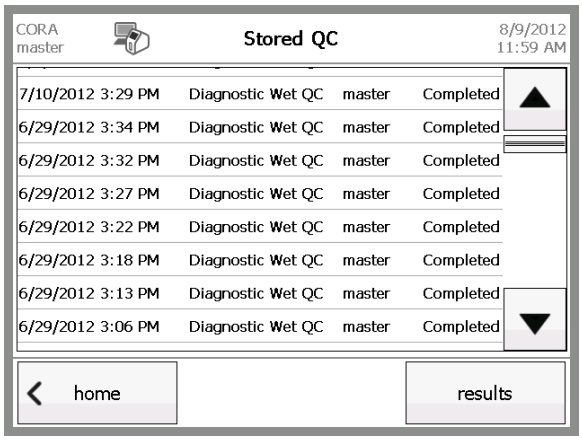


Figure 32. Stored QC Results screen

The entire results will then appear on the LCD screen as the parameters (as shown in the patient assay results of Figure 28).

3. To view the tracings, press “tracings”.

4. To cycle through superimposed, offset and single-tracing views, press ”next tracing” until the desired view is shown (see Figures 20-22).

5. To return to the data selection page, press “back”.

6. Select other WQC data to view, or press “home” to return to the main menu.

Citrated Reagent QC

The CORA analyzer performs internal QC checks during a pretest when the cartridge is inserted. This verifies that all electromechanical and pneumatic functions of the analyzer-cartridge combination are operating satisfactorily. Whereas the internal QC of the analyzer effectively tests analyzer functions, a QC methodology is required to verify that reagents in cartridges are still viable at time of use. This ensures that cartridges have not been mishandled between production and arrival at the lab, or have not been subject to adverse environmental conditions or otherwise mishandled while in lab storage. This can supplement the laboratory’s development of its own Individualized Quality Control Plan (IQCP) based on the lab’s risk analysis, in accordance with CLSI EP23. This risk analysis would take into account the lab’s specific situations that could affect reagent quality, such as environmental storage controls. Coramed recommends that laboratories perform QC tests on each new shipment of cartridges using blood from a known normal donor and Abnormal WQC material representing an abnormal sample, following instructions in the Citrated Multichannel Cartridge Insert, #01-180. It is also recommended that the lab perform this WQC testing whenever indicated by the IQCP.

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SECTION V: OPERATIONAL PRECAUTIONS AND LIMITATIONS

General

Read and understand the entire contents of this manual before operating the CORA system – especially precautionary information and specifications.

The CORA system is to be operated by professionally trained healthcare workers only.

If this equipment is used in a manner inconsistent with this manual, protections provided by the device may be impaired.

Use only Coramed parts and accessories with the CORA system. Third-party accessories may cause improper performance.

DO NOT use malfunctioning equipment. Have the unit repaired by an authorized Coramed service representative.

Common Errors and How to Correct Them

The CORA system is designed such that should any error appear on the screen, there will be clear instructions as to how to correct the error. If the problem persists after performing the recommended solution, call a customer service technician.

Errors require some form of action on the part of the operator, whereas warnings only require acknowledgement, after which the analyzer may continue to be used. Every report of an error generated on the CORA system will provide the user with a description of the error, an error code number, and response actions to the error. Please follow the response actions exactly to prevent further errors. There should be no need to refer to the user manual for error solutions. The typical error screen will look like figure 33 and a typical warning screen will look like figure 34. An error will cause the test to stop and require the analyzer to be power-cycled in an attempt to clear the error, and may ultimately require the assistance of Service personnel. A warning occurs when the device encounters a problem which is not critical to operation of the analyzer. A warning does not require any action by the user (other than pressing the acknowledge button).

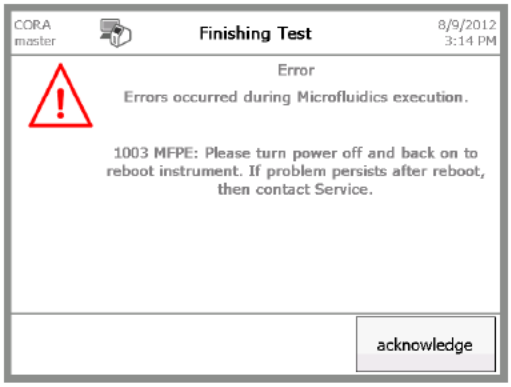


Figure 33: Typical Error Screen

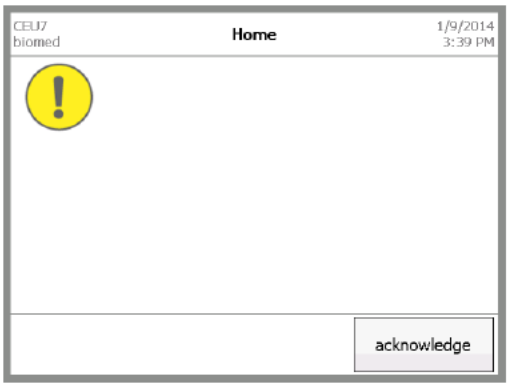


Figure 34: Typical Warning Screen

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If at any point the user encounters a message that reads "Please turn power off and back on to reboot analyzer. If problem persists after reboot, then contact customer service", the user should follow the given instructions. If the problem does persist after a successful power off followed by a power on then a call to the customer service number, 847-647-8800 should be initiated. Make sure you report the error code that appears on the screen next to the error information. NOTE: When an error occurs during data collection, the data is NOT saved.

Warnings require no action to be taken by the user; they simply alert the user to an occurring event which the user must then acknowledge. NOTE: When a warning occurs no data is lost.

If the error is triggered by a faulty cartridge, simply remove the cartridge and rerun the test with a new cartridge. DO NOT attempt to repair or reuse the old, faulty cartridge.

Below are examples of errors which may be encountered by the user, including the error and warning numbers, probable cause, and recommended solution in order of code number. For error codes reported that are not on this list, please contact customer service.

Error Code	LCD Display Reading	Probable Cause	Solution
1016	Bubble detected in channel	Bubbles have been detected in one or more channels.	Remove cartridge and use new cartridge. Verify that quantity of blood sample is sufficient for test. If problem persists, call customer service.
1030	Pretest Fault - Pressure Leak in analyzer	Pressure leak in analyzer	Contact Service
1031	Pretest Fault - Pressure Leak in cartridge	Pressure leak in cartridge	Remove cartridge and rerun test with new cartridge. If problem persists, contact Service.
1032	Pretest Fault - Vacuum Leak in analyzer	Vacuum leak in analyzer	Contact Service
1033	Pretest Fault - Vacuum Leak in cartridge	Vacuum leak in cartridge	Remove cartridge and rerun test with new cartridge. If problem persists, call Service.
2001	LED Error	Front panel LED failure	The analyzer will continue to operate OK, but the failure should be reported to customer service.
2003	Unexpected Reset while Running a Test	The analyzer has unexpectedly been reset during a Test	Please turn power off and back on to reboot analyzer. Discard cartridge and result. If problem persists after reboot then contact Service.
3000	Temperature out of range - Set point above 30°C	Sample temperature out of range for one or more channels	Remove cartridge and call Service
3019	Firmware Update Cortex Failed	Firmware update failed.	Reset the system to the previous firmware revision. This requires administrator access; if no administrator is available or if the problem persists, contact Service.

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Error Code	LCD Display Reading	Probable Cause	Solution
3020	Firmware Update Piccolo Failed	Firmware update failed.	Reset the system to the previous firmware revision. This requires administrator access; if no administrator is available or if problem persists, contact Service.
3027	POST Fault - Diskspace is critically low	Power-On-Self-Test Fault - Diskspace is critically low	Delete unneeded test results from analyzer, then turn power off and back on to reboot analyzer. NOTE: This requires administrator access, if no administrator is available Contact Service
3032	Cortex Firmware Not Found	Analyzer program error.	Update the System firmware. NOTE: This requires administrator access, if no administrator is available or If the problem persists, contacts Service.
3033	Piccolo Firmware Not Found	Analyzer program error.	Update the System firmware. NOTE: This requires administrator access; if no administrator is available or If problem persists, contact Service.

Basic Cleaning and Disinfecting Requirements

Because the CORA system is a self-contained device, the analyzer exterior should be cleaned and disinfected weekly, or more frequently as needed according to laboratory medical disinfecting procedures, to prevent contamination of the analyzer and limit potential exposure of bloodborne pathogens to operating personnel. The Laboratory Administrator or Supervisor should contact Coramed or an authorized distributor concerning questions about the compatibility of decontamination or cleaning agents with parts of the equipment. In general, the users should clean and disinfect according to the state and local regulatory bodies and laboratory policy.

The CORA system must also be cleaned and disinfected prior to return shipment if servicing is necessary. For further information, refer to "Packaging the CORA system for return" below.

All materials used for the disinfecting should be disposed of in the proper biohazard waste receptacles.

CAUTION: Do not steam-sterilize or autoclave the analyzer or any cartridge. Do not immerse the analyzer or cartridge in any solution. Do not clean the analyzer or cartridge with acetone or any other plastic solvent or abrasive cleaner.

The CORA analyzer has a filter assembly mounted at the rear of the unit to filter air as it is drawn into the unit by the fan (see figure 2). This filter should be periodically removed and cleaned if required.

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Unpacking the CORA System

The CORA system is packaged to reduce the risk of damage during shipment. Remove all Styrofoam inserts and carefully remove the CORA system from the box. The power adapter and cables are wound up and packaged separately. Save the packing materials for future use since it is required for the safe return of the analyzer for service or repair.

Simply place the CORA system on a flat surface, e.g. table or lab bench. Attach all of the cables to the appropriate inputs on the device, and the appropriate inputs for successful operation, e.g. power cable to a wall outlet.

Placement of the CORA system

Care should be taken in the placement of the CORA analyzer, so that it is not positioned in such a way as to make it difficult to reach and operate the power switch and power cord disconnection.

Storage and Handling of the CORA system

Safe and successful operation depends in part on the proper routine handling of the CORA system, disposables, and blood samples. The operator should be aware of the problems that could result if these items are stored, installed, or used incorrectly. Whenever the user is using the CORA system he or she should be wearing latex or nitrile gloves.

The CORA Analyzer needs only to be placed on a flat surface and operated at room temperature (10° to 32°C). The analyzer may be stored at a temperature between -20°C and +50°C, however, prior to use the unit must be brought to operating temperature. The CORA system is designed for indoor use only.

Storage and Handling of the CORA system cartridges

The storage and handling of CORA® system Citrated Multichannel cartridges and WQC materials may differ depending on the type of reagent or control. Refer to each product insert for storage and handling instructions.

Transporting the CORA system

To transport the CORA system, remove all plugs, cords, and cartridges from the device.

Product Return Guidelines

Should the user need to return the CORA system or any of its component parts for service, the following procedures should be followed to ensure no further damage comes to the device and to ensure personnel safety.

- Make sure the system and any component parts have been thoroughly cleaned and disinfected according to the cleaning guidelines above to prevent biohazard contamination during shipment.
- Use the original packing material, as appropriate.
- Use only the Styrofoam originally provided in the original packaging.
- Place the CORA system in the CORA box exactly as when you received it.

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Power Outlet Connection

Do not power the device using a power cord other than the one originally supplied by Coramed or an authorized Coramed distributor for the CORA system. Always ensure the power cord is connected to an appropriately grounded power source per your institution's policy.

Caution: *Grounding reliability can only be achieved when the equipment is connected to a properly grounded outlet.*

Caution: *Do not unplug the male single-pin connector end of the power cord from the analyzer while leaving the power cord connected to a live power source. Electrical shorting and power supply damage may occur.*

FCC Compliance

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case users will be required to correct the interference at their own expense.

Warning: Any changes or modifications not expressively approved by Coramed Technologies could void the user's authority to operate this equipment.

Warranty

Coramed Technologies warrants its manufactured products (excluding disposable or consumable supplies) to be free from defects in materials or workmanship for one year from the original date of purchase subject to these terms and conditions. Returns will not be accepted without authorization from a Coramed Representative. Products must show no evidence of improper handling or operation, including unauthorized repairs.

At its discretion, Coramed Technologies may repair or replace defective products covered by this warranty. Even if Coramed Technologies cannot repair or replace, its entire liability shall in no event exceed the purchase price. Coramed Technologies expressly disclaims all other warranties, whether express, implied, or statutory, including the warranty of merchantability and fitness of use. In no event will Coramed Technologies be liable for consequential, incidental, or special damages arising out of the use of its products.

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SECTION VI: HAZARDS

Electrical Shock Hazards

The CORA system operates at a low-rated voltage. The risk of electrical shock is, therefore, minimal. However, the operator should never remove the CORA system's covers. Maintenance that requires the removal of these covers remains the responsibility of a Coramed-trained service technician.

Blood Borne Pathogens

Users should adhere to Standard Precautions when handling or using this device. All parts of the Coramed Hemostasis System should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. Although the CORA system does not present a significant biohazard risk in itself, the unit is used to analyze human blood, so care must be taken to properly handle, clean, and disinfect the equipment as appropriate.

Warning: Special cleaning needs, such as a blood spill, should be dealt with promptly. Follow local standard operating procedure for blood precautions when cleaning up a blood spill or dealing with blood contaminated components. Dispose of all cleaning materials as biohazardous waste.

While operating the CORA system, wear powder-free examining gloves and wash hands immediately after removing the gloves. Wear fluid-resistant clothing.

Proper Handling of Blood Contaminated Material

Even though the only working surfaces that routinely come into contact with blood are the internal surfaces of the disposable cartridge, any CORA system surface that could be contaminated by a blood spill should be properly cleaned and decontaminated with an appropriate disinfectant (refer to above "Basic Cleaning and Disinfecting Requirements"). This should only need to be done as required by laboratory protocol and immediately after any blood spill.

Precautions must be taken to eliminate or reduce the hazards involved with removing the CORA system from its point of use, transporting it from one place to another, or disposing of the analyzer. If any blood-contaminated material must be returned to Coramed for further inspection, see "Product Return Guidelines" above for instructions.

Warning: Coramed products must be properly cleaned and packaged prior to their return. It remains an important responsibility of the customer to reduce potential health hazards by being aware of the risks involved in the shipping, handling and testing of this material. Units returned to Coramed for repair may be subject to biohazard charges if any component is contaminated with blood or blood products.

Proper Disposal of Biologically Contaminated Materials

Any disposable material used during a procedure is considered to be biologically contaminated and biohazardous. It must be disposed of according to local standard operating procedures for the removal of such material and should not be mixed with non-biohazardous waste.

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External Symbols on the Analyzer

	***CAUTION: BIOHAZARD*** *Turn off and lock out power before servicing.*	IVD	In-vitro Type Medical Device
	***CAUTION: Risk of danger*** *Consult documentation for information relating to potential HAZARDS and actions to be taken*		

NAME AND PLACE OF BUSINESS OF MANUFACTURER



Coramed Technologies
6225 W Howard St
Niles, IL 60714 USA

DATE OF ISSUANCE OF LAST LABELING REVISION:

January 6, 2015

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CORA

CORA® System

SMS (Service Maintenance and Setup)

USER GUIDE

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Welcome

The purpose of this document is to provide instructions for the System Service Maintenance and Setup (SMS) software – a component of the CORA (Coagulation Resonance Analyzer) System. This manual provides instructions only for using the SMS software. For instructions on operating the CORA System analyzer, please refer to the *CORA System User Manual*.

Section I: About the CORA system and SMS software

In this section you will find information on the CORA system's operating principles, intended use, indications for use, and a brief description of the SMS software.

Section II: Getting Started

This section provides an overview of the software and describes installation and hardware requirements.

Sections III: Logging into SMS

This section provides instructions for launching and logging into the SMS software.

Sections IV - XII: Using the SMS software

These sections include complete instructions for using the SMS software.





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Important Precautions

1. Read and understand the entire contents of this manual before operating the SMS software – especially precautionary information and specifications.
2. The SMS software is to be operated by qualified personnel only.
3. If this software is used in a manner inconsistent with this manual, protections provided by the software may be impaired.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section I: About the CORA System

Background on the CORA system

Hemostasis is the physiological control of bleeding and is a complex process incorporating vasculature, platelets, coagulation factors (FI-FXIII), fibrinolytic proteins, and coagulation inhibitors. Normal hemostasis is a delicate balance between hemorrhage and thrombosis. The CORA System is an In Vitro Diagnostics (IVD) device that can be used to quantify the hemostatic function of a blood sample.

Intended Use

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The CORA System records the kinetic changes in a sample of citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

Indications for Use

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Software Overview

The CORA system consists of an analyzer, disposable cartridges, and remote software that controls the CORA analyzer's Service, Maintenance and Settings (SMS) functions. The SMS software allows an administrator or technician to access the CORA analyzer via an Ethernet connection, and perform a number of functions, including querying existing data, managing user accounts, updating analyzer settings, and backing up data.

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Section II: Getting Started

Overview

The SMS software is a program that controls the CORA analyzer's Service, Maintenance and Settings (SMS) functions. The SMS software is intended to run on a separate computer connected to the analyzer via the Ethernet network interface connection.

The SMS software allows only a single remote user, with Administrative privileges or above, to log into the analyzer and do the following:

- Lock the analyzer for exclusive administrative access – and unlock.
- Manage users accounts (add and delete accounts, assign user roles and temporary passwords)
- Retrieve the following information:
    - Cartridge tables
    - Patient and Wet QC tests
    - System settings
- Update the following information:
    - Cartridge tables
    - System and user settings
    - Custom normal ranges for patient tests
    - Analyzer firmware
- Back up and restore analyzer data.

SMS software installation

The SMS software is a Windows application that connects to the analyzer over the Local Area Network (LAN). No files need to be installed on the computer. Instead, a set of application files must reside locally on the computer. These files are set up by the service technician who installs CORA analyzer at your site.

Hardware requirements

The SMS software runs in hardware with the following minimum system requirements:

- Windows 7
- 1GB RAM
- 500 MB Storage
- Ethernet connection to a local network where the analyzer(s) are present.

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Section III: Logging into SMS

Note: *Only users assigned the roles of Administrator, Field Technician, or Distributor can log into the SMS software.*

You can use one of the following two methods to launch the SMS software:

- Run the Discovery program and select the desired analyzer to connect to within the LAN subnet.
- Manually launch the SMS software using a known IP address.

Run Discovery to launch SMS

The Discovery program allows you to discover all analyzers that are connected within a LAN subnet (these are the analyzers that are connected to the same router your computer is connected to). You can then select one of the listed analyzers to connect to and launch the SMS software.

Note: *You can connect to an analyzer only if it shows "Disabled" in the Current State column and has no local user logged into it (no user ID appears in the Local User column).*

To run Discovery:

1. On the computer, navigate to **CORADiscovery.exe** and double click the file to launch the program.
2. In the *CORADiscovery* screen, click **Find Instruments**.

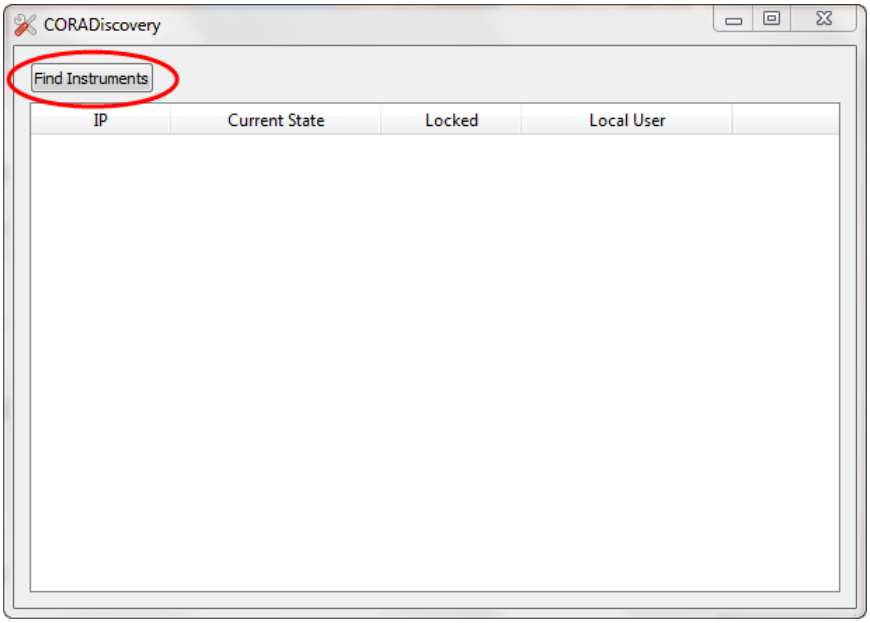


Figure 1: CORADiscovery screen

Each analyzer within the subnet appears in the list on the *CORADiscovery* screen and displays its IP address, current state, whether it is locked by an SMS user, and whether a local user is logged in.

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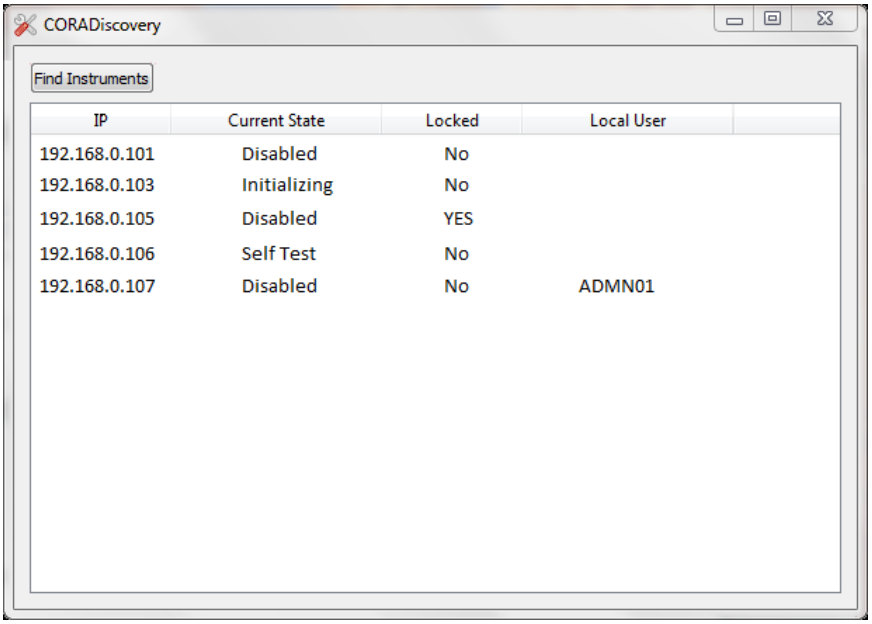


Figure 1.2: List of discovered analyzers

3. Double-click the IP address of the desired analyzer to open the SMS software.

Manually launch SMS

If you know the IP address of the analyzer, you can manually launch the SMS software by doing the following:

1. On the computer, navigate to **CORASMSMain.exe** and double click the file to launch the program.
2. In the *Select IP* screen, enter the IP address for the analyzer, and then click **OK**.

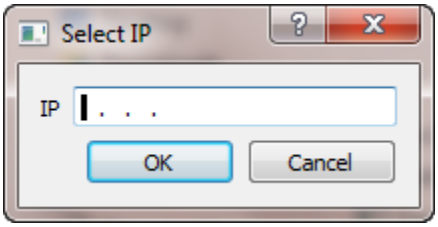


Figure 2: Select IP

Connect to the analyzer

Once the SMS software is open, you can connect to the analyzer if no user is logged on locally. This locks the analyzer for your exclusive use.

1. On the SMS-T *Main* screen, click the **Connect** button at the top left.

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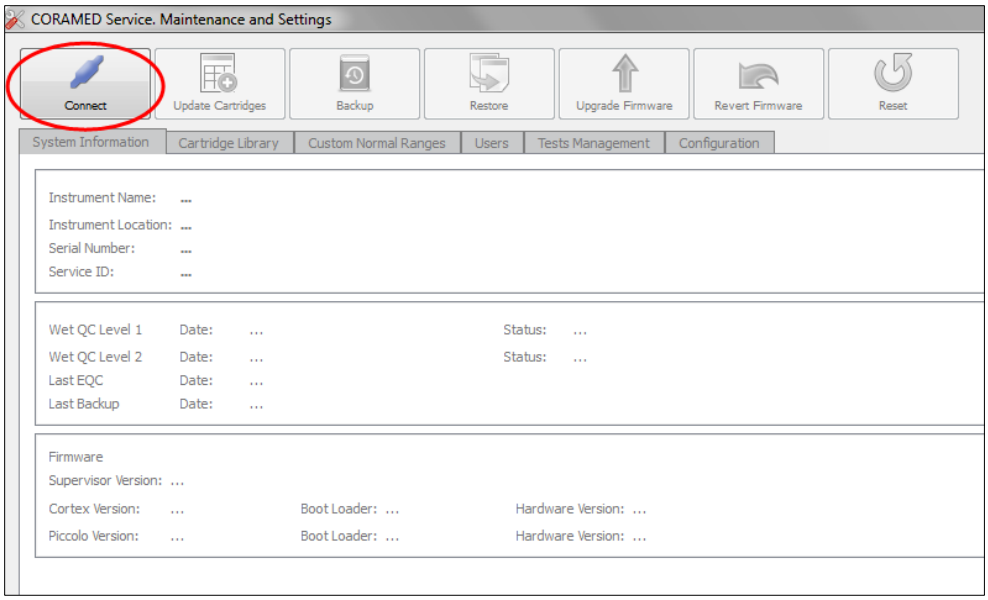


Figure 3: SMS Main screen before connecting

2. In the *User Login* screen, enter the user name and password appropriate to the specific CORA analyzer that you are connected to, and then click **Login**.

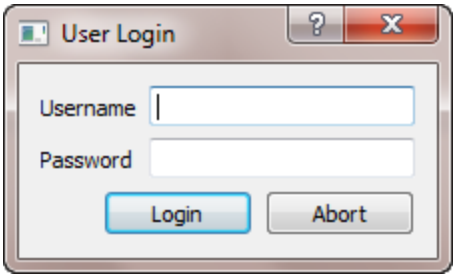


Figure 4: User Login

Login error messages

If SMS displays the following error message, it means that a user is still logged into the TEG analyzer. If this is the case, log out of the analyzer and log into SMS again.

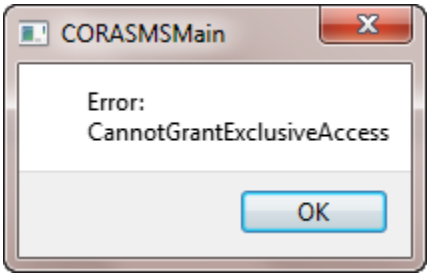


Figure 5: Error – user logged into analyzer

If SMS displays the following timeout error message, it means that the computer cannot communicate with the analyzer.

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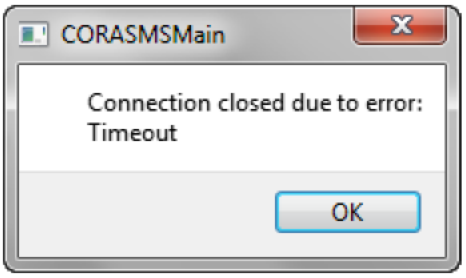


Figure 5.2: Error – timeout

Refer to the following table for possible sources of the error and suggested methods to resolve the issue.

Possible source of error	Suggested resolution
You used an incorrect IP address when logging into SMS.	Check the analyzer's IP address.
The Ethernet cables are not hooked up properly.	Make sure the computer/analyzer Ethernet cables are plugged into "LAN" ports, not the Internet port.
The router is not powered on.	Make sure the router is plugged in.
Either the computer or the analyzer has not successfully obtained an IP address from the router.	Check the computer IP address: 1. From the computer's **Start** menu, type "cmd" in the *Search* box, and then press **Enter**. 2. In the command prompt screen, type "ipconfig" and press **Enter**. 3. View the IP address next to "IPv4 Address." Check the analyzer IP address: 1. Verify that the LAN settings are set to DHCP. 2. Verify that the IP address appears on the About screen.

Note: *It is recommended that you power cycle the analyzer (turn the analyzer off and then back on again) after making any adjustments to the cables or router.*

Successful login

Upon successful login, the SMS *Main* screen is enabled and the TEG analyzer displays the *Remote Control* screen.

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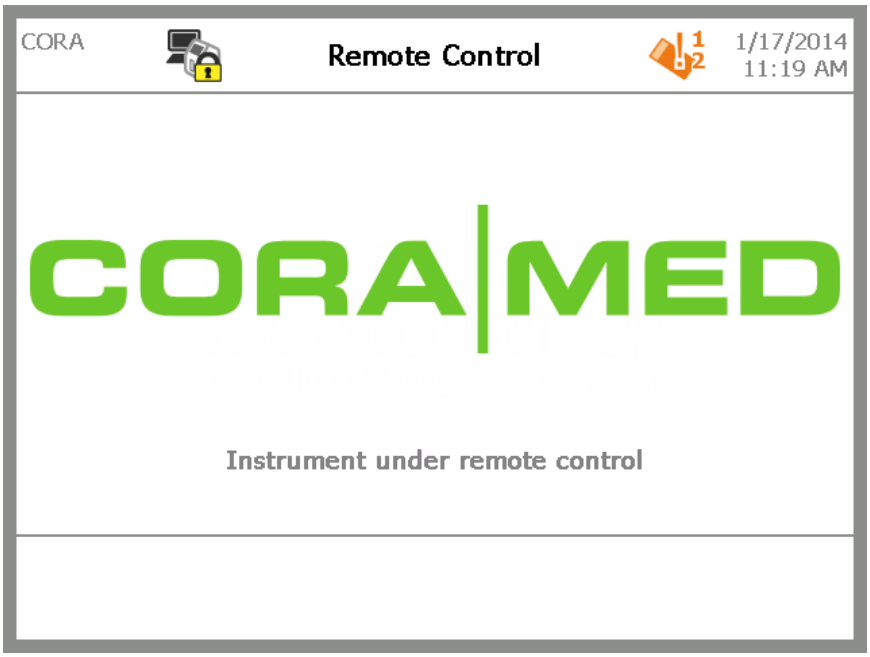
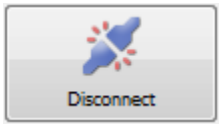


Figure 16: Remote Control screen

Log out of SMS

1. On the SMS *Main* screen click the **Disconnect** button.



You are logged out of the SMS software. The analyzer is no longer under remote control and can be logged into by local users.

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Section IV: Viewing System Information

Information about the analyzer can be viewed on the **System Information** tab. The information is organized into three sections. The top section displaying analyzer details such as name, location, serial number and service ID. The middle section displays status information including the most recent Wet QC and backup dates. The bottom section displays the firmware versions installed on the analyzer.

To view system information:

1. From the SMS *Main* screen, click the **System Information** tab.

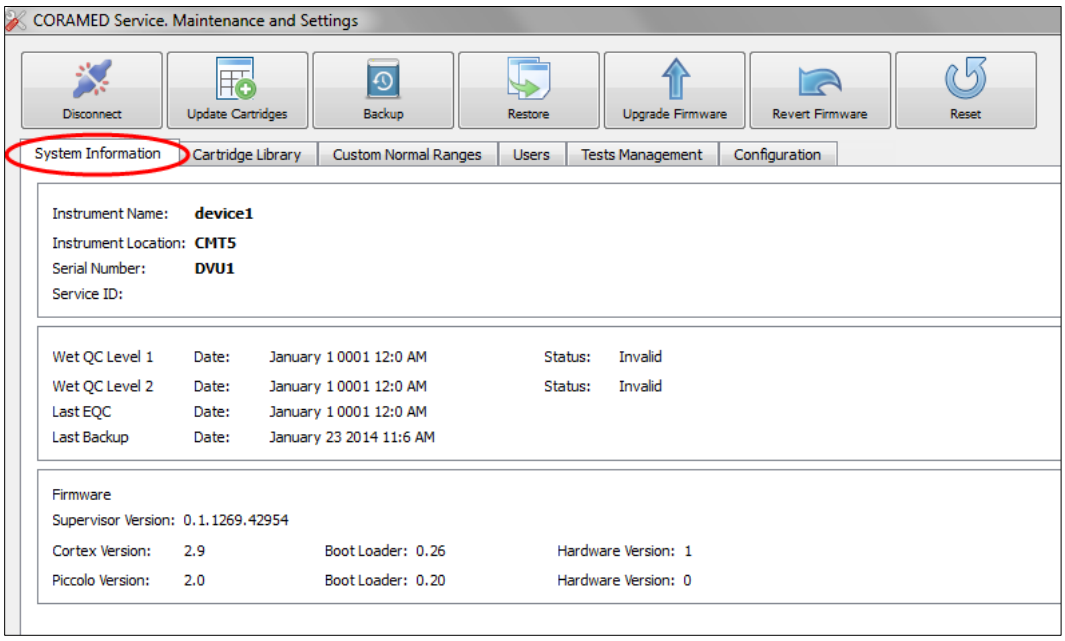


Figure 6: System Information tab

2. View the system information.

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Section V: Managing the Cartridge Library and Scripts

In addition to the barcode on the cartridge, the analyzer system also uses a cartridge library to determine the type of test the cartridge is intended to perform. The cartridge library holds information about each test such as microfluidic scripts, names of channels, reference ranges, etc.

You can view cartridge library information on the Cartridge Library tab. You can also upload the latest library version to the analyzer.

View the cartridge library information

The current cartridge library information is available for viewing on the **Cartridge Library** tab. The following information is displayed:

- Current cartridge library version
- Cartridge Name
- Sample type
- Test Type (Patient or Wet QC)
- Revision
- ID
- Channel Tests (CH1,CH2,CH3,CH4)

To view cartridge library information:

1. On the SMS *Main* screen, click the **Cartridge Library** tab.

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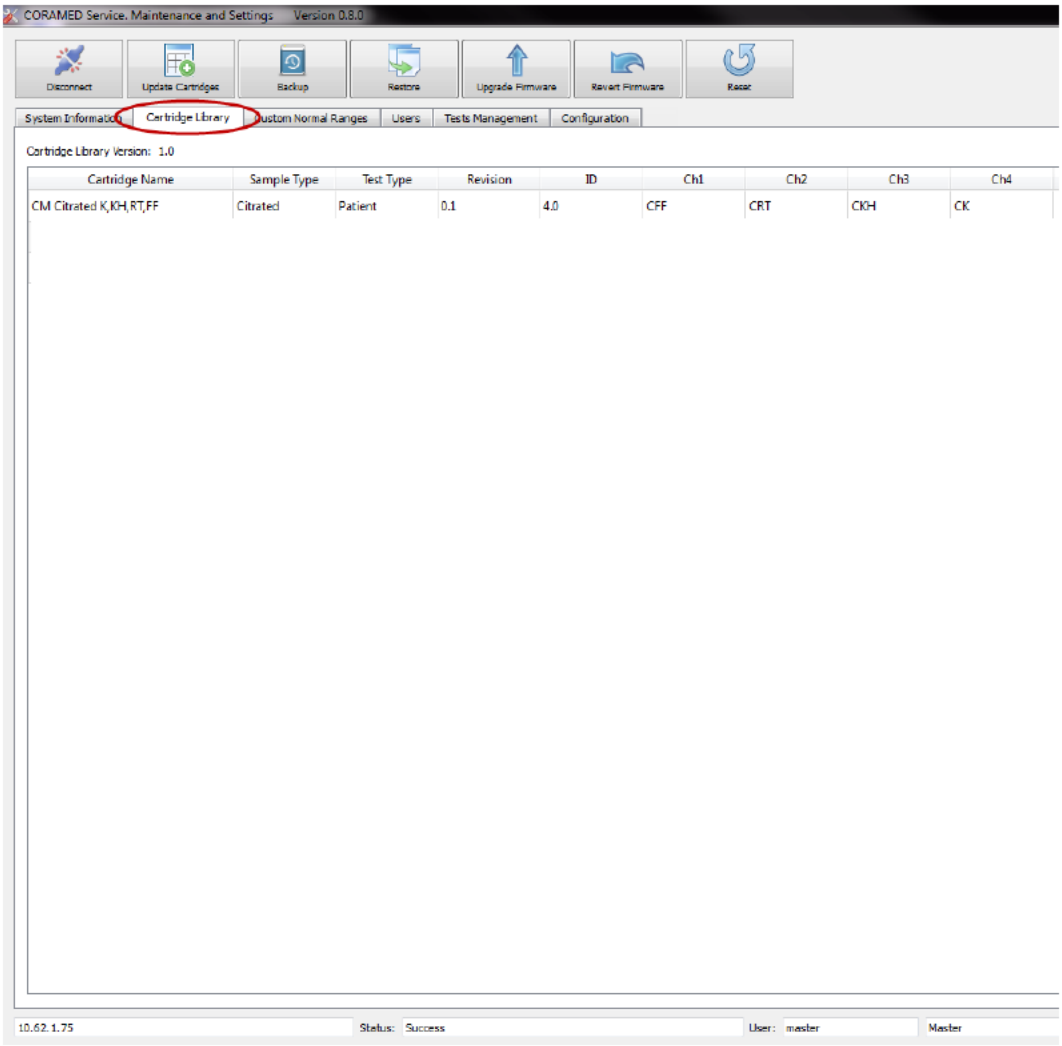


Figure 7: Cartridge Library tab

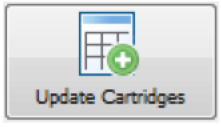
2. View the cartridge library information.

Update the cartridge library

Periodically, the cartridge library is updated by Coramed Technologies. When this occurs, you can upload the latest version to the analyzer. The cartridge library file is made up of two zipped files: the cartridge library file and the microfluidic scripts file.

To update the cartridge library:

1. On the SMS *Main* toolbar, click **Update Cartridges**.



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2. In the *Open cartridge release* window, navigate to the location of the latest cartridge zip file, and then click **Open**.

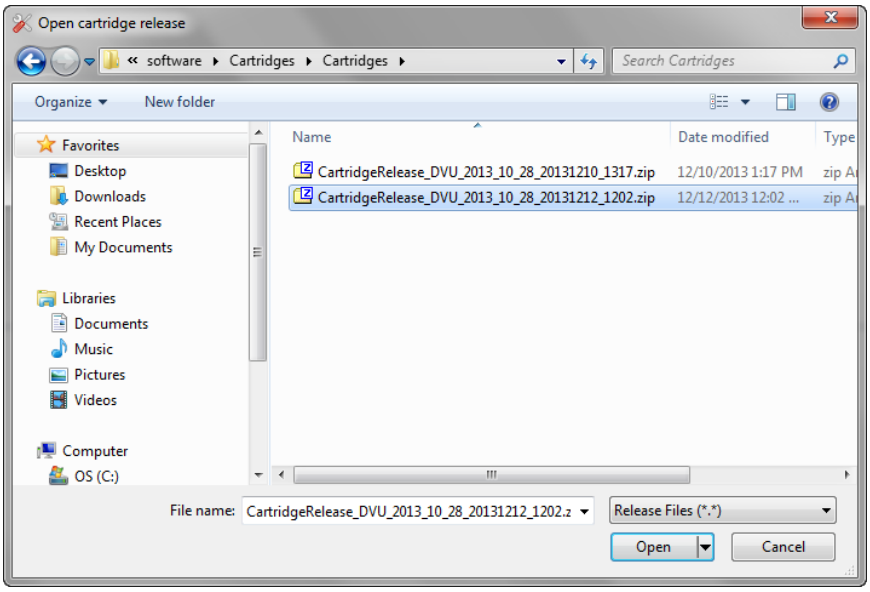


Figure 8: Open cartridge release window

A progress message appears as the cartridge and script files are uploaded.

3. In the power cycle message that appears, click **Yes**.

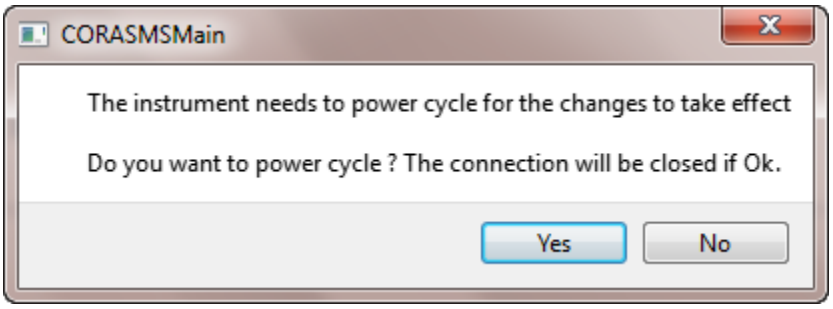


Figure 9: Power cycle message

The SMS software resets the analyzer automatically.

When you log back into SMS, the new version number appears at the top of the table on the **Cartridge Library** tab.

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Section VI: Managing Custom Normal Ranges

The manufacturer's normal ranges that are defined for each test are contained in the cartridge library. However, if a site chooses to establish their own reference ranges, these values can be defined on the **Custom Normal Ranges** tab.

Add custom normal ranges

To add a new user-defined normal range for a test type:

1. On the SMS *Main* screen, click the **Custom Normal Ranges** tab.

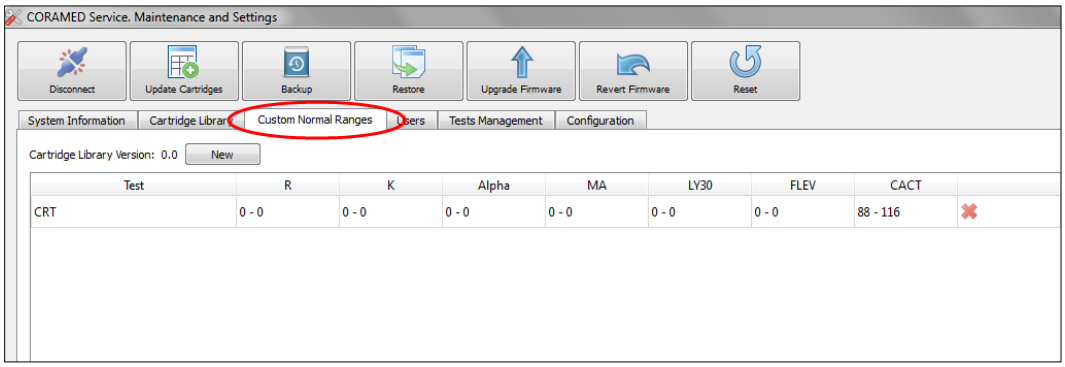


Figure 10: Custom Normal Ranges tab

2. Click **New**.

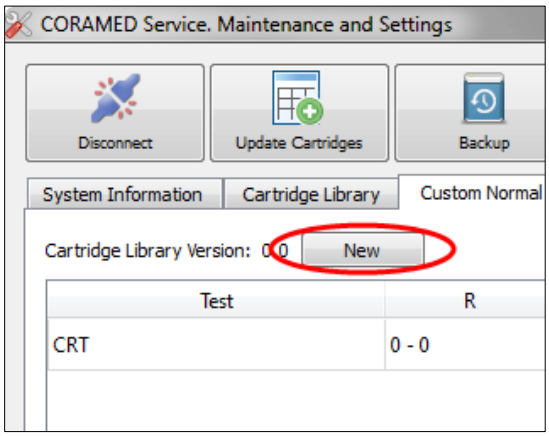


Figure 11: New button

3. In the *New Normal Ranges* screen, do the following:
    a. In the *Name* field, enter the name for the test.

    Note: *Make sure the name is entered exactly as it appears on the analyzer results screen. This field is case sensitive.*

    b. Next to each parameter for which you want to specify custom ranges, type or use the arrows to enter the low (left box) and high (right box) ranges. If a parameter is

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not required for the test, leave the value at 0-0. Figure 12 shows an example of custom ranges entered for citrated kaolin tests.

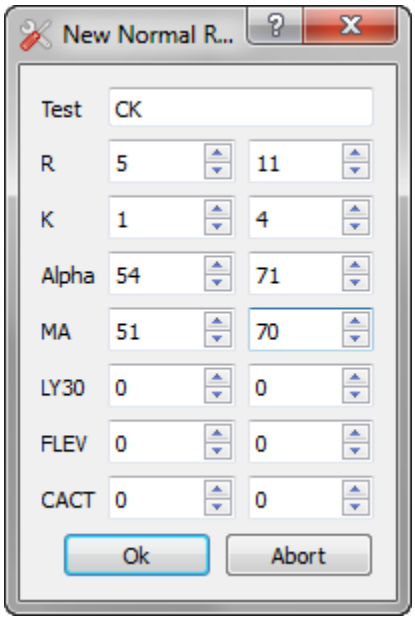


Figure 12: New Normal Ranges

4. Click **Ok**.
5. In the power cycle message that appears, click **Yes**.

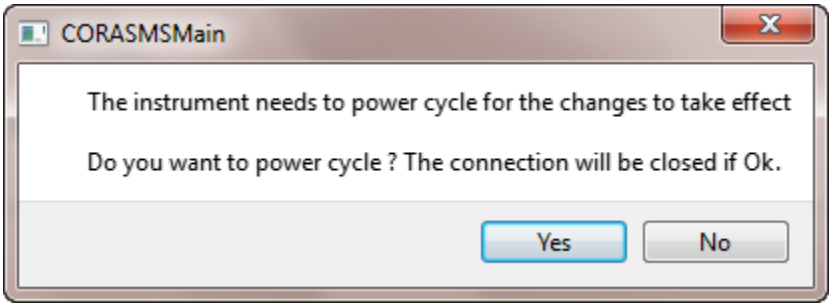


Figure 13: Power cycle message

The SMS software resets the analyzer. When you log back into SMS, the new custom normal ranges appear in the list.

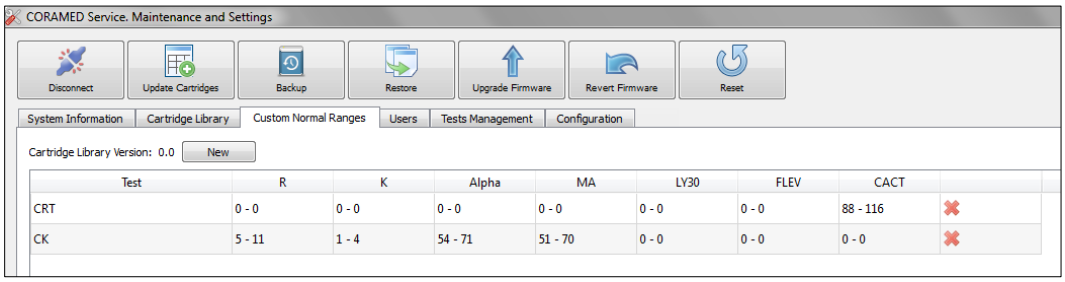


Figure 14: New custom ranges on the Custom Normal Ranges tab

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Delete custom normal ranges

To delete user-defined normal ranges for a test type:

1. On the **Custom Normal Ranges** tab, next to the desired test type, click the delete button.

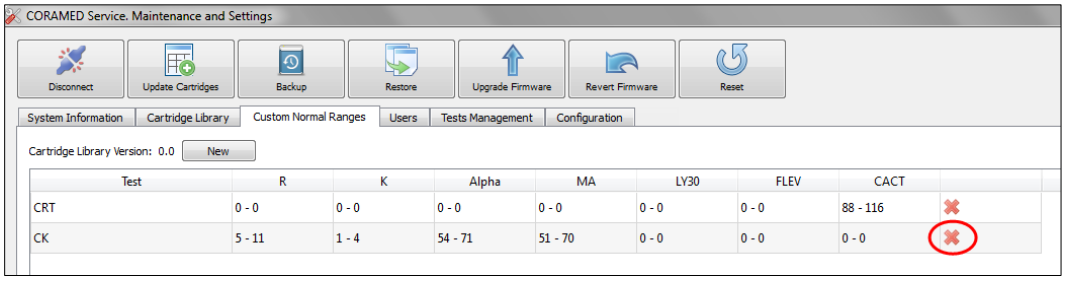


Figure 15: Delete button

2. In the *Delete Normal Range* confirmation message, click **OK**.

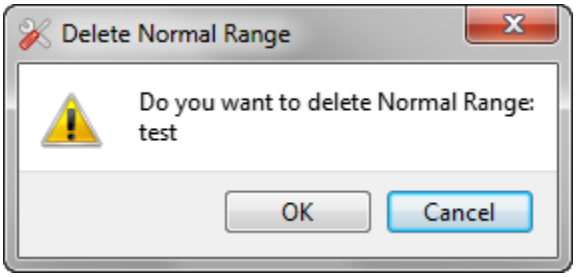


Figure 16: Delete Normal Range confirmation message

3. In the power cycle message that appears, click **Yes**.

   The SMS software resets the analyzer automatically.

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Section VII: Managing Users

Add a new user account

With the appropriate privileges, you can add a new user to the system and assign the user a role. The role that you assign to the new user must be lower in hierarchy than your own user role. From the top down, the hierarchy levels are as follows: Distributor, Field Technician, Administrator, and Operator.

To add a new user account:

1. From the SMS *Main* screen, click the **Users** tab.

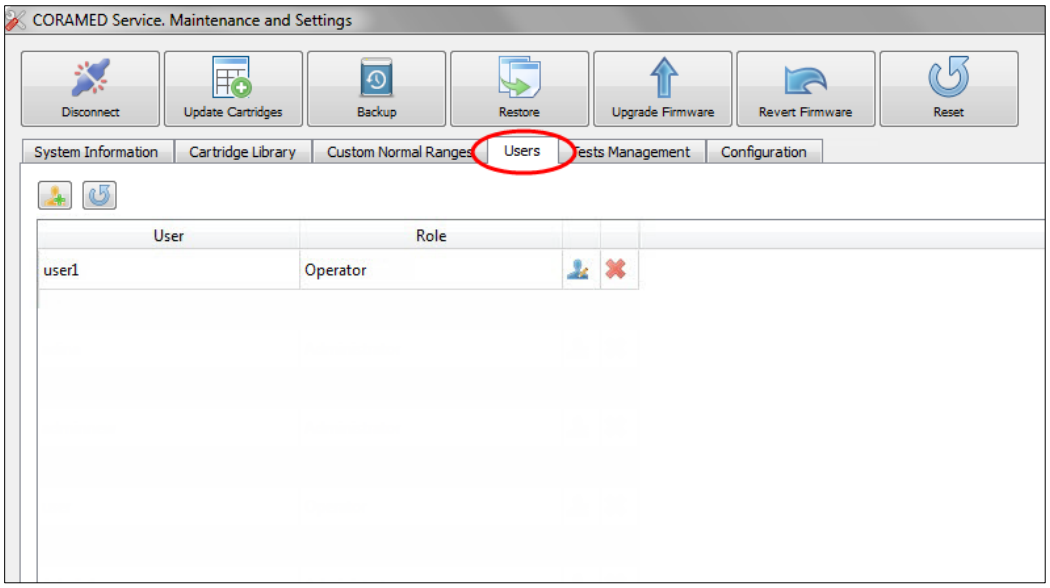


Figure 17: Users tab

2. Click the **Add User** button.

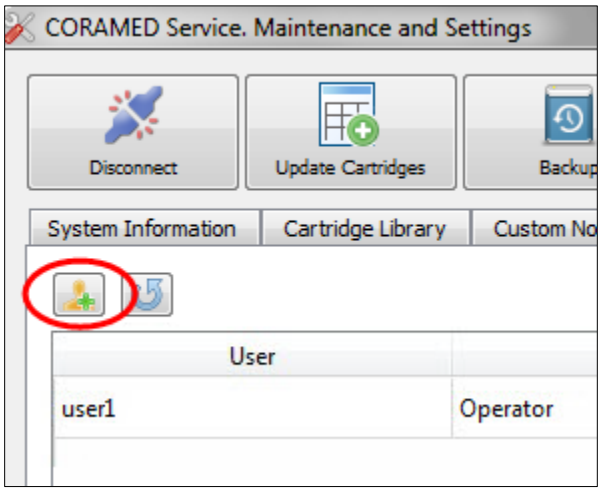


Figure 18: Add user button

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3. In the *Create user* screen, do the following:

    a. In the *User field*, enter a name for the new user. Note that user names are case sensitive.

    b. In the *Password* and *Password re-type* fields, enter a password based on the following criteria:

    - The password cannot contain the user's user name.
    - The minimum length of the password is 8 characters.
    - The maximum length of the password is 12 characters.
    - The password must contain at least one numeric character or symbol (the special characters "&" and "#" are not accepted).
    - The password cannot be a duplicate of any of the user's previous eight passwords.

    Note: *This is a temporary password only. Upon first login to the analyzer, the user is requested to change this password.*

    c. In the *Role* drop-down list, select the appropriate role for the user.

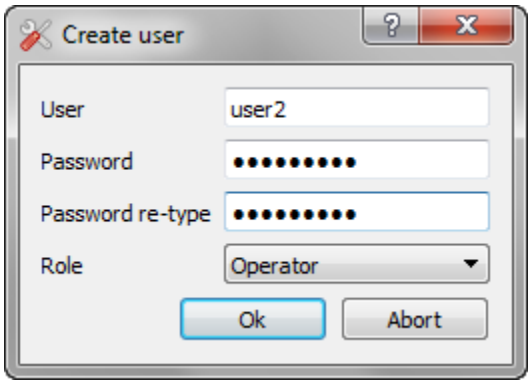


Figure 19: Create user

4. Click **OK**.

    The new user account appears on the **Users** tab.

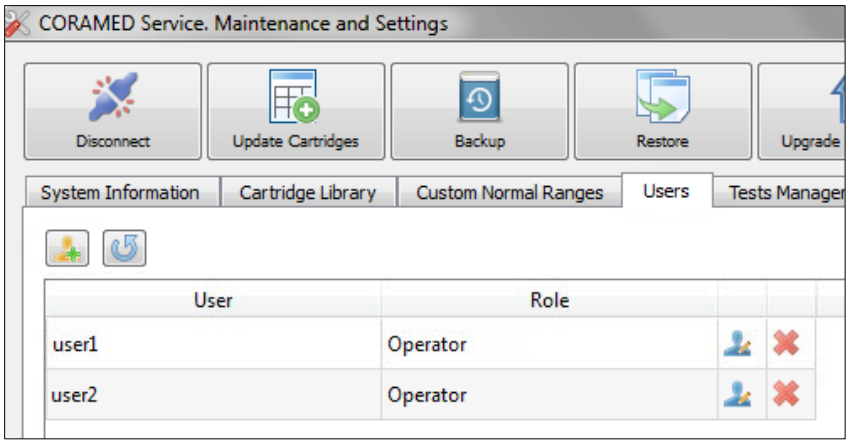


Figure 20: New user on Users tab

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Modify a user account

To modify a user account password or role:

1. On the **User** tab, click the **Modify** button next to the desired user account.

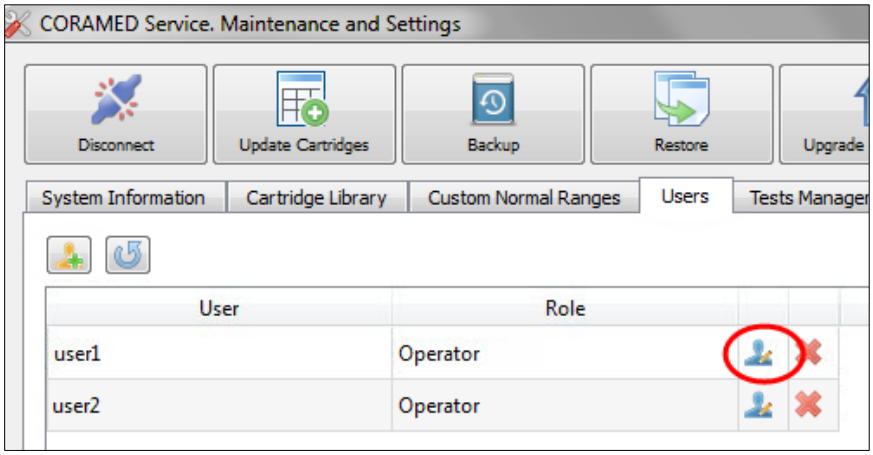


Figure 21: Modify user button

2. On the *Modify user* screen, change the password and/or role information for the user account.

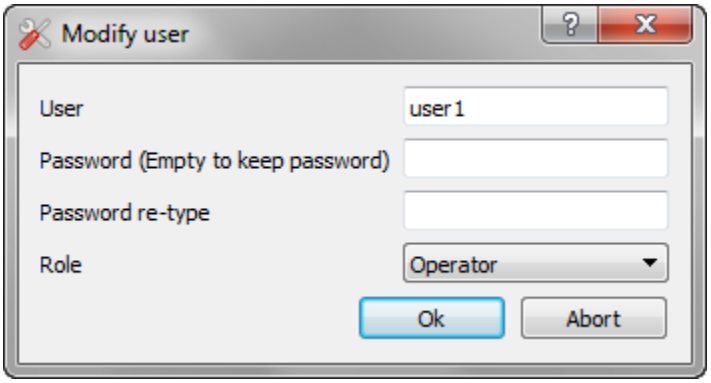


Figure 22: Modify user

3. Click **Ok**.

Delete a user account

To delete a user account from the system:

1. On the **User** tab, click the **Delete** button next to the desired user account.

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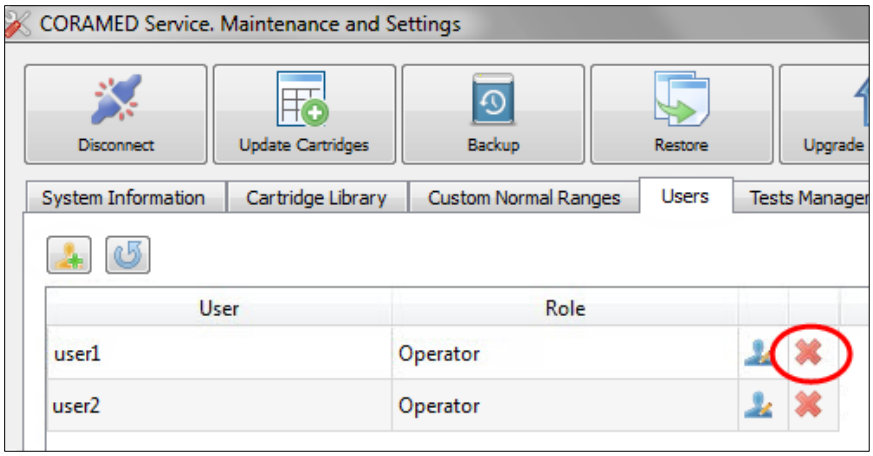


Figure 23: Delete button for the user account

2. In the confirmation message, click **OK**.

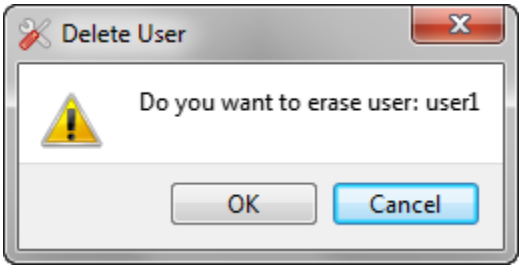


Figure 24: Delete User confirmation message

3. Click **Ok**. The user account no longer appears in the list on the **Users** tab.

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Section VIII: Viewing Test information

All Wet QC and patient test results stored in the analyzer are available for viewing on the **Tests Management** tab. The following information is displayed for each test:

- Patient ID
- Cartridge name
- Date and Time of test
- Status of results

To view test information:

1. On the SMS *Main* screen, click the **Tests Management** tab.

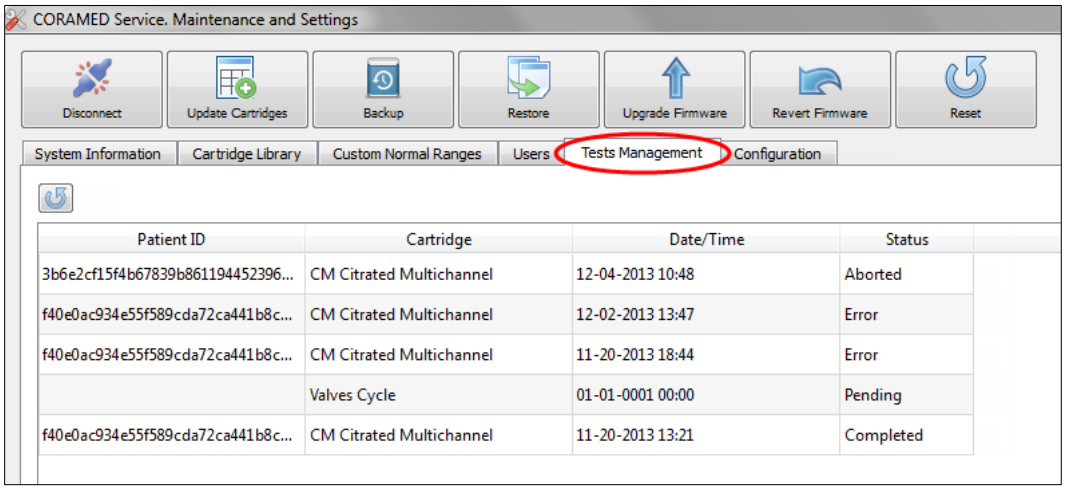


Figure 25: Tests Management tab

2. View the test information.

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Section IX: Configuring the Analyzer

Configuration settings that you apply in SMS apply only to the analyzer to which you are connected. These settings are maintained for all users that log into the analyzer.

To view or change configuration settings for the analyzer:

1. On the SMS *Main* screen, click the **Configuration** tab.

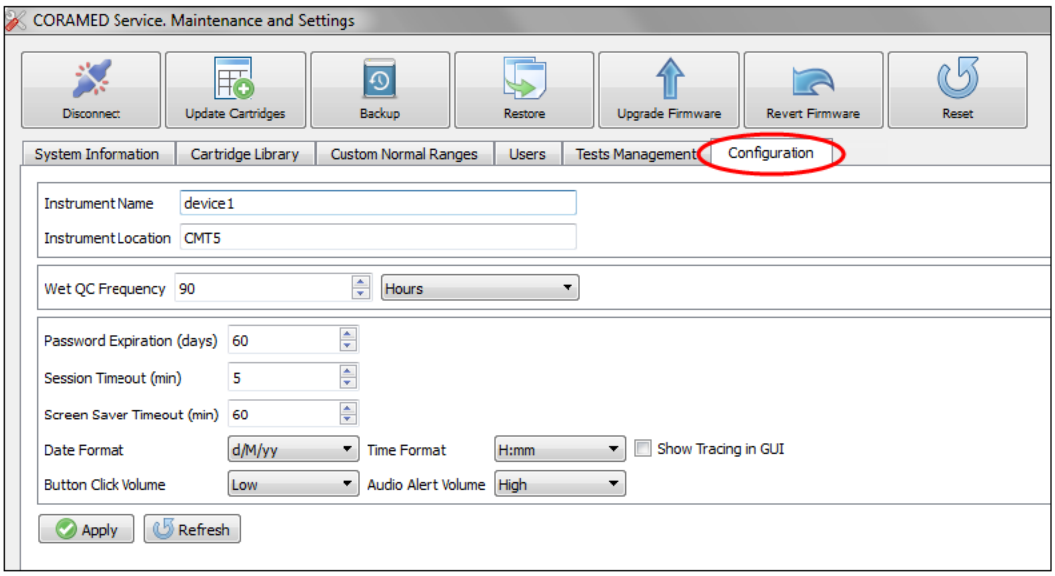


Figure 26: Configuration tab

2. View or change the values for the following fields:

Field	Action
Instrument Name	Enter a name for the analyzer up to a maximum of 20 characters.
Instrument Location	Enter a location for the analyzer up to a maximum of 20 characters.
Wet QC Frequency	Enter a value up to a maximum of 90.
Hours/Days	Select Hours or Days for the desired unit of time for Wet QC frequency.
Password Expiration (days)	Enter a value up to a maximum of 90.
Session Timeout (min)	Enter a value up to a maximum of 60.
Screen Saver Timeout (min)	Enter a value up to a maximum of 60.
Date Format	Select from 10 available date formats.
Time Format	Select from 5 available time formats.
Button Click Volume	Select from 5 available volume levels.
Audio Alert Volume	Select from 5 available settings

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3. Click **Apply**.
4. In the power cycle message that appears, click **Yes**.

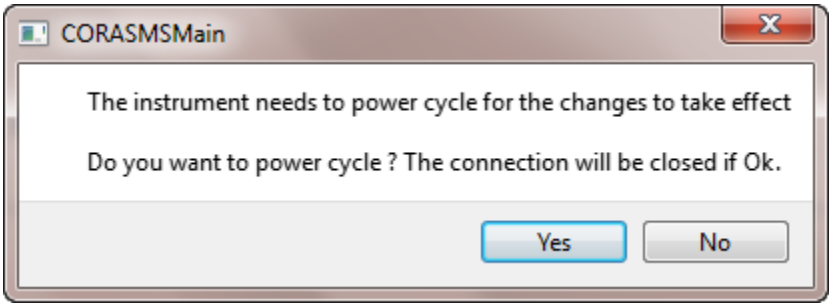


Figure 27: Power cycle message

The SMS software resets the analyzer automatically.

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Section X: Upgrading the Firmware

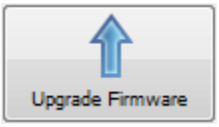
Upgrading the TEG 6000 analyzer firmware is performed using the SMS software in a two-step process: uploading the firmware files and committing the firmware. In the first step, a binary file is uploaded to the analyzer. The analyzer checks the CRC (Cyclic Redundancy Check) Values file and returns a CRC response message. In the second step, the firmware is committed, which resets the analyzer and conducts the actual upgrade upon initialization.

The SMS software also provides a mechanism to revert to a previous firmware version.

Upgrade to a newer firmware version

To upgrade the firmware version:

1. On the SMS *Main* screen toolbar, click **Upgrade Firmware**.



2. In the *Upgrade Firmware* screen, next to *File*, click **Browse**.

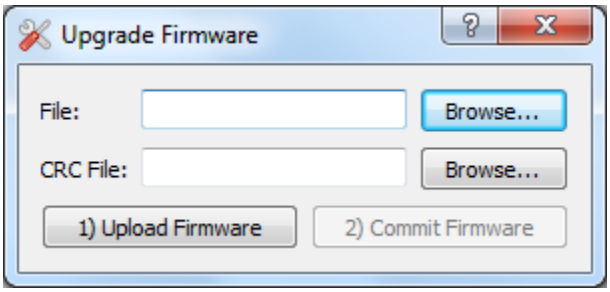


Figure 28: Upgrade Firmware screen

3. In the *Open firmware release* screen, navigate to the location of the latest firmware zip file, and then click **Open**.

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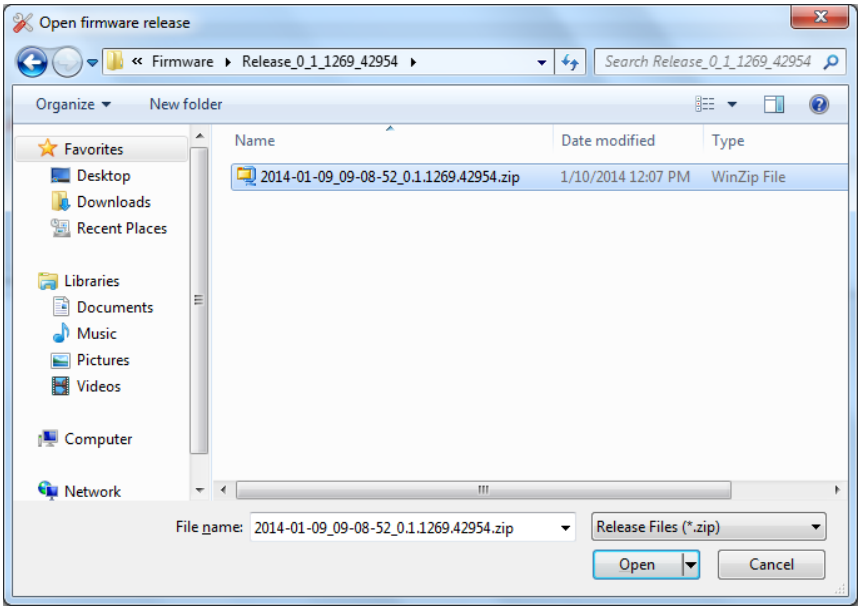


Figure 29: Browse to the location of the current firmware zip file

4. In the Windows *Open* screen, select the current firmware file, and then click **Open**.
5. In the *Upgrade Firmware* screen, next to *CRC File*, click **Browse** and navigate to the location of the latest CRC file.

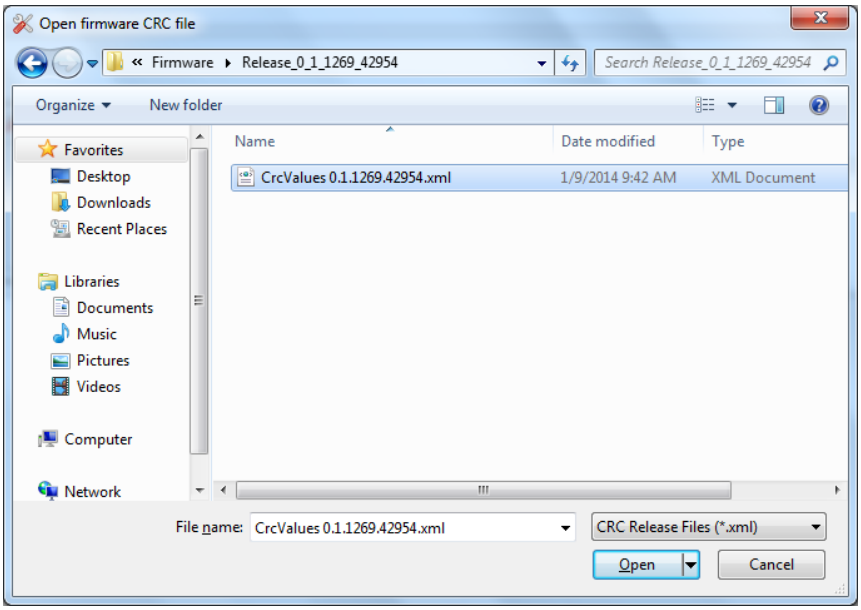


Figure 30: Browse to the location of the current CRC file

6. In the *Upgrade Firmware* screen, click **Upload Firmware**.

   When the analyzer finishes checking the binary and CRC Values files, the **Commit Firmware** button is enabled.

7. Click **Commit Firmware**.

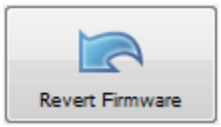
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The SMS software closes and the analyzer resets. The upgrade of the firmware is completed during re-initialization of the analyzer.

Revert to a previous firmware version

1. On the SMS *Main* screen toolbar, click **Revert Firmware**.



The SMS software closes and the analyzer resets. The previous firmware version is loaded during re-initialization of the analyzer.

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Section XI: Managing Backups

The TEG analyzer stores a maximum of 300 patient tests and 300 WQC tests (L1 and L2 combined). When the number of patient or WQC tests reaches 270, the analyzer prompts you to back up the data. The SMS includes functionality to perform backups and to restore a previously generated backup.

Each backup includes the following data:

- User accounts
- Configuration settings
- Cartridge tables
- Normal ranges
- Patient test results
- WQC test results
- Analyzer unique ID
- Audit trail logs

Note: *Patient ID data is hashed during the backup process.*

If a backup is restored to a machine that already includes data, all data is restored with the exception of test results and configuration settings.

Perform a backup

To perform a backup of the analyzer:

1. On the SMS *Main* toolbar, click **Backup**.



2. In the *Save As* window, do the following:
    a. Accept the default location for the backup file (Backups folder in the application directory) or navigate to a location of your choice.

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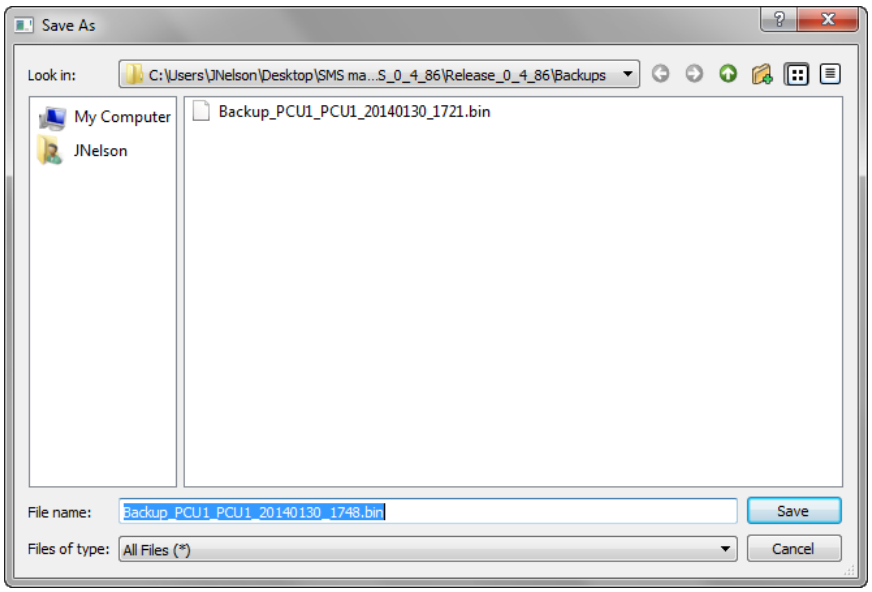


Figure 31: Select a location for the backup file

b. Accept the default name for the backup file (Backup_<serial number>_<instrument name>_ <yyyyMMdd>_<hhmm>.bin), or rename the file.

c. Click **Save**.

   A process message appears during the backup process, which can take up to ten minutes to complete. When the process is complete, the new file appears in the specified location.

Restore a previous backup

When you restore a backup to an analyzer, the data that is restored depends on whether or not the analyzer contains test results.

If there are *no* test results on the analyzer, the SMS software restores the following information from a backup:

- User accounts
- Configuration settings
- Cartridge tables
- Normal ranges
- Patient test results
- WQC test results (only if the backup is from the same analyzer)
- Audit trail logs

If there are test results already on the analyzer, the SMS software prevents the overwriting of test results and logs. Therefore, only the following information is restored from a backup:

- User accounts

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- Configuration settings
- Cartridge tables
- Normal ranges

To restore a previously generated backup file:

1. On the SMS *Main* toolbar, click **Restore**.



2. In the *Open* window, navigate to the Backup folder.

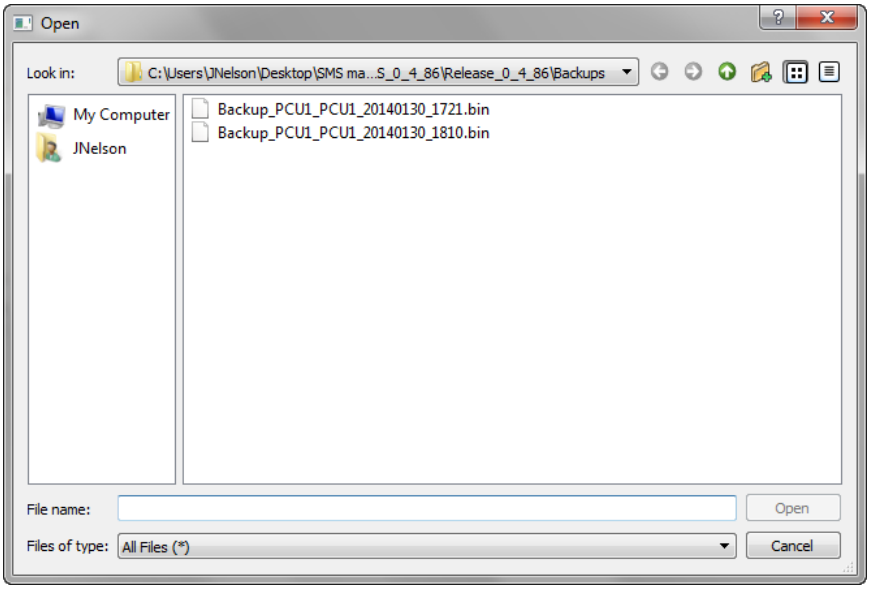


Figure 32: Navigate to the Backup folder

3. Select the desired backup file and click **Open**.

   A process message appears during the restore process.

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Section XII: Manually Resetting the Analyzer

The SMS software provides the ability to reset the analyzer manually. To reset the analyzer, click the **Reset** button on the SMS toolbar.



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Proprietary Name and Established Name

Proprietary Name: CORA® (Coagulation Resonance Analysis) System and the following citrated assays and reagents

CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent

Established Name: Whole Blood Hemostasis System

Intended Use

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The Citrated Multichannel Cartridge, to be used with the CORA System analyzer, contains four independent assays (CK, CRT, CKH and CFF), described below.

The CK assay monitors the hemostasis process via the intrinsic pathway in citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).

The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA).

The CKH assay monitors the effects of heparin in citrated whole blood specimens on the CORA System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests.

The CFF assay monitors hemostasis of citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Summary and Explanation of the Test

The CORA System and the Citrated Multichannel Cartridge are used to test the hemostasis properties of citrated blood samples using four different assays/reagents simultaneously, one in each of the four cartridge channels. For the CK assay, Kaolin-activated test methods are used to reduce variability and to reduce the running time of a native whole blood sample. The CRT assay maximally accelerates the clotting process by simultaneously activating the intrinsic and extrinsic coagulation pathways, allowing for the maximum clot strength to be reached more quickly. CKH is similar to CK but with the addition of

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heparinase, to neutralize the effects of heparin in the blood. If there is heparin present, the R time for CK will be significantly longer than the R time for CKH. The CFF assay fully inhibits all the platelets, thereby excluding their contribution to clot strength, and therefore measures only the functional fibrinogen contribution to clot strength.

Principles of the Procedure

CK Principle

Kaolin is a standardized reagent consisting of dry Kaolin and 0.85% Saline solution. Kaolin-activated test methods are used to reduce variability and to reduce the running time of a native whole blood sample. Use of these particles of hydrated aluminum silicate shortens coagulation time because Kaolin acts as a contact surface activator (intrinsic pathway), which activates Factor XII and platelets and stimulates the reserve clotting ability of a blood sample. Kaolin is combined with $CaCl_2$ to neutralize any sodium citrate in the blood.

CRT Principle

RapidTEG maximally accelerates the clotting process by simultaneously activating the intrinsic and extrinsic coagulation pathways using a high concentration of Kaolin and Tissue Factor (TF). This closely reflects the physiological clotting process and yields results significantly faster than a native, Kaolin, and/or TF activated test. $CaCl_2$ is included to neutralize any sodium citrate in the blood.

CKH Principle

Heparin is commonly used as an anticoagulant in surgical procedures. Even very low concentrations of Heparin, fractions of IU/mL of blood, can noticeably increase the R time and can even completely anticoagulate the blood, making it difficult if not impossible to monitor developing coagulopathies that are masked by high levels of therapeutic Heparin. The Kaolin with Heparinase assay will rapidly and specifically neutralize the anticoagulant property of Heparin. $CaCl_2$ is included to neutralize any sodium citrate in the blood

CFF Principle

The Functional Fibrinogen reagent activates the extrinsic pathway using tissue factor and inhibits platelet aggregation using a platelet inhibitor that binds to GPIIb/IIIa receptors. The Functional Fibrinogen reagent fully inhibits all the platelets, thereby excluding their contribution to clot strength (MA), and therefore measures only the functional fibrinogen contribution (MA_{PI}) to clot strength. Functional Fibrinogen is combined with $CaCl_2$ to neutralize any sodium citrate in the blood. Determining the independent contribution of platelets and fibrinogen further improves the use of the CORA System in helping to detect and diagnose hemostasis defects.

Reagents

CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
Dried Kaolin and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 35.45% Kaolin (concentration 0.011896% w/w), 21.97% water, and 42.58% Calcium Chloride 2 M solution.

CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
Dried Kaolin, Tissue Factor and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 11.73% Kaolin (concentration 14.098 % w/w), 46.92% Tissue Factor (concentration 3.88 µg/mL), and 41.35% Calcium Chloride 2M solution.

CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
Dried Kaolin and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 57.42% Kaolin (concentration 0.012854% w/w) and 42.58% Calcium Chloride 2 M solution; dried Heparinase,

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900 nL spot in blood well of channel, consisting of 23.66% Heparinase (concentration 0.38 IU) and 76.34% water.

CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent
Dried Tissue Factor and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 58.65% Tissue Factor (concentration 0.00055 µg/mL) and 41.35% Calcium Chloride 2 M solution; dried ReoPro®, 900 nL spot in blood well of channel, consisting of 100% ReoPro®.

Warnings or Precautions:

For In-Vitro Diagnostic Use

Sources of Reagent Error

Cartridges should be refrigerated (2° C to 8° C) when not in use.

Sources of Procedural Error

Use only citrated tubes. Do not collect blood samples into heparin tubes or any other tubes not specifically recommended.

Instructions for reconstitution, mixing, dilution, etc.

None required.

Storage instructions

CORA Citrated Multichannel cartridges are for single use only and should be stored refrigerated at 2°C to 8°C prior to removal from storage for use. Cartridges should be discarded after use.

Analyzer

Refer to CORA System User's Manual

Specimen Collection and Preparation for Analysis

Use only citrated tubes for blood draws. No additives or preservatives are necessary to maintain the integrity of the sample, but samples must be used within 2 hours of draw to maintain in-use stability.

Known Interfering Factors

CK assay was tested for interference factors according to CLSI EP7-A2. Potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Only Hemolysis, and Hemodilution levels above 20%, were found to be interferents.

CRT assay was tested for interference factors according to CLSI EP7-A2. Potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). All except EACA and Absence of a Discard Tube were found to be interferents, with Hemodilution being an interferent above 20% concentration.

CKH assay was tested for interference factors according to CLSI EP7-A2. The potential interferent tested was Protamine. Results show that Protamine is an interferent at concentrations above 0.062 mg/mL.

CFF assay was tested for interference factors according to CLSI EP7-A2. Potential interferents tested were Heparin and Hemodilution. Heparin was found to be an interferent for Functional Fibrinogen above Heparin concentrations of 1 IU/mL, and Hemodilution was found to be an interferent above hemodilution levels of 30%.

Procedure

Materials Provided

One (1) Citrated Multichannel cartridge sealed with desiccant pack in foil pouch. Cartridge contains the following dried reagents: Kaolin, RapidTEG, Kaolin with Heparinase and Functional Fibrinogen, all with Calcium Chloride.

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Materials Required (but not supplied)

CORA® Analyzer (Coramed Technologies) – see User's Manual for instructions for use.
Transfer pipette(s) (Samco Scientific #212 or equivalent)
Blood drawing supplies (any medical supplier)

Test Procedure

1. Remove the cartridge from refrigerated storage.
2. Tear open the pouch, remove the cartridge and discard the pouch and desiccant pack.
3. From the main menu on the CORA analyzer, select "new test".
4. Select the patient ID you wish to use. If the patient is not listed, you may add a new patient by selecting the "+" option and entering a patient ID on the screen. Then press "next".
5. Insert the cartridge into the slot as indicated on the screen with the bar code on the left side.
6. After the cartridge pretest is completed and you have verified that the assay is what you intended to run, press "next". If the cartridge is not the desired assay, press "stop" and start over.
7. Add blood to the cartridge sample port to above the level indicated on the cartridge.
8. After loading the sample press "next".
9. The test will run and results will be displayed as they become available.
10. When the test is completed, the analyzer will prompt to remove the cartridge and will return to the table of results.
11. Remove the used cartridge from the slot as demonstrated on the LCD display, and discard the cartridge.
12. Press "done" from the results screen to return to the home page.

Calibration

The CORA analyzer does not require routine calibration.

Quality Control Procedures

The CORA analyzer performs internal QC checks during a pretest when the cartridge is inserted. This verifies that all electromechanical and pneumatic functions of the analyzer-cartridge combination are operating satisfactorily. Laboratories should perform additional QC testing as required by their laboratory's procedures. Coramed provides Abnormal WQC materials to be used for this purpose.

Whereas the internal QC of the analyzer effectively tests analyzer functions, a QC methodology is required to verify that reagents in cartridges are still viable at time of use. This ensures that cartridges have not been mishandled between production and arrival at the lab, or have not been subject to adverse environmental conditions or otherwise mishandled while in lab storage. This can supplement the laboratory's development of its own Individualized Quality Control Plan (IQCP) based on the lab's risk analysis, in accordance with CLSI EP23. This risk analysis would take into account the lab's specific situations that could affect reagent quality, such as environmental storage controls. Coramed recommends that laboratories perform QC tests on each new shipment of cartridges using blood from a known normal donor and Abnormal WQC material representing an abnormal sample. The "normal" donor should have prior coagulation test results that have fallen within established reference ranges. For the Abnormal WQC sample, reagent performance is verified if parameters fall within the following Reference Ranges. It is also recommended that the lab perform this QC testing whenever indicated by the IQCP.

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Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (degrees)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563 - 873

Results

No calculations are necessary to obtain test results; these are displayed on the CORA analyzer display, and may be printed if a printer is attached.

CK Test Results

The R, K, Angle and MA parameters are measured and displayed at the conclusion of the test, along with the corresponding reference ranges established for these parameters.

CRT Test Results

The MA parameter is measured and displayed at the conclusion of the test, along with the corresponding reference ranges established for these parameters.

CKH Test Results

The R parameter is the only one of importance for this test. It is measured and displayed at the conclusion of the test, along with the corresponding reference range established for the R parameter for Kaolin with Heparinase.

CFF Test Results

The MA parameter and the estimated Functional Fibrinogen Level (FLEV) are measured and displayed at the conclusion of the test.

Limitation of the Procedure

Use of Results

CORA results should always be considered within the clinical context of the individual patient's case. In the event of inconsistencies with the patient's clinical status, samples should be repeated or supplemented with additional clinical information and/or data.

Expected Values

Expected values for test results are within the Reference Ranges for a reference population that were established according to CLSI C28-A3c. The following tables contain the reference range data for each reagent and parameter. It is recommended that customers validate reference ranges based on their local population.

CK Reference Ranges

Citrated Blood Parameter	N	Range
R (min)	157	4.6 – 9.1
K (min)	157	0.8 – 2.1
Angle (deg)	155	63 - 78
MA (mm)	151	52 - 69

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CRT Reference Ranges

Citrated Blood Parameter	N	Range
MA	152	52 - 70

CKH Reference Ranges

Citrated Blood Parameter	N	Range
R	155	4.3 – 8.3

CFF Reference Ranges

Citrated Blood Parameter	N	Range
MA	151	15 - 32
FLEV	152	278 - 581

Specific Performance Characteristics

CK Precision

The precision of the CORA Kaolin test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, multi-site reproducibility tests were performed across three sites, three lots, three operators and three analyzers. Results included Coefficient of Variance (CV) values for all tests completed. For all precision tests, the precision for the Kaolin Assay was CV less than 15% for the R parameter, less than 10% Angle and MA parameters, and less than 25% for the K parameter (which is not used for clinical decisions).

CK Sensitivity and Specificity

The Kaolin reagent is often used in conjunction with tests performed on blood samples from patients administered with heparin, with the goal of either determining heparin effect (titration of dose) or determining full reversal (post-protamine) of heparin administered. It is, therefore, important that the Clinical Sensitivity and Specificity for the presence of heparin be determined. Five different heparin spiked samples were examined, with concentrations spread across the heparin therapeutic ranges (0.2 to 6.0 IU/mL). 0.2 IU/mL is the lowest therapeutic dose typically used and 6.0 IU/mL represents a typical dose of heparin used when patients are fully heparinized during cardio-pulmonary by-pass. In addition, five (5) non-heparin spiked samples were analyzed. Kaolin's sensitivity to Heparin was 100%, with the R parameter elongated and out of range for all concentrations. Specificity was also 100%, with all un-spiked samples having an R parameter within normal range.

CRT Precision

The precision of the CORA RapidTEG test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, multi-site reproducibility tests were performed across three sites, three lots, three operators and three analyzerss. Results included Coefficient of Variance (CV) values for all tests completed. For all tests, the precision for the RapidTEG Assay was less than 10% for the MA parameter.

CKH Precision

The precision of the CORA Kaolin with Heparinase test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, multi-site reproducibility tests were performed across three sites, three lots, three operators and three analyzers. Results included Coefficient

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of Variance (CV) values for all tests completed. For all tests, the precision for the Kaolin with Heparinase Assay was CV less than 15% for the R parameter.

CKH Neutralization

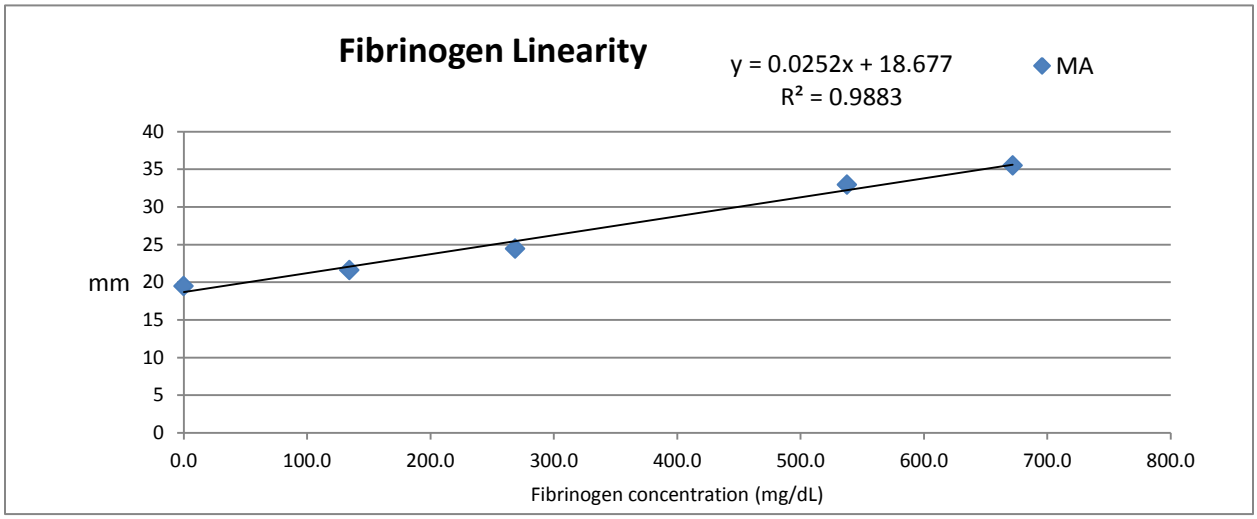
The Kaolin with Heparinase assay was tested to verify that 6 IU of Heparinase per 1 mL of blood will effectively neutralize the effects of both Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) on Kaolin-activated citrated whole blood samples. This is the amount of Heparinase used in the Kaolin with Heparinase assay. Tests were performed using UHF and LMWH spiked samples and un-spiked samples. All tests reported R parameter values within the normal range, confirming the neutralization effectiveness of the assay.

CFF Precision

The precision of the CORA Functional Fibrinogen test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, multi-site reproducibility tests were performed across three sites, three lots, three operators and three analyzers. Results included Coefficient of Variance (CV) values for all tests completed. For all tests, the precision for the Functional Fibrinogen Assay was CV less than 10% for the MA and FLEV parameters.

CFF Linearity

The Function Fibrinogen assay was tested for linearity according to CLSI EP6-A. Linearity with respect to Fibrinogen concentration levels is shown below.



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Kaolin

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Name and Place of Business of Manufacturer:

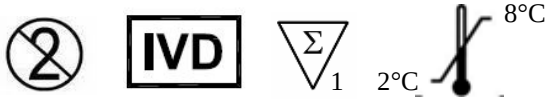


Coramed Technologies
6225 W Howard St
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Date of Issuance of Last Labeling Revision: January 6, 2015

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REF CRT-CC-0L2

Rx Only

CONTROL

Proprietary Name and Established Name

Proprietary Name: Abnormal QC Material to be used with the CORA® (Coagulation Resonance Analysis) System

Established Name: Whole Blood Hemostasis System

Intended Use

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The CORA System records the kinetic changes in a sample of citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The Abnormal QC Material is to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Summary and Explanation of the Test

The CORA System is used to test the hemostasis properties of blood samples. The CORA analyzer performs internal QC checks during a pretest when the cartridge is inserted. This verifies that all electromechanical and pneumatic functions of the analyzer-cartridge combination are operating satisfactorily. Laboratories should perform QC testing as required in accordance with their laboratory policies and procedures.

Principles of the Procedure

The CORA Hemostasis System whole blood coagulation Abnormal Quality Control contains a preparation of animal citrated plasma. It has been formulated specifically as a quality control for the CORA System, representing an "abnormally low" level of coagulation. This control contains no human material. It is for in vitro diagnostic use and professional use only.

Reagents

Abnormal Quality Control Material

The Abnormal QC Material consists of one 1 mL vial of lyophilized bovine citrated plasma and one 1 mL vial of diluent water for reconstituting the lyophilized material.

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Warnings and Precautions:

For In-Vitro Diagnostic Use

Hazards

The Abnormal QC Material is potentially hazardous in case of ingestion, inhalation, skin contact and eye contact. It contains animal source material; therefore, it should be treated as potentially infectious. Use universal precautions for handling potentially bio-hazardous material. It may cause adverse effects for the environment if discarded improperly.

Sources of Reagent Error

- Do not freeze the controls.

Sources of Procedural Error

- Carefully follow the instructions for the preparation of the Abnormal QC Material. For correct reconstitution, the full vial of diluent water must be poured into the vial of lyophilized control. Failure to do so may result in inaccurate results.
- Timing - Do not use controls if they have been reconstituted for more than 2 hours

Instructions for reconstitution, mixing, dilution, etc.

The entire contents of the diluent water vial must be placed into the Abnormal QC vial for proper concentration, and thoroughly mixed.

Storage instructions

Abnormal QC Materials are for single use only and should be stored refrigerated at 2°C to 8°C prior to removal from storage for use.

Analyzer

Refer to CORA System User's Manual

Specimen Collection and Preparation for Analysis

No specimen collection is required for running this Quality Control test. No additives or preservatives are necessary to maintain the integrity of the material, but reconstituted Abnormal QC Material must be used within 2 hours of reconstitution.

Procedure

Materials Provided

One (1) Abnormal QC vial and one (1) Water vial.

Materials Required (but not supplied)

CORA® Analyzer (Coramed Technologies)
Transfer pipette(s) (Samco Scientific #212 or equivalent)

Test Procedure (used in conjunction with Citrated Multichannel cartridges)

1. Remove the cartridge from refrigerated storage.
2. Tear open the pouch, remove the cartridge and discard the pouch and desiccant pack.
3. From the main menu on the CORA analyzer, select "new qc".
4. Insert the cartridge into the slot as indicated on the screen with the bar code on the left side.
5. After the cartridge pretest is completed and you have verified that the assay is what you intended to run, press "next". If the cartridge is not the desired assay, press "stop" and start over.
6. Prepare the Abnormal QC sample according to the following instructions:
   a) Allow the control and the diluent water vial(s) to sit for approximately 10 minutes to equilibrate to room temperature.
   b) Make sure the control is on the bottom of the vial. You may need to tap the vial a few times.

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c) Remove the seal and stopper of the lyophilized control, taking care to avoid sharp metal edges.
d) Into each vial of lyophilized control, slowly pour 1 vial of 1 mL of diluent water, provided. Make sure no water drips out.
e) Re-insert the stopper into the control vial.
f) Hold the stopper in place, vigorously shake the vial until fully reconstituted, and then let it stand for 5 minutes at room temperature.
g) Shake the vial vigorously again and let stand 5 more minutes.

7. Using the transfer pipette, deliver the Abnormal QC material to the cartridge sample port to above the level indicated on the cartridge.
8. After loading the sample press "next".
9. The test will run and results will be displayed as they become available.
10. When the test is completed, the analyzer will prompt to remove the cartridge and will return to the table of results.
11. Remove the used cartridge from the slot as demonstrated on the LCD display, and discard the cartridge.
12. Press "done" from the results screen to return to the home page.

Results

No calculations are necessary to obtain test results; these are displayed on the CORA analyzer display, and may be printed if a printer is attached.

Limitations of the Procedure

Use of Results

- Results outside of the normal ranges listed below may be caused by improperly prepared control material or product deterioration. It is recommended that any failed Abnormal QC test should be repeated. Repeated failures should be reported to the supervisor.
- Do not report any patient results until the control parameters are within their appropriate ranges.

Expected Values

Expected values for test results are within the Reference Ranges that were established based on testing by Coramed, following Clinical and Laboratory Standards Institute (CLSI) publication C28-A3c, Defining, Establishing and Verifying Reference Intervals. Each laboratory may establish its own level of performance to monitor quality assurance. Follow your institution's policy to establish mean target values and ranges for the quality controls.

Reference Ranges for Abnormal QC and Citrated Multichannel Reagents

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (degrees)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563 - 873

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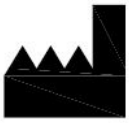
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Specific Performance Characteristics

Precision

The precision of the CORA Abnormal QC Material was evaluated according to CLSI EP5-A2. Testing was performed in Coramed' laboratory for within-device (20-day tests using Abnormal QC with citrated reagents), and multi-site reproducibility tests were performed across three sites, three lots, three operators and three analyzers. Results included Coefficient of Variance (CV) values for all tests completed. For these precision tests, the precision for the Abnormal QC Material was CV less than 10% for all parameters.

Name and Place of Business of Manufacturer:



Coramed Technologies
6225 W Howard St
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Date of Issuance of Last Labeling Revision: January 6, 2015

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Sterilization and Shelf Life

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Section 15: Biocompatibility

This section does not apply to the CORA System 510(k) because there are no patient contacting parts and operators are instructed to wear gloves.

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SECTION 16: SOFTWARE-RELATED DOCUMENTATION

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(b)(4) Software Requirements Specification

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Commercial in Confidence

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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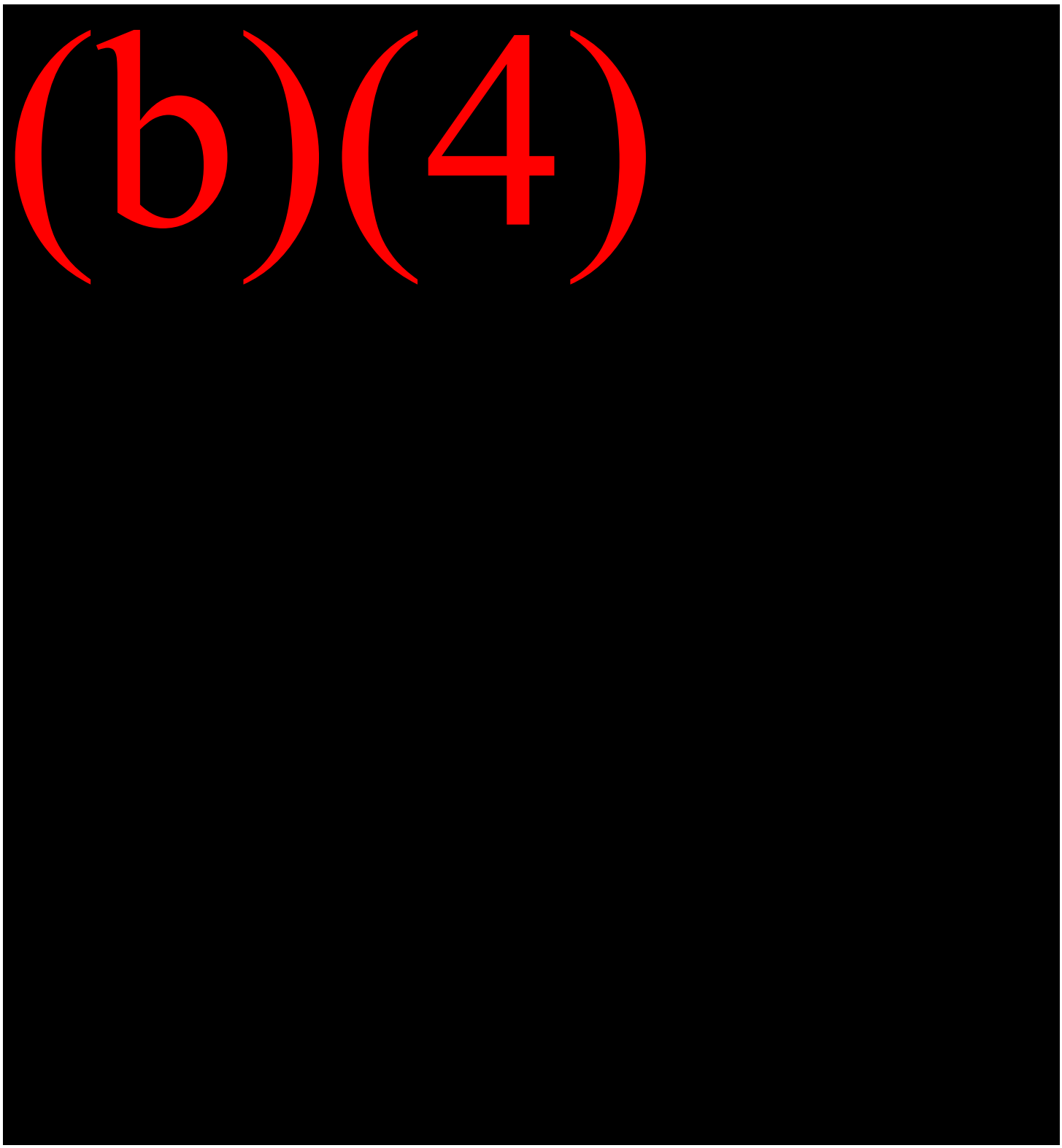
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(b)(4) Software Architecture Description

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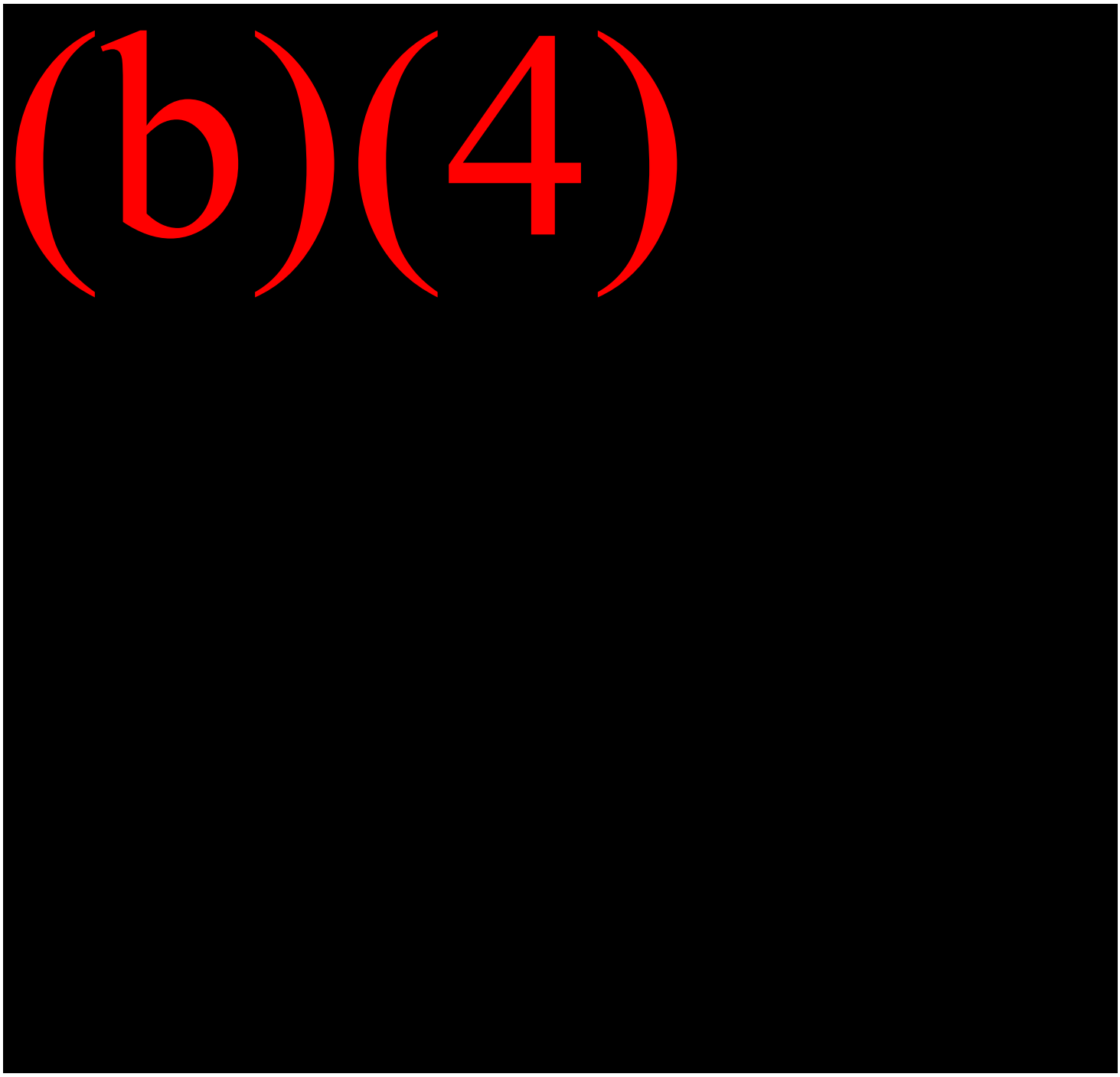
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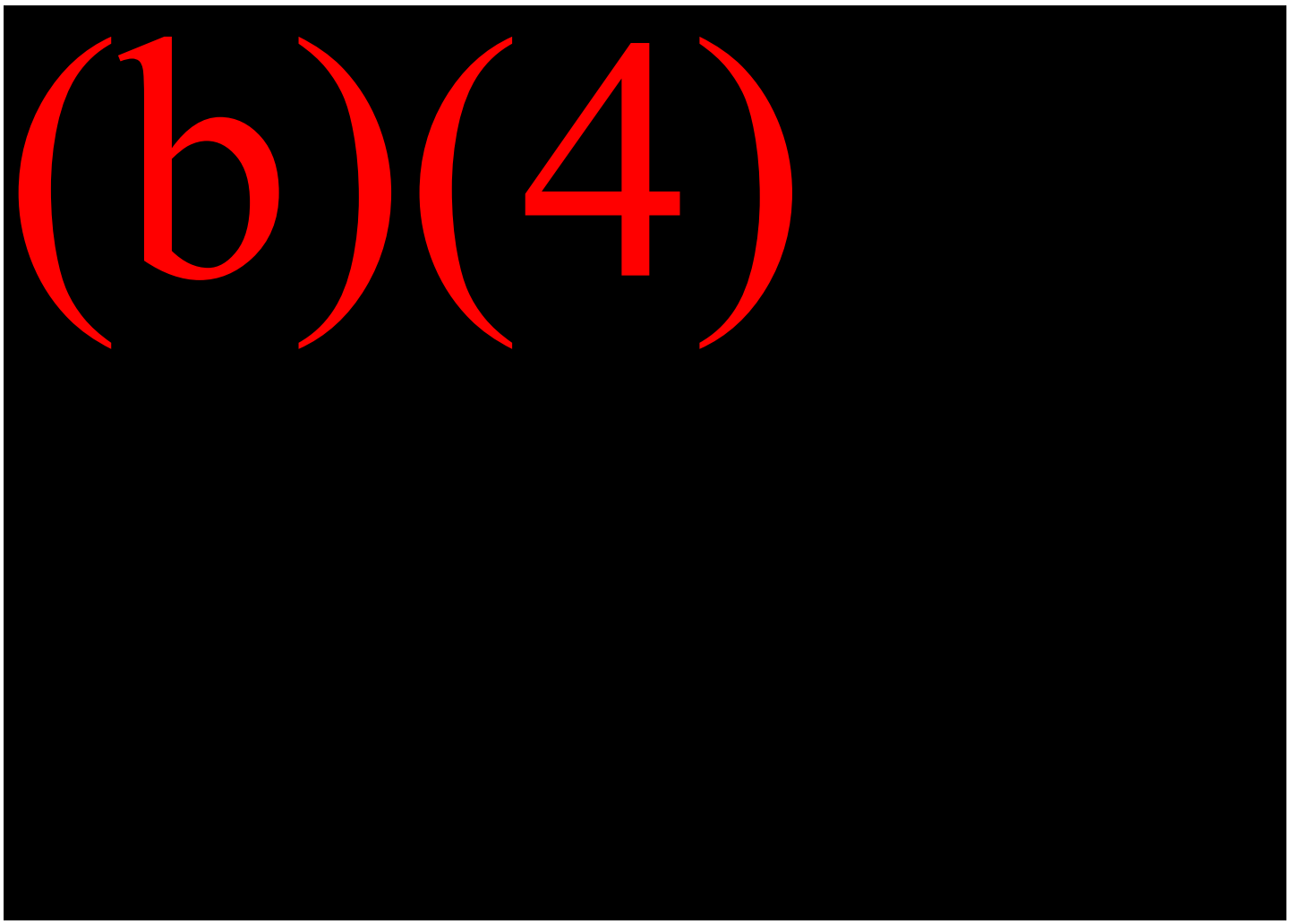
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SW Verification Traceability Matrix



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Records Processed under FOIA request 2016-2049; Released by CDRH

(b)(4) Software Configuration Management and Development Environment Description

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

Software Version Level History and Unresolved Anomalies

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2018-3048; Released by CDRH on 01/25/2017

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

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Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

50.	Use the pressure meter to measure and record the pressure range during the POST.	Pressure: 40 kPa	✓
51.	*Verify that the recorded pressure range is adequate using the pressure meter.* *i.e. check that the pressure level recorded falls within RegulatedPressureHighMin and RegulatedPressureHighMax* *Note: During POST, the RegulatedPressureHighMax is increased by 5kPa*	*SRS_013*	(P)/F
52.	Power off the Instrument		✓
53.	Attach the following onto the hardware: • Pressure meter to record the vacuum range	N/A	✓
54.	Power on the Instrument		✓
55.	Use the pressure meters to measure and record the vacuum range during the POST.	Vacuum: 41 kPa	✓
56.	*Verify that the recorded vacuum range is adequate using the pressure meter.* *i.e. check that the vacuum level recorded falls within RegulatedVacuumHighMin and RegulatedVacuumHighMax*	*SRS_013*	(P)/F
57.	Wait for POST to complete	N/A	✓
58.	Power off the Instrument		✓
59.	Attach the following onto the hardware: • Oscilloscope to record active time of the compressor	N/A.	
60.	Power on the Instrument		
61.	Use the oscilloscope to capture the response from the compressor. (ie use the Run/stop feature to capture the waveform). From this, measure the active time of the compressor during the POST	Active time:_____	
62.	*Verify that the recorded active time of the compressor is at least a couple of seconds* *(This is to ensure the pump builds enough pressure in the accumulators)*	*SRS_013* N/A	P/F
63.	Wait for POST to complete		

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Test Report Document #[redacted]

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Failure Mode, Effects and Criticality Analysis (FMECA) - CORA® SMS Software



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CORA™ Service-Maintenance-Settings (SMS) Control Software Requirements Specification (SRS)



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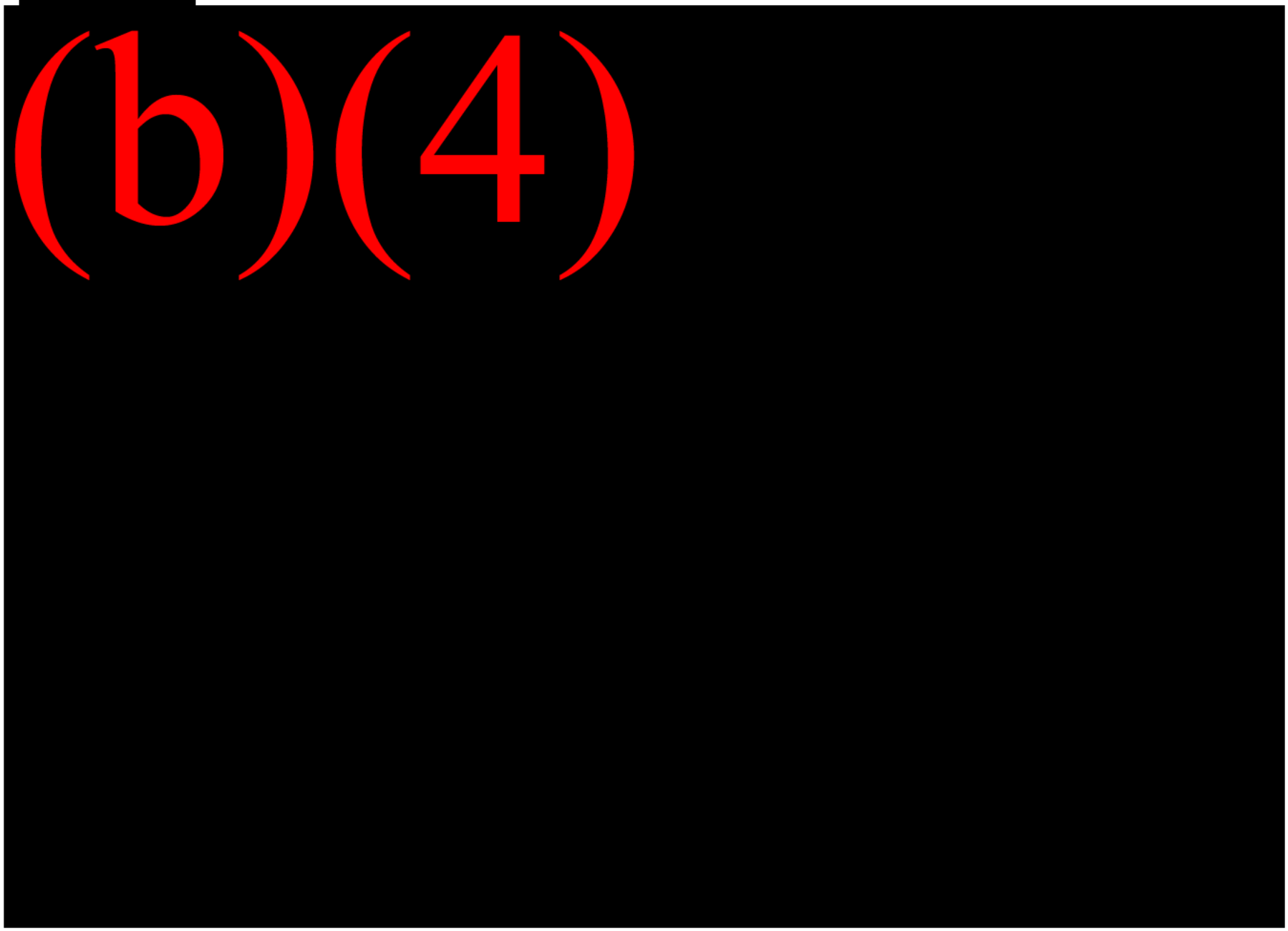
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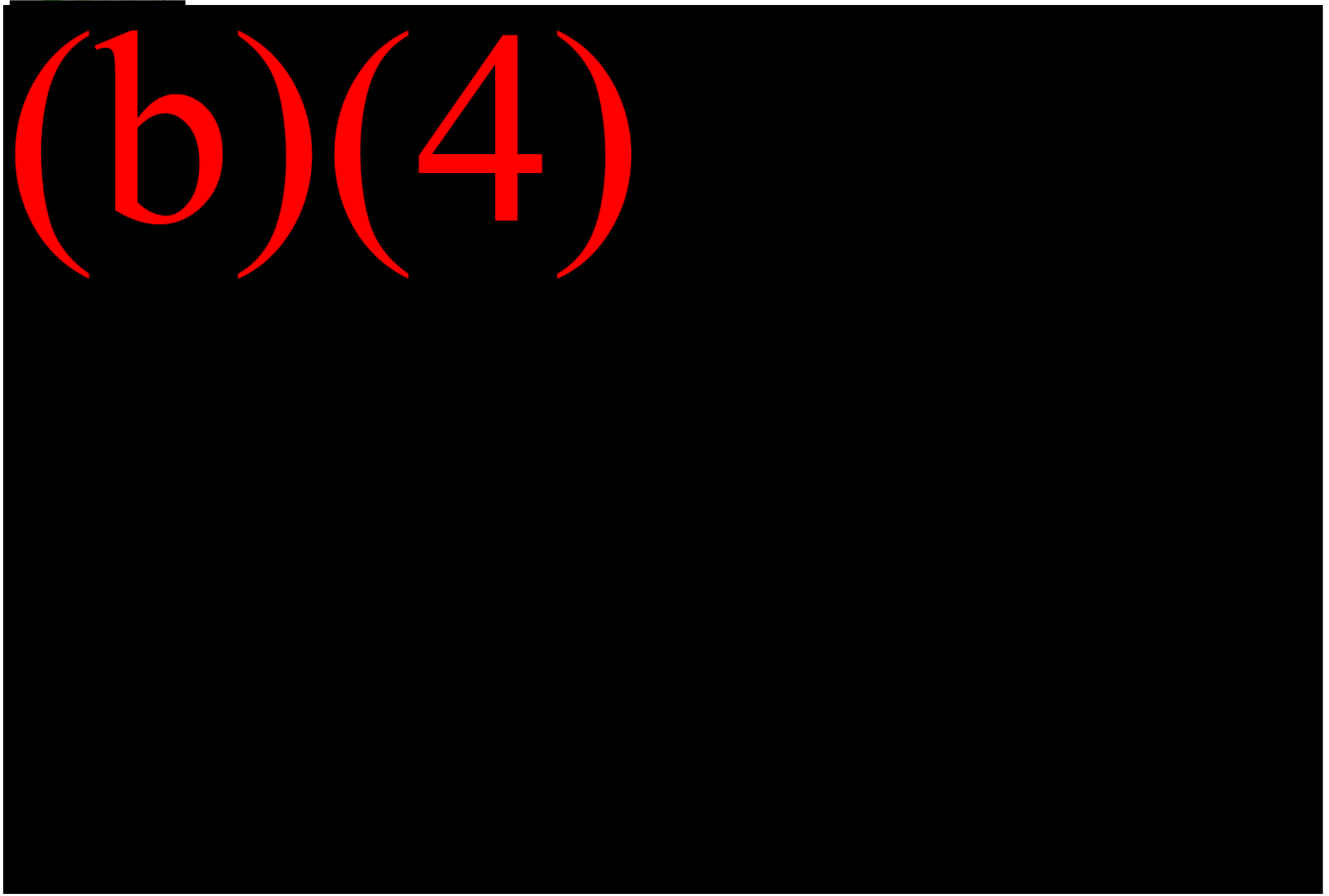
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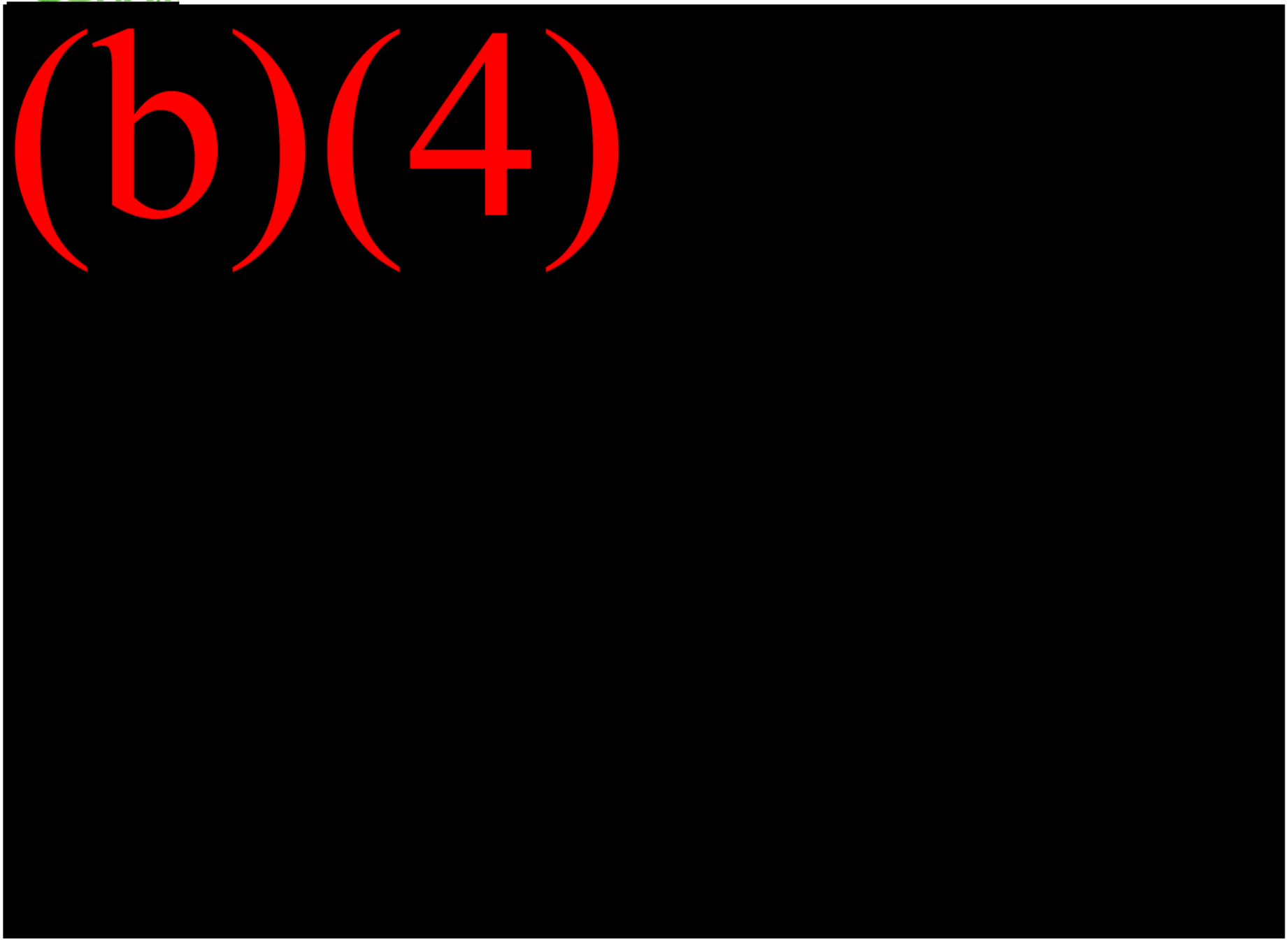
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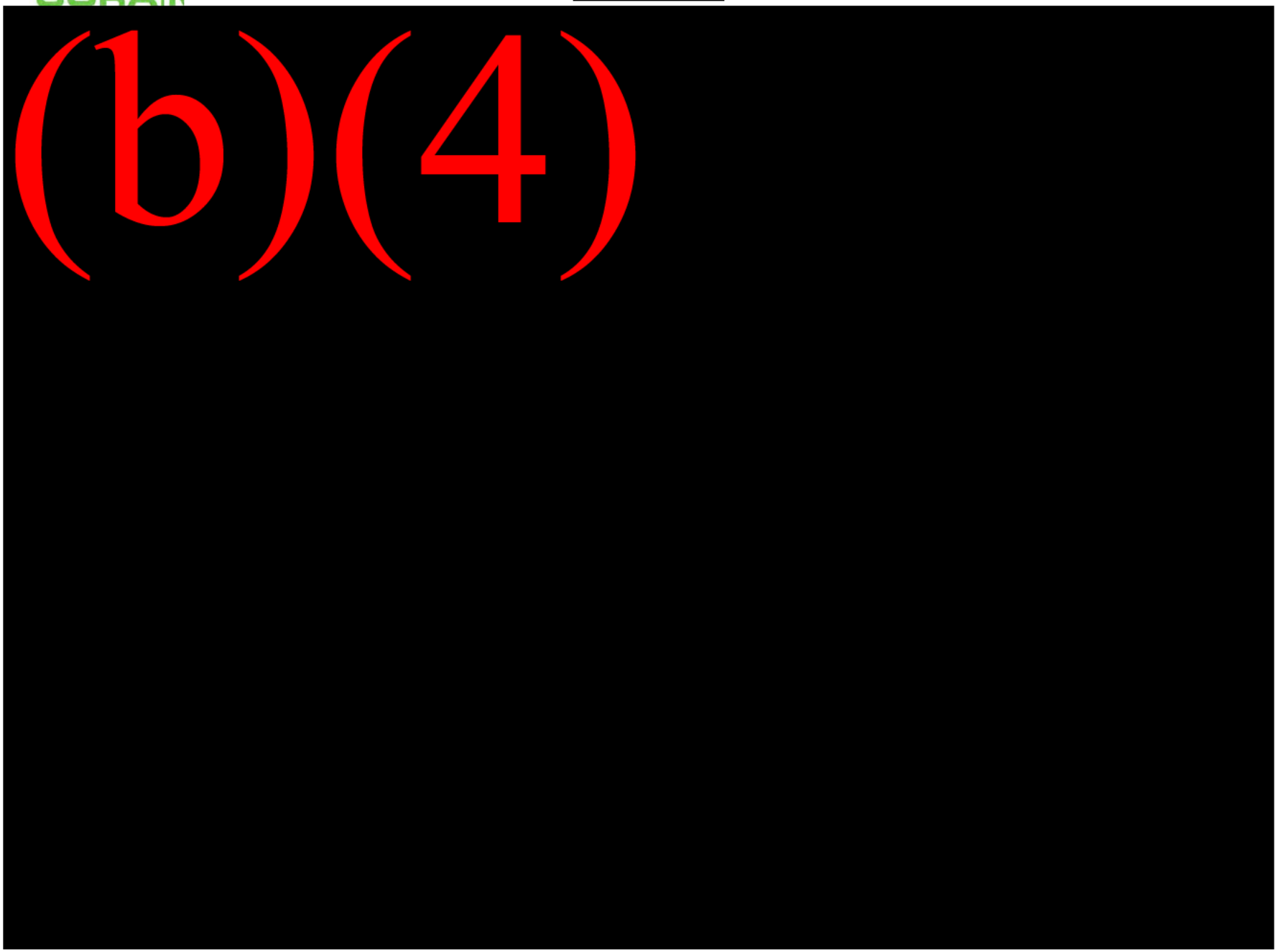
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Coramed Technologies

Software Architecture Document Number (b)(4)

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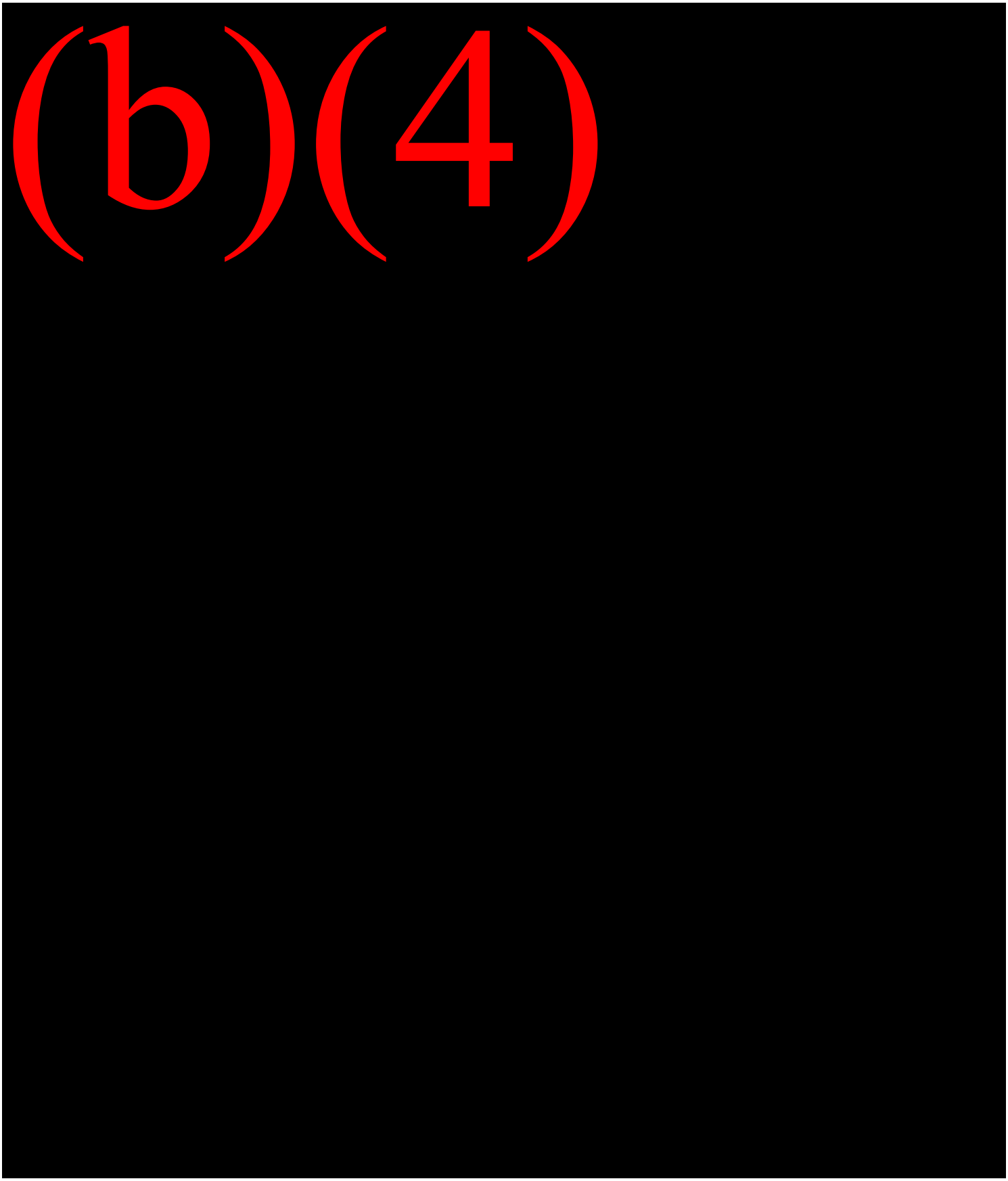
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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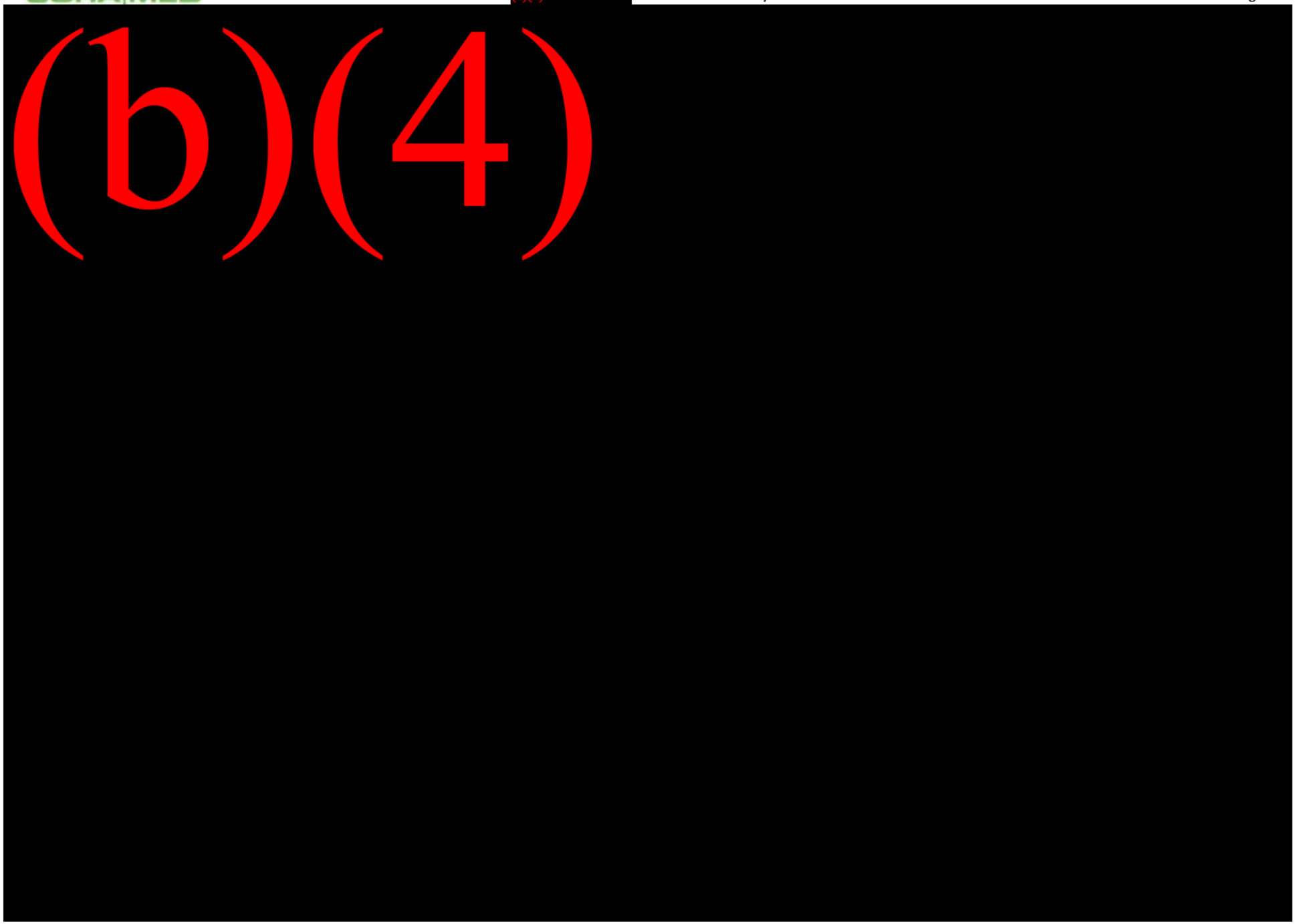
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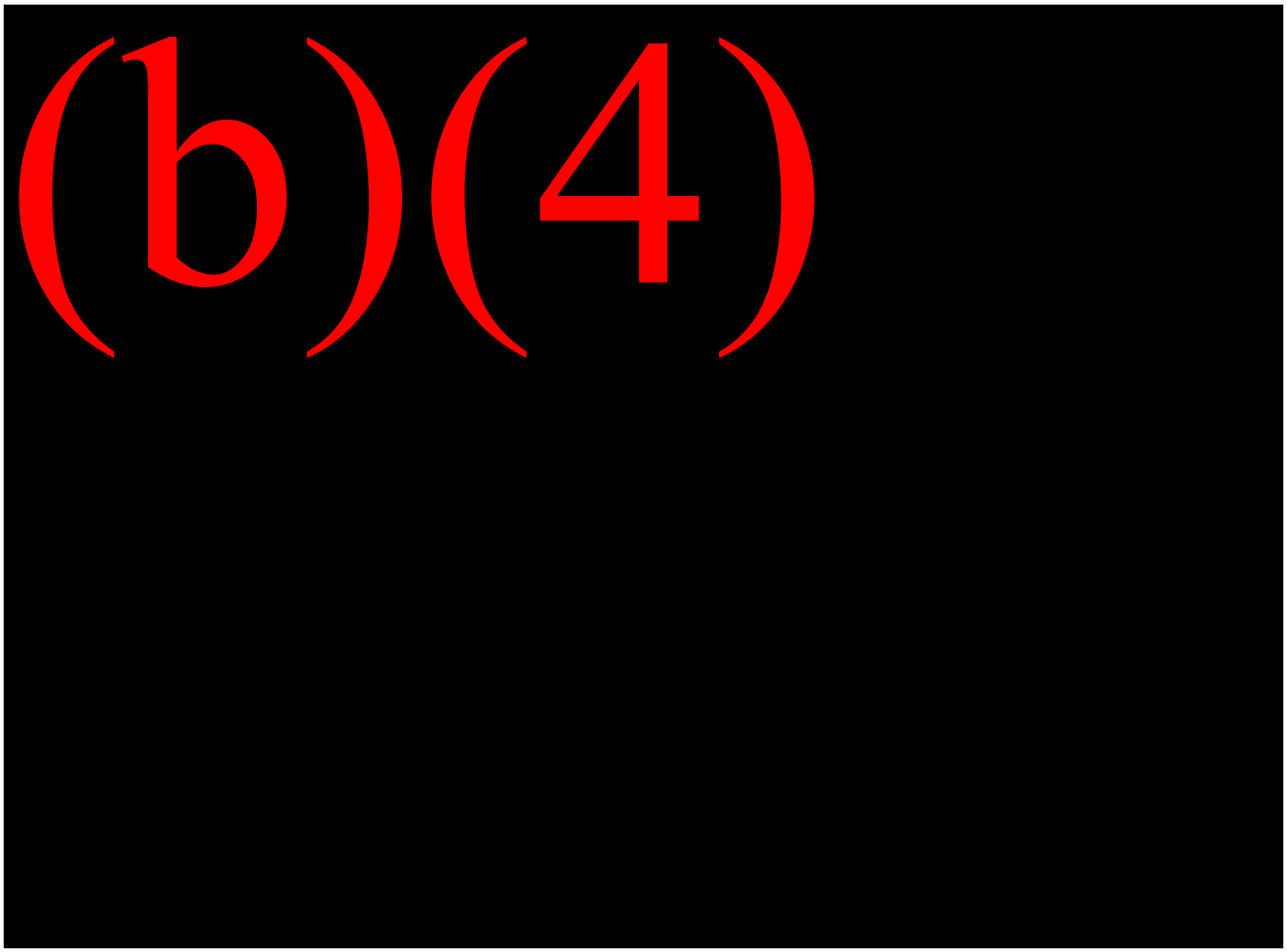
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Software Development Environment Description



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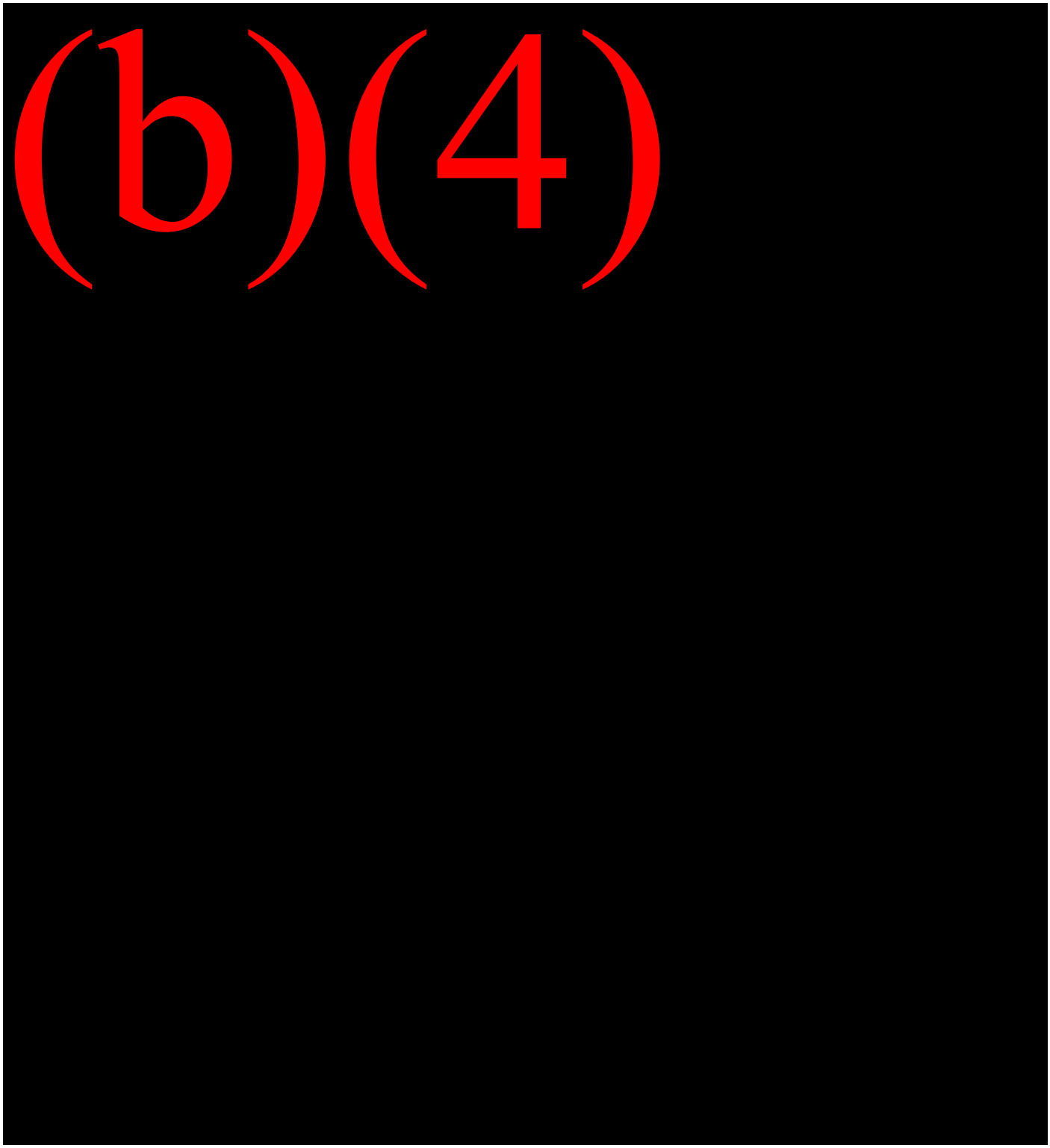
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Questions? Contact FDA/CDRH/OIDP at CDRH-PCHSTAT@fda.hhs.gov or 301-796-8118

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Software Verification and Validation Plan

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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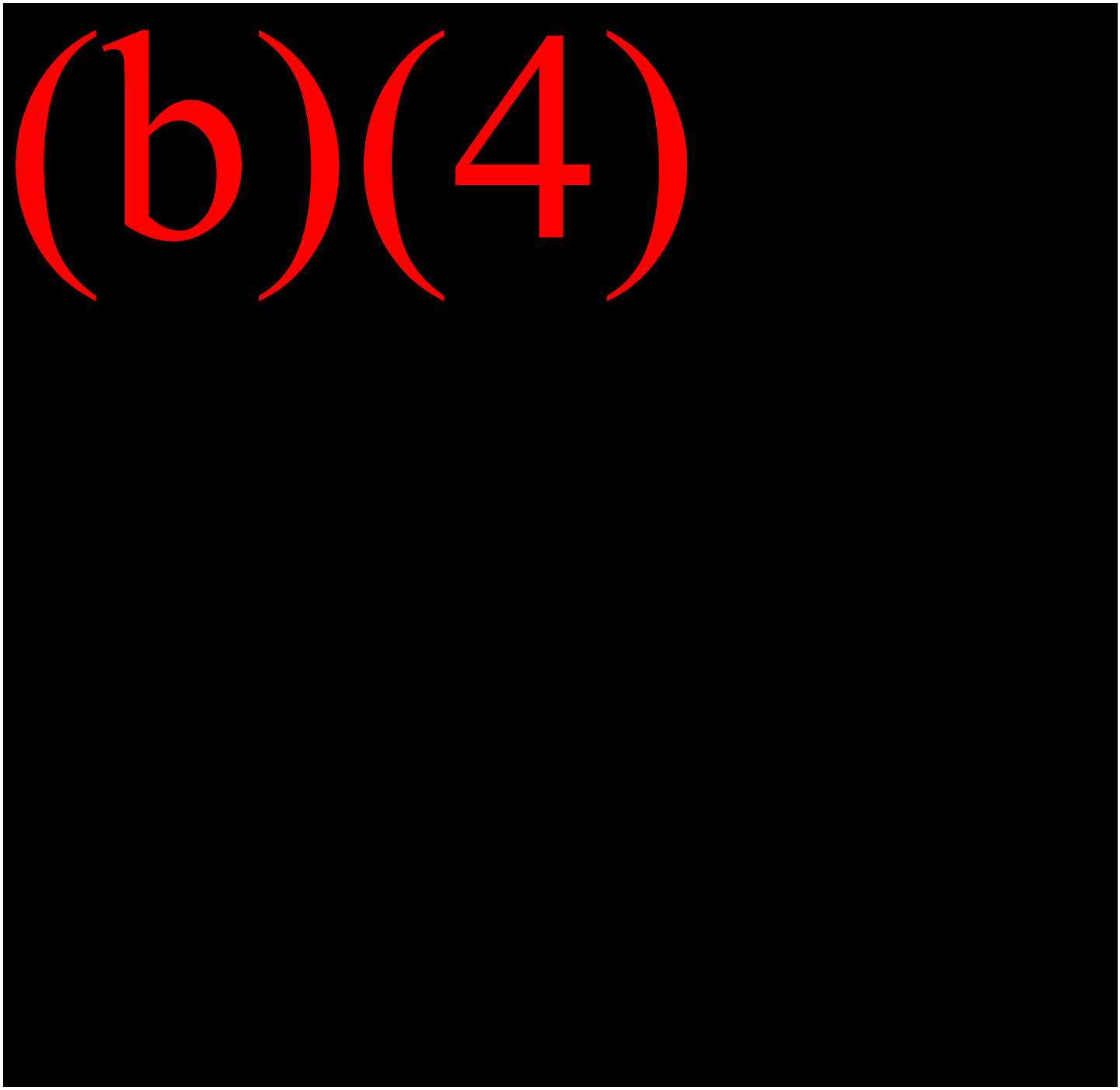
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Test Report Number (b)(4)



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Software, Volume 1
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(b)(4) Software Configuration Management and Development Environment Description
(b)(4) System Software Revision Level History and Unresolved Anomalies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Coramed Technologies CORA® System 510(k)
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Software Verification Traceability Matrix
Software Development Environment Description
(b)(4) Software Test Protocol and Test Cases
(b)(4) Software Verification and Validation Plan
(b)(4) Test Report

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 17: Electromagnetic Compatibility and Electrical Safety

Electromagnetic Compatibility

The CORA instrument was tested for Electromagnetic Compatibility (EMC), encompassing both emissions (interference with electronic products) and immunity (interference with device performance created by emissions from other electronic products).

Testing was performed according to IEC60601-1-2:2007 Ed 3: Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests. The Certificate of Compliance is attached (EMC Technologies Report No. M120908-2).

Because the CORA instrument is an IVD device, testing was also performed according to EN61326-1:2006 (IEC 61326-1:2005 Ed 1) Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements. Part 1: General Requirements. The Certificate of Compliance is attached (EMC Technologies Report No. M120908-1).

Electrical Safety

The CORA instrument does not have electrically power components that are patient-contacting, so electrical safety testing was performed for compliance with the following standards relating to Safety Requirements for Electrical Equipment For Measurement, Control, and Laboratory Use:

- UL 61010-1 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements - Edition 2 - Revision Date 2008-10-28
- CSA C22.2 NO. 61010-1 – Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use. Pt. 1, General Requirements - Edition 2 - Revision Date 2008-10-01
- IEC61010-1 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use. Pt. 1, General Requirements - Edition 2 - Revision Date 2003-04-01
- IEC61010-2-010 : Particular requirements for laboratory equipment for the heating of materials, Second Edition, 2003-06
- IEC 61010-2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment, First Edition, 2002-01
- IEC 61010-2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes, Edition 1.1 2009-08

The following documents relating to Electrical Safety testing are attached:

- UL Certificate of Compliance No. 20130205-E359802
- UL Test Report and Procedure E359802-A1-UL
- CB Test Certificate US-20815-UL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)Third Party Test Data

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Section 19: Performance Testing - Animal

This section does not apply to the CORA System 510(k) because performance testing was not performed on animals.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 20: Performance Testing - Clinical

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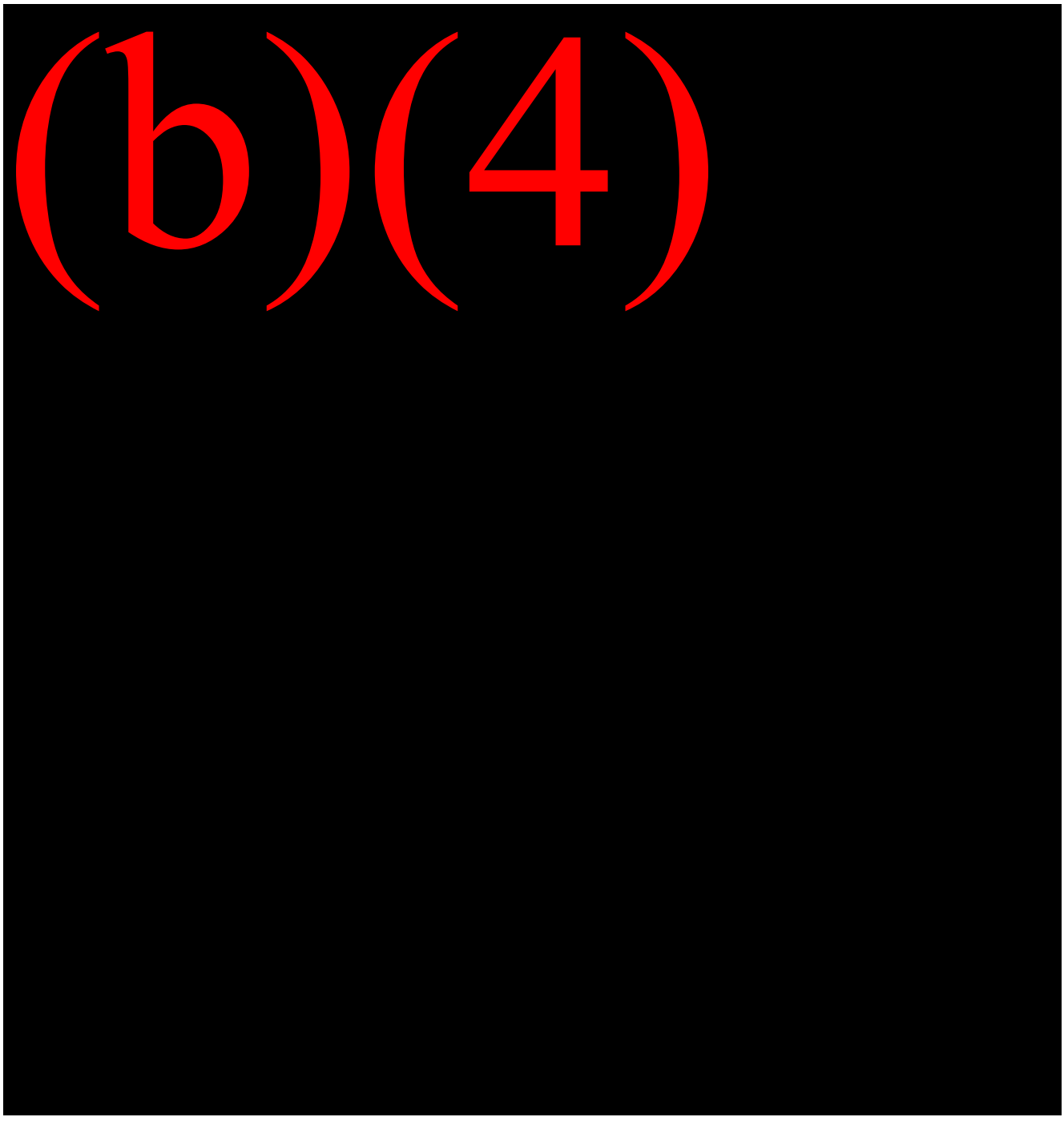
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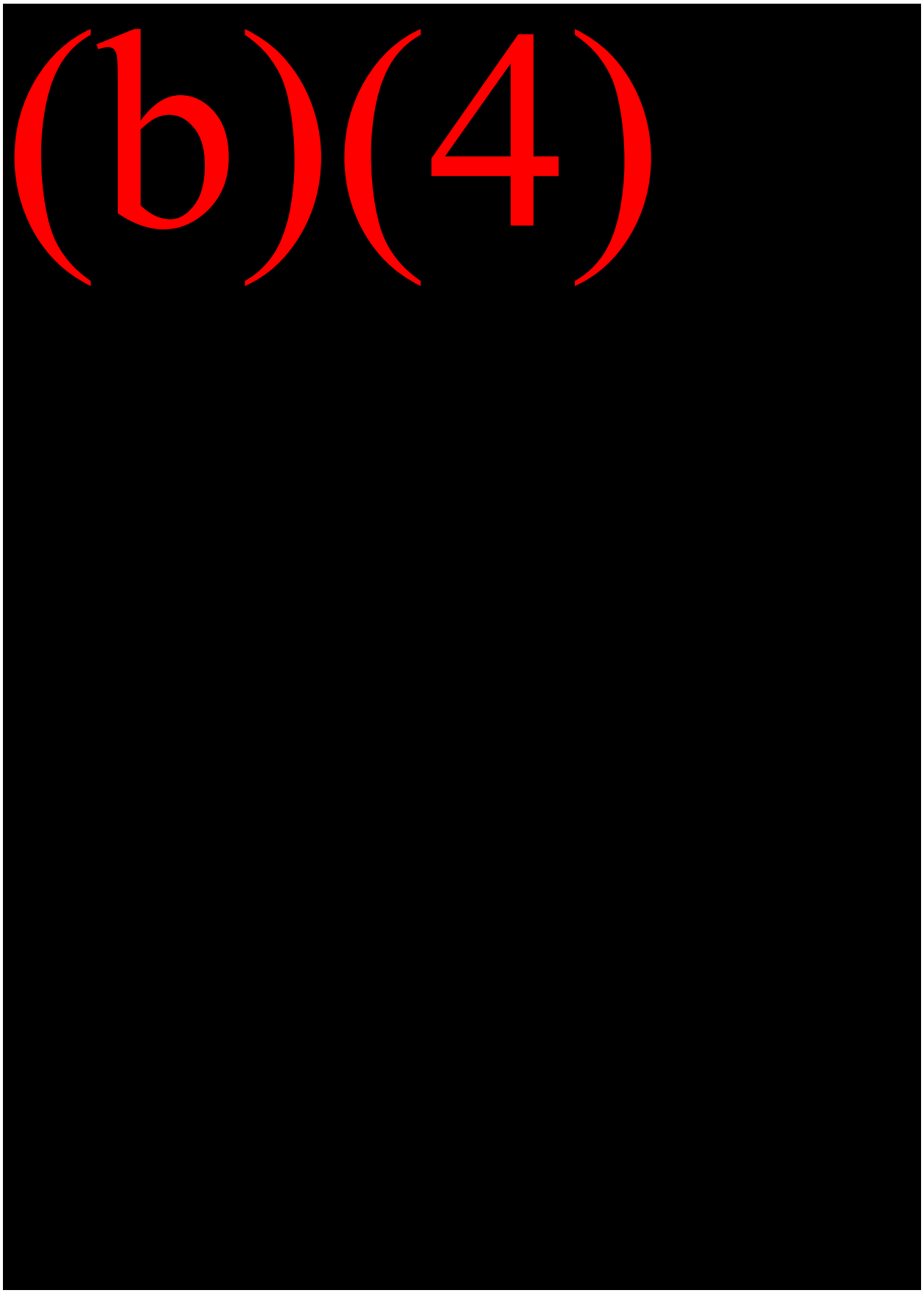
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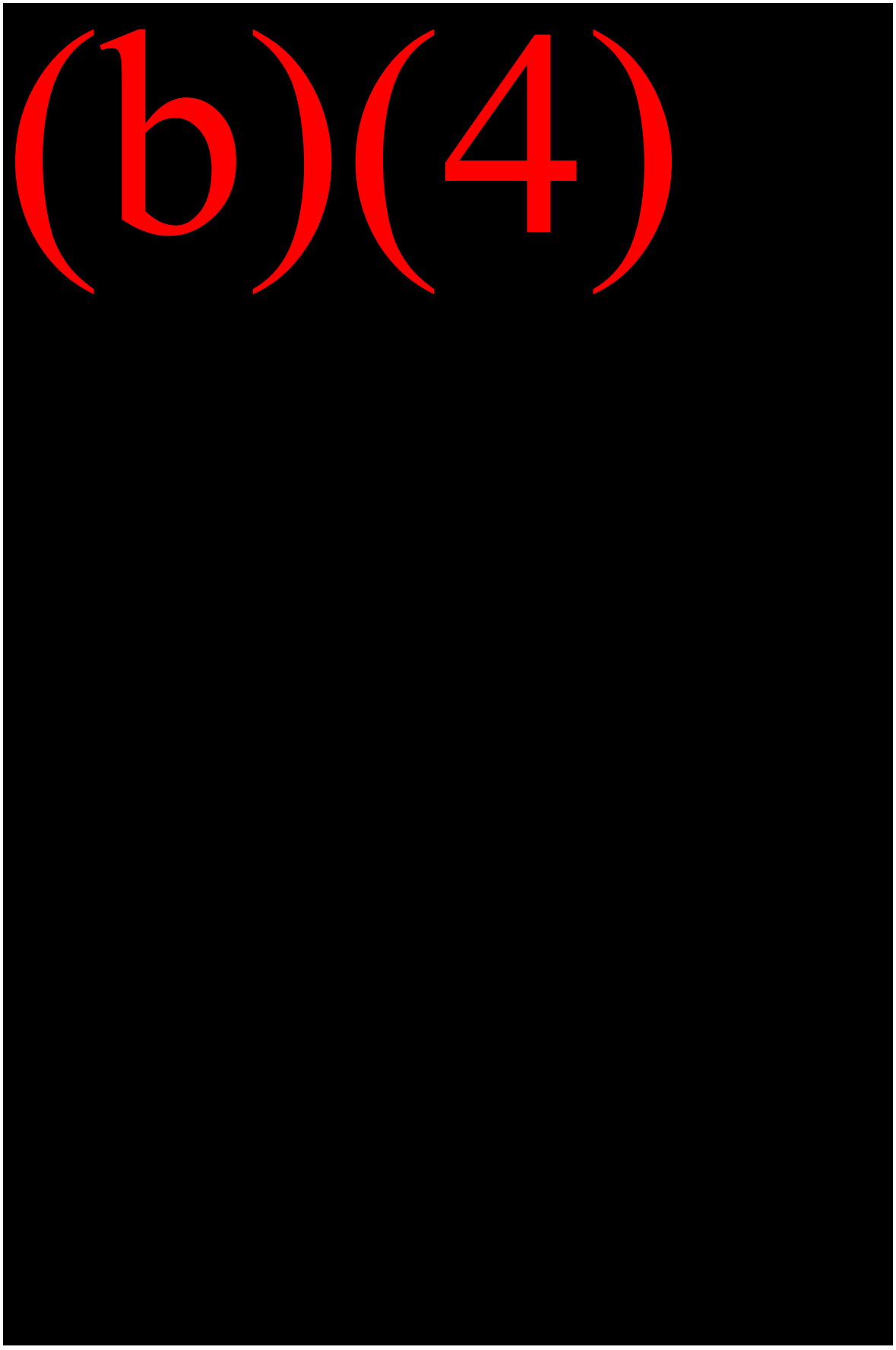
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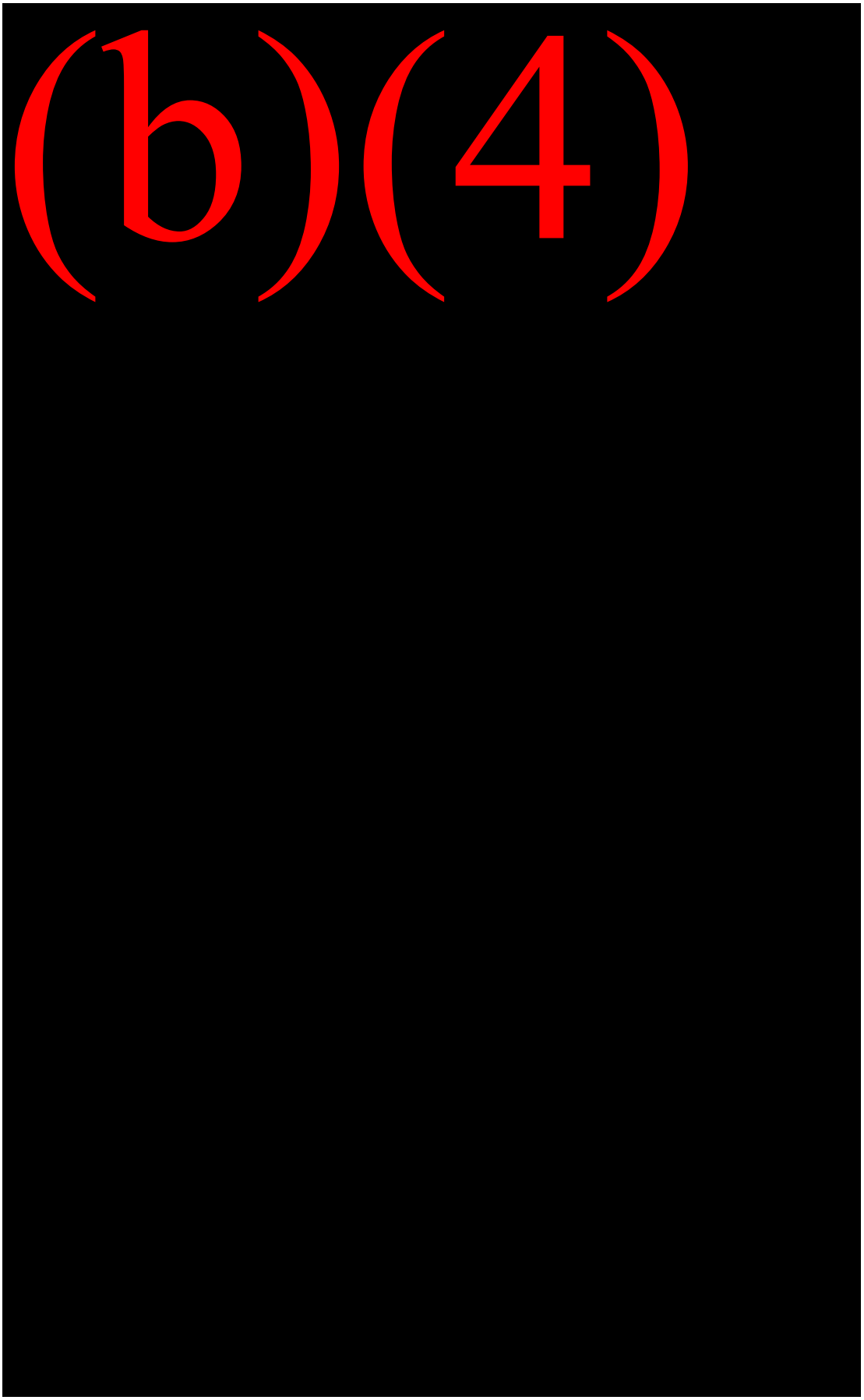
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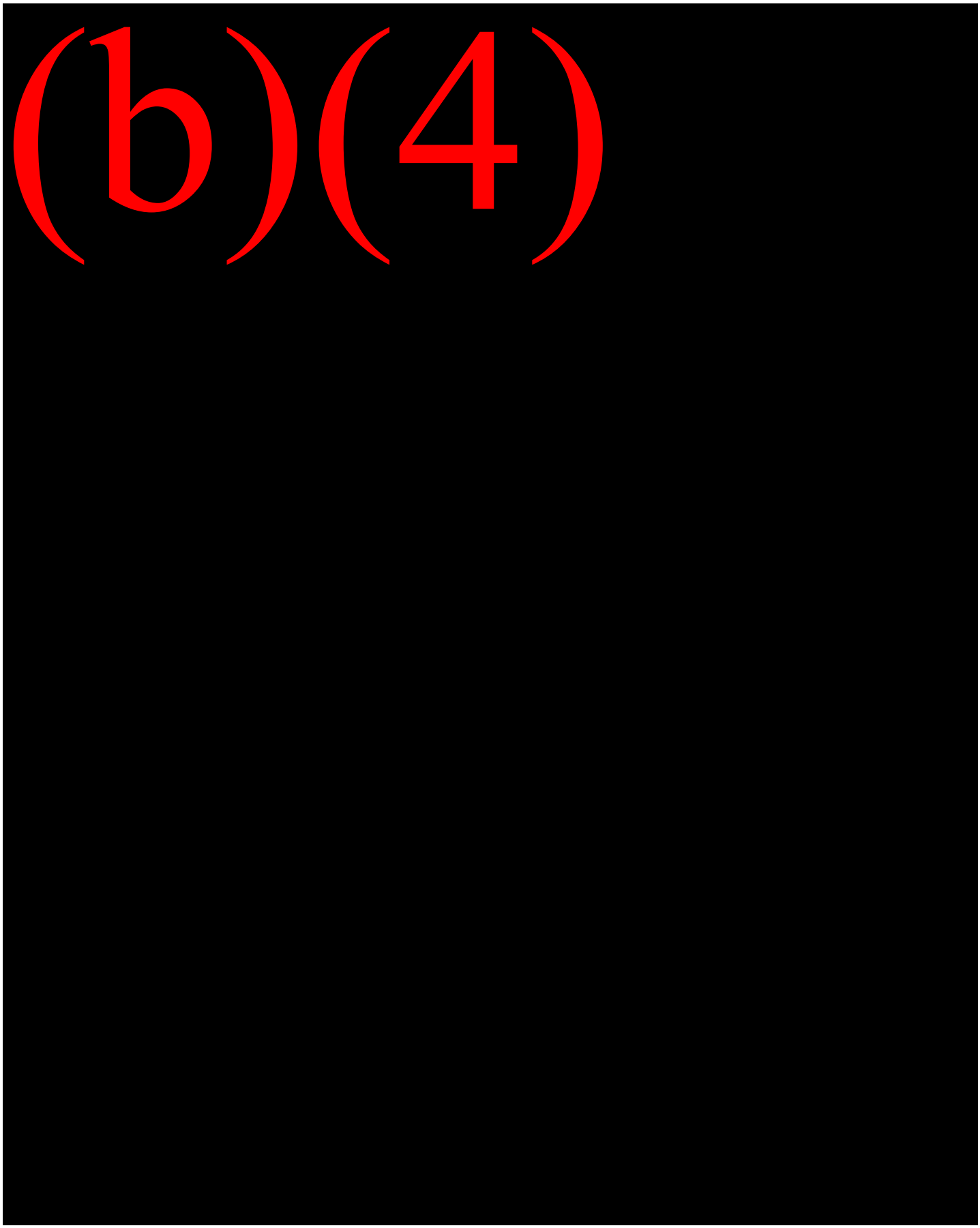
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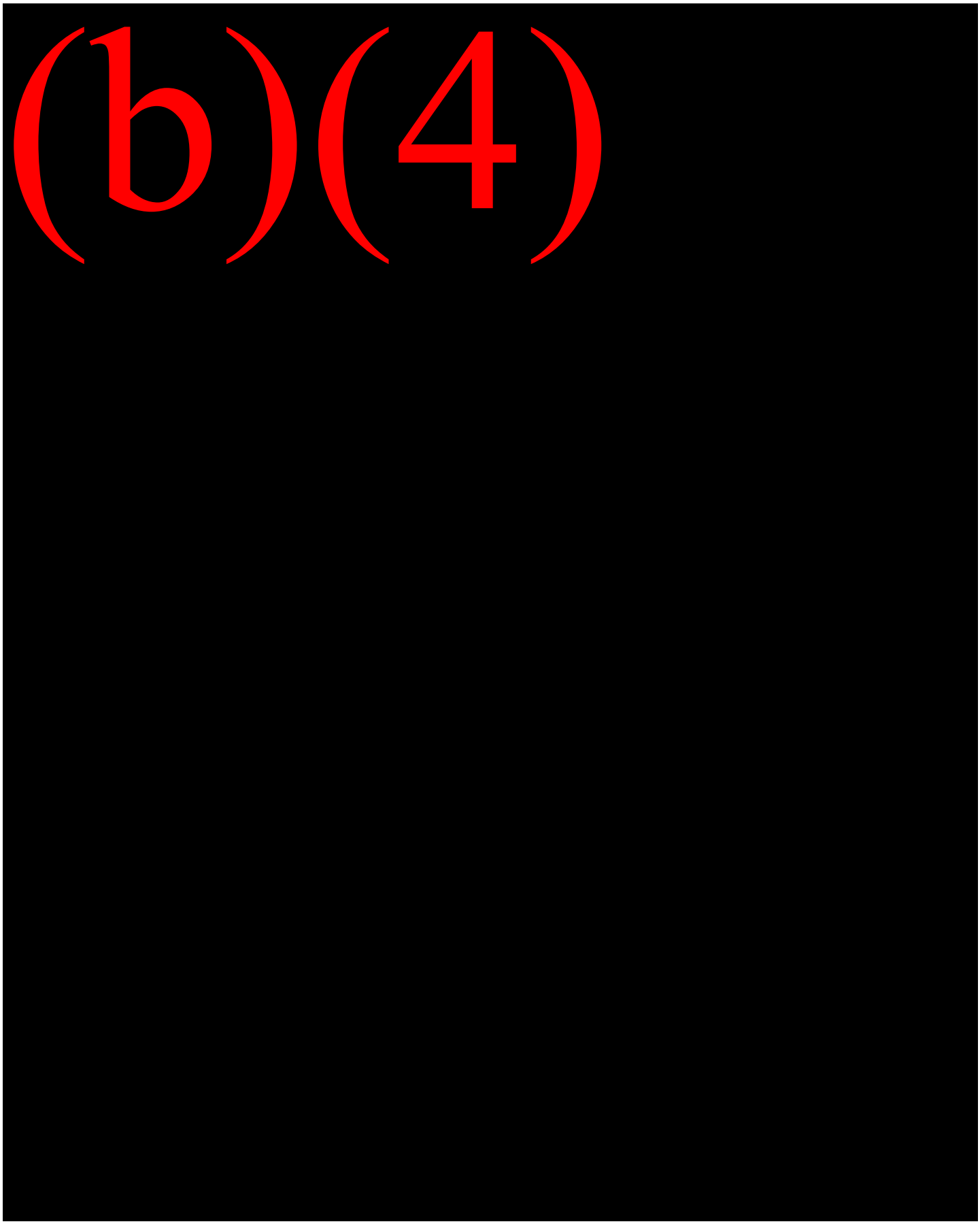
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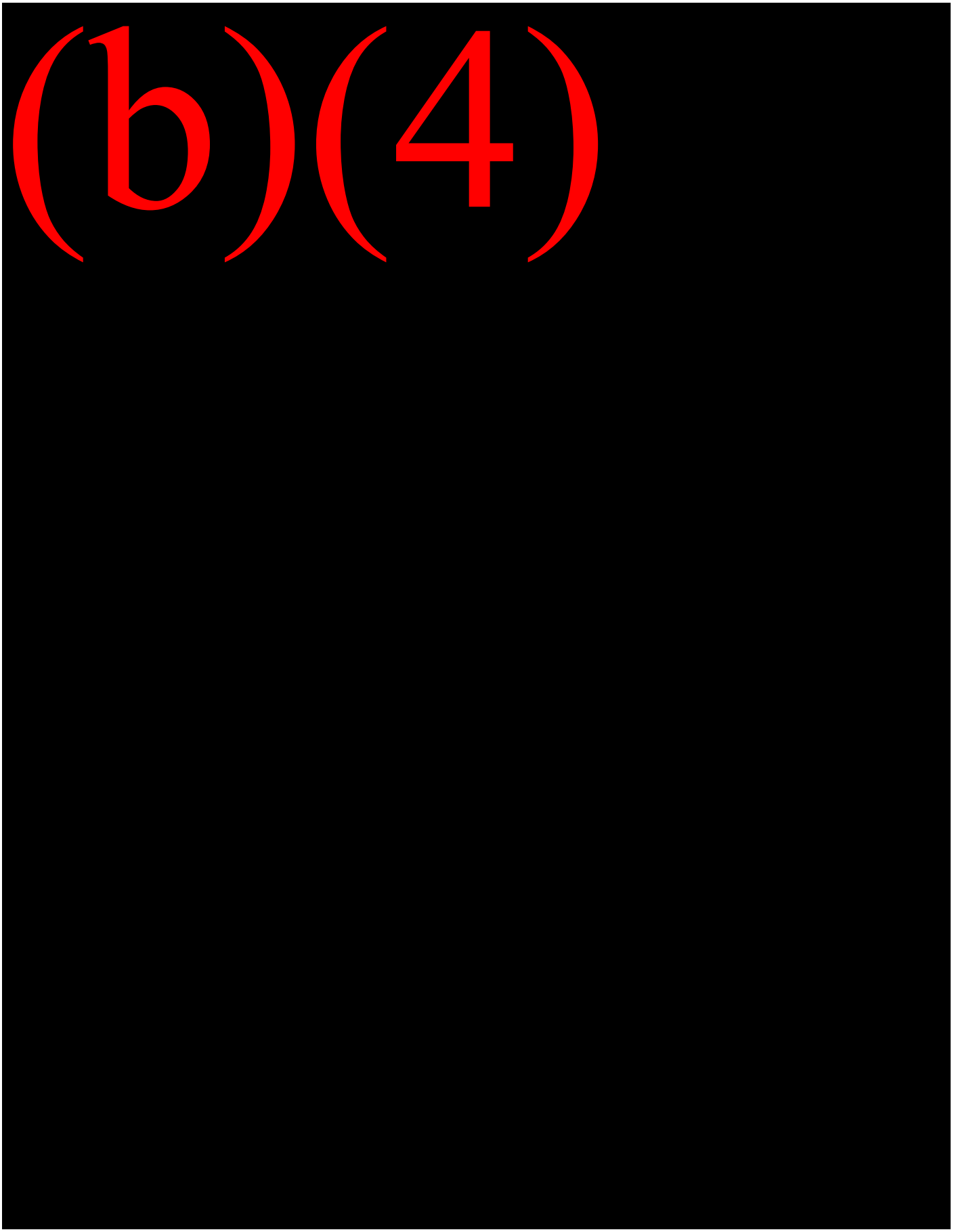
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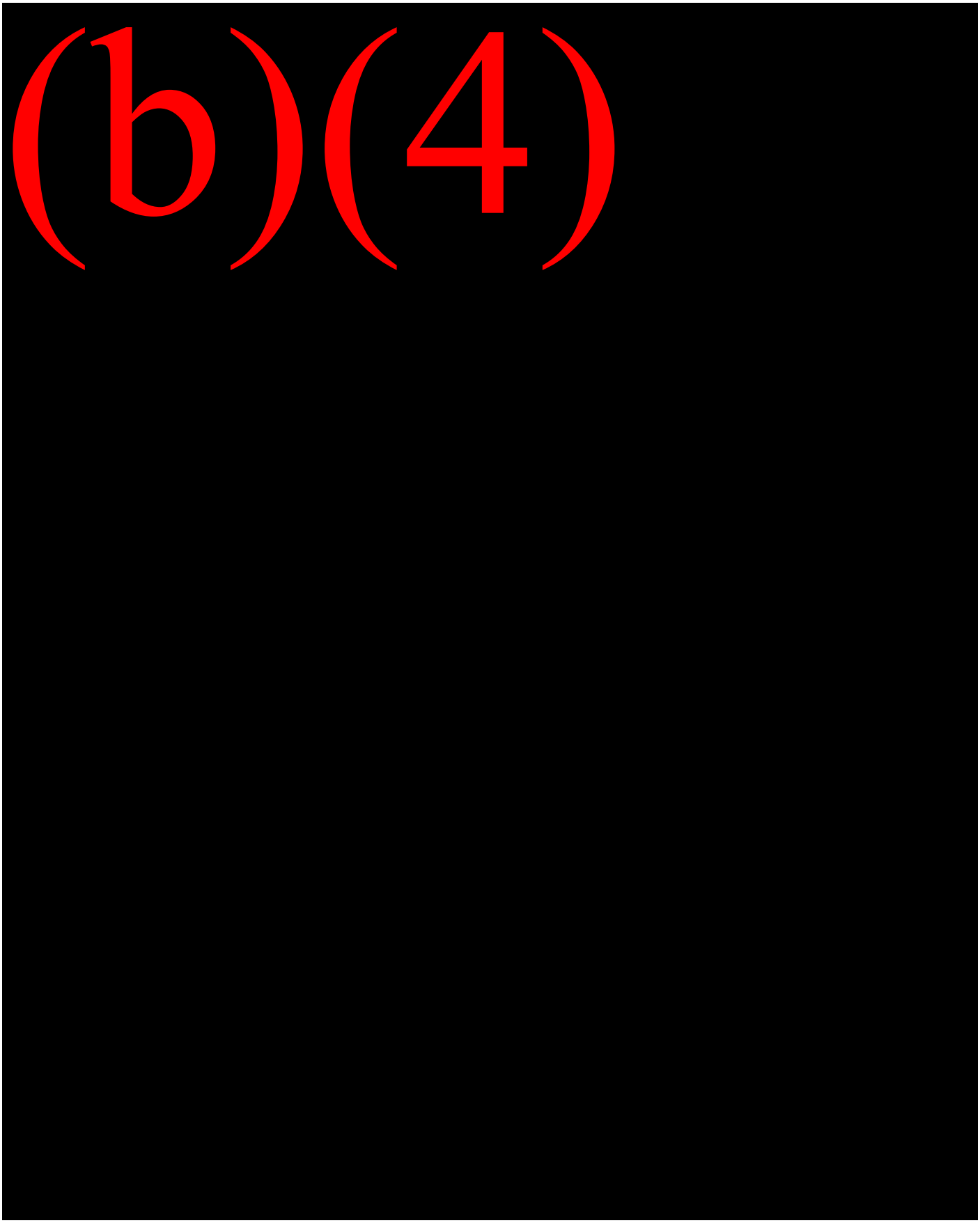
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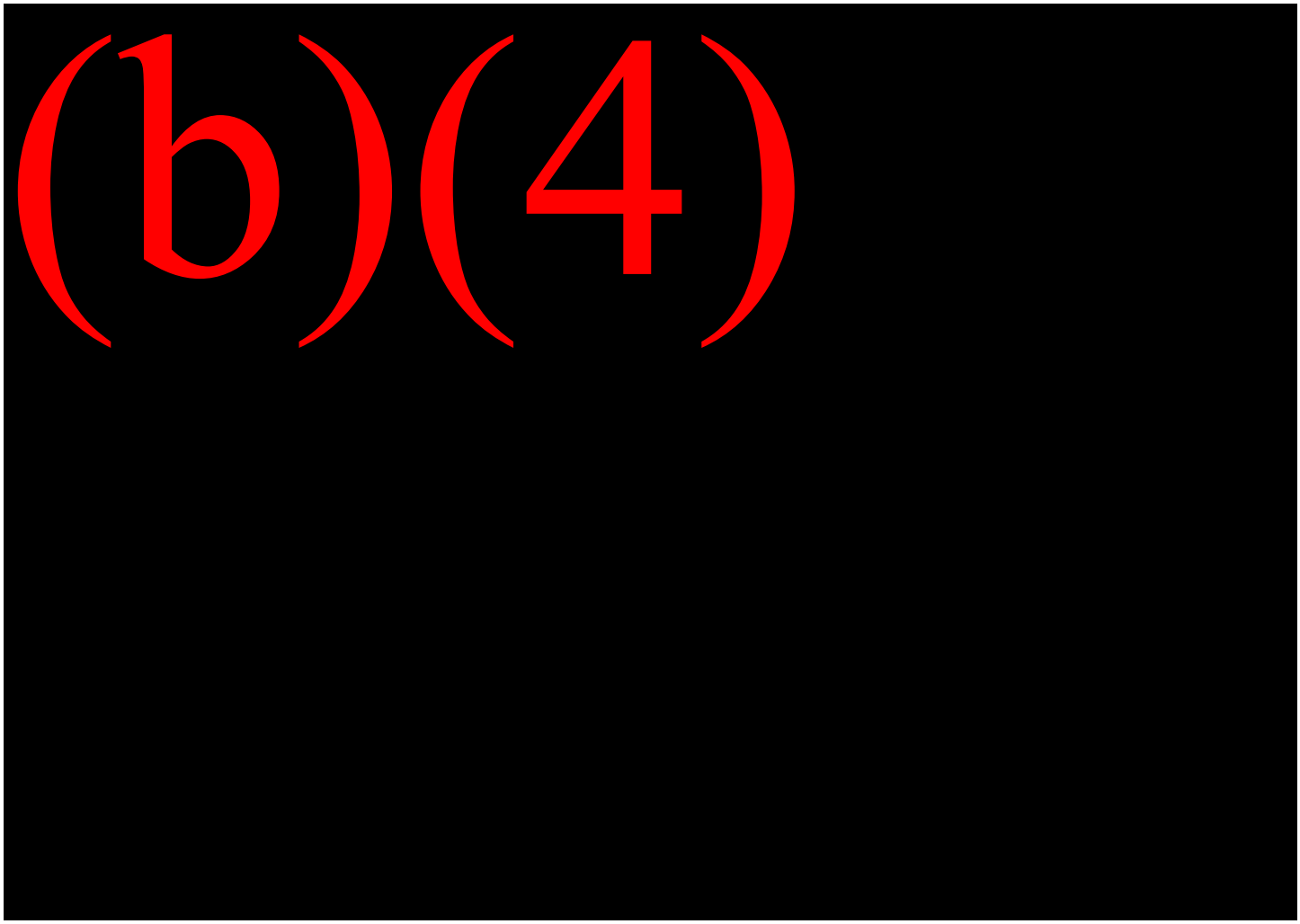
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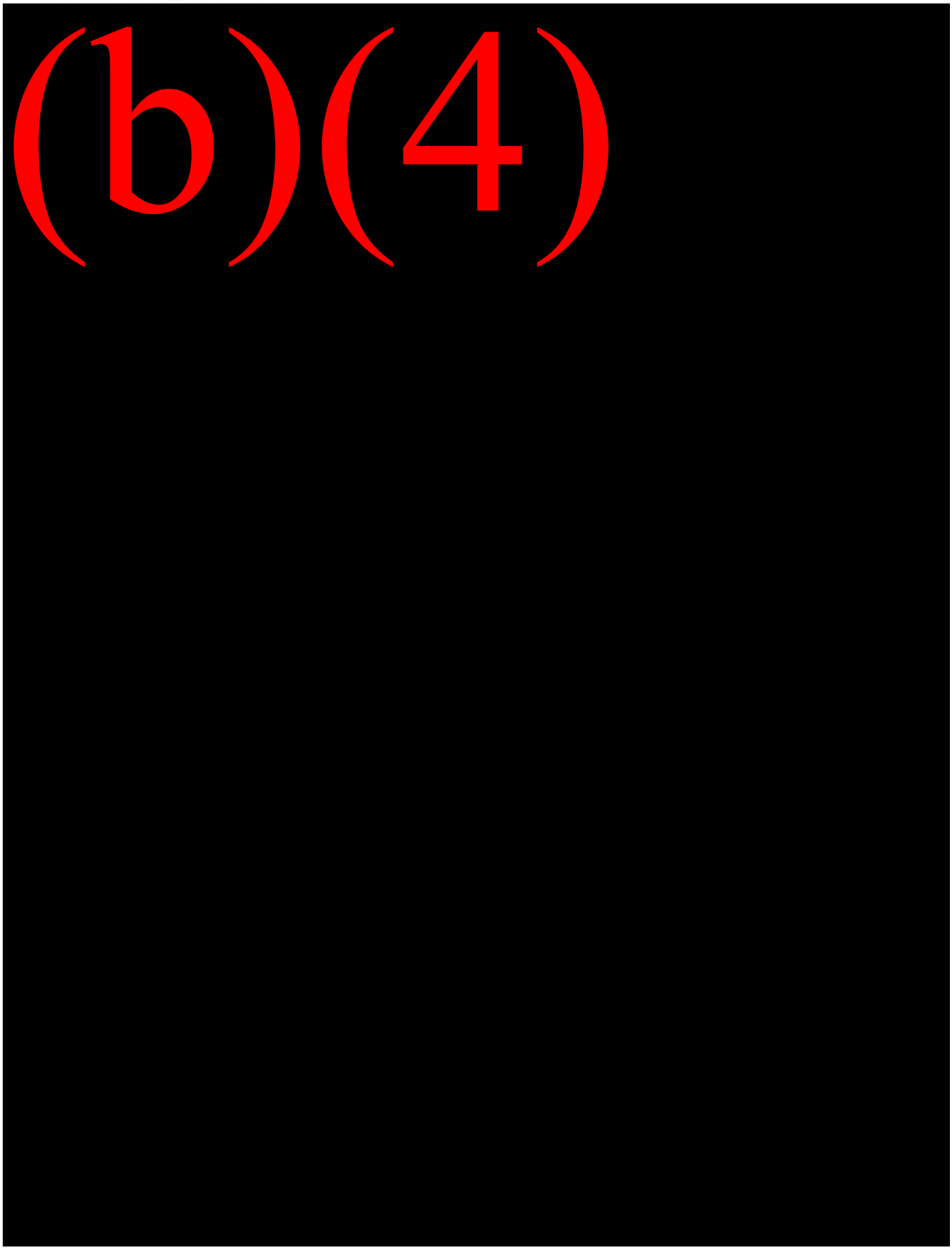
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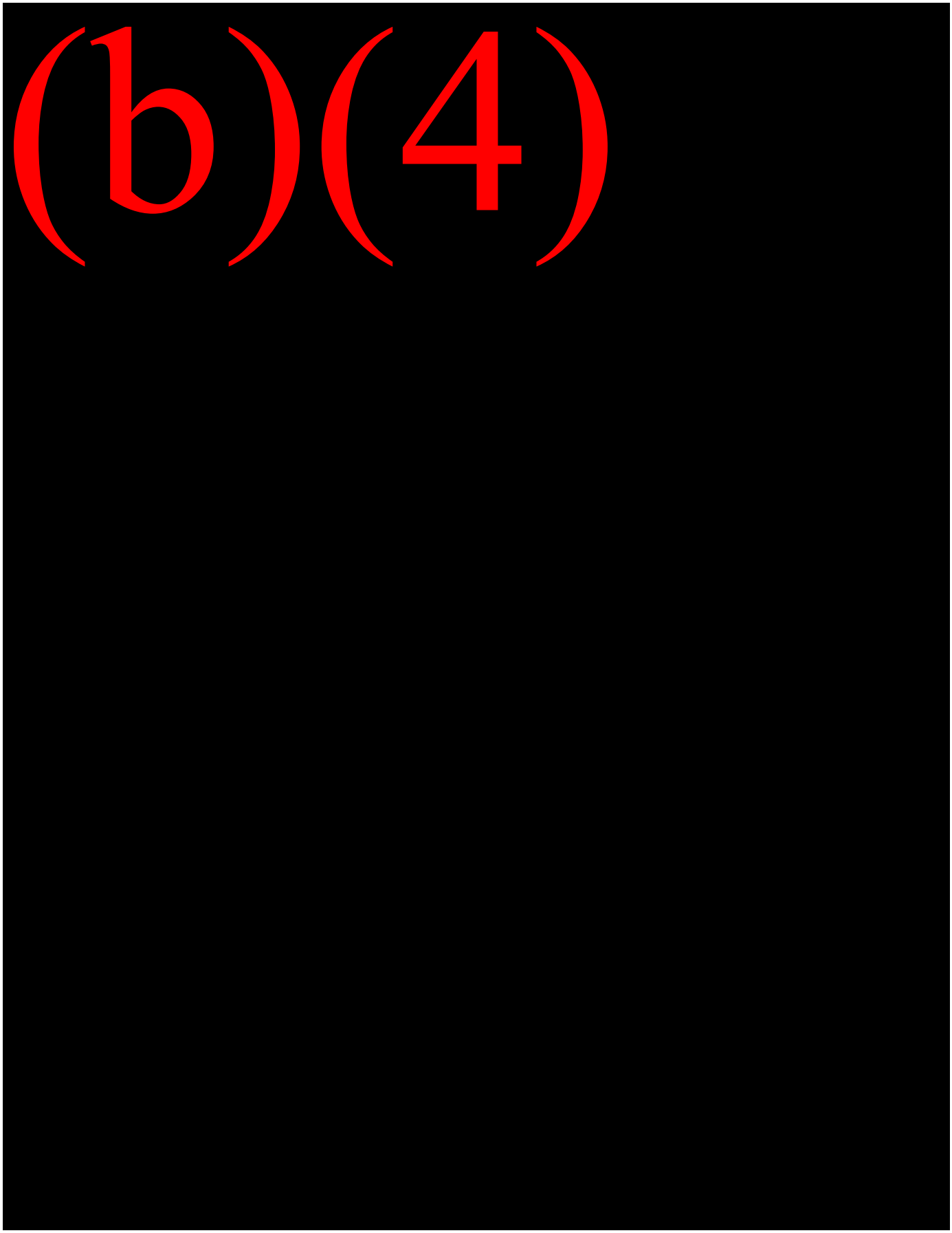
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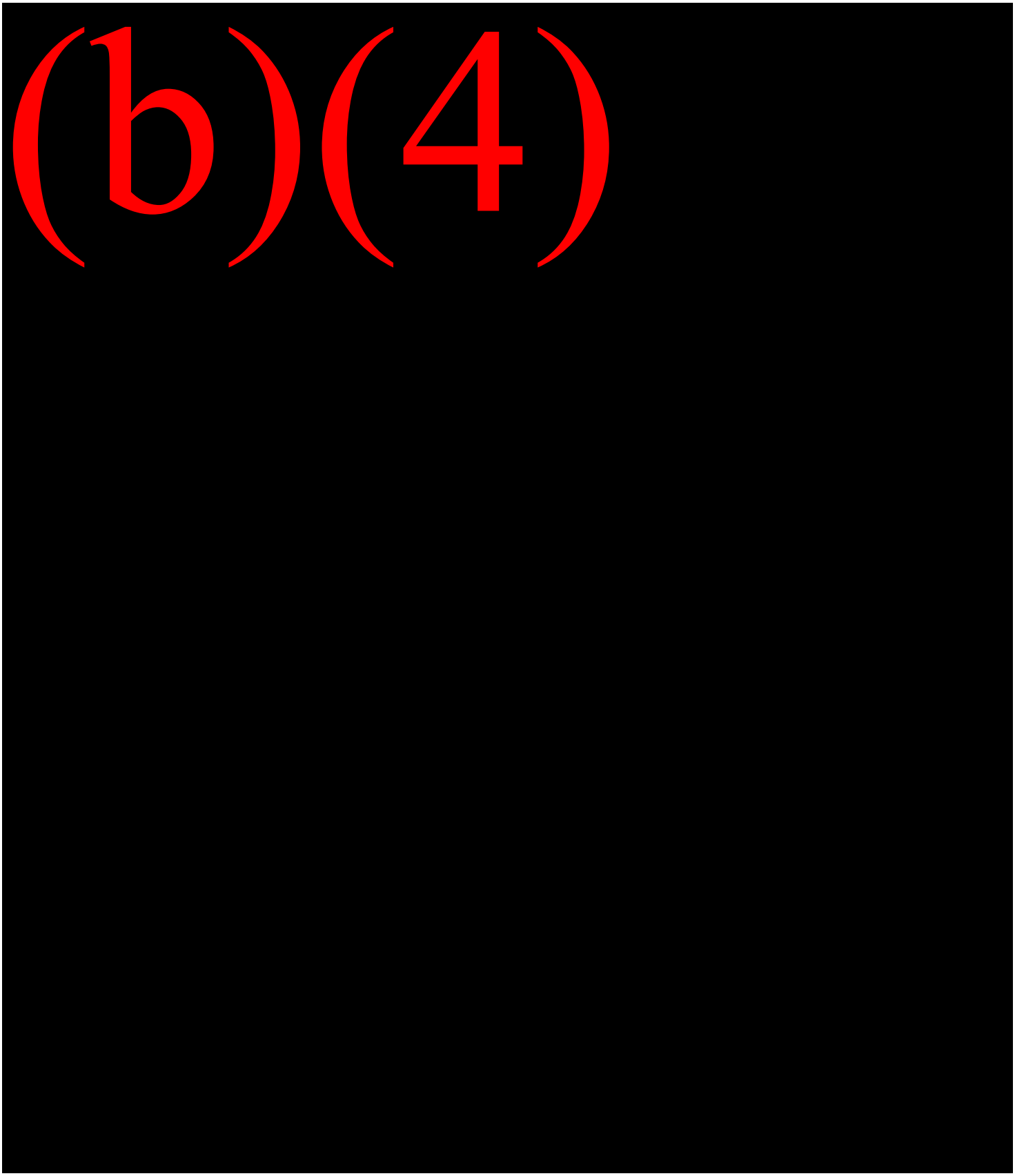
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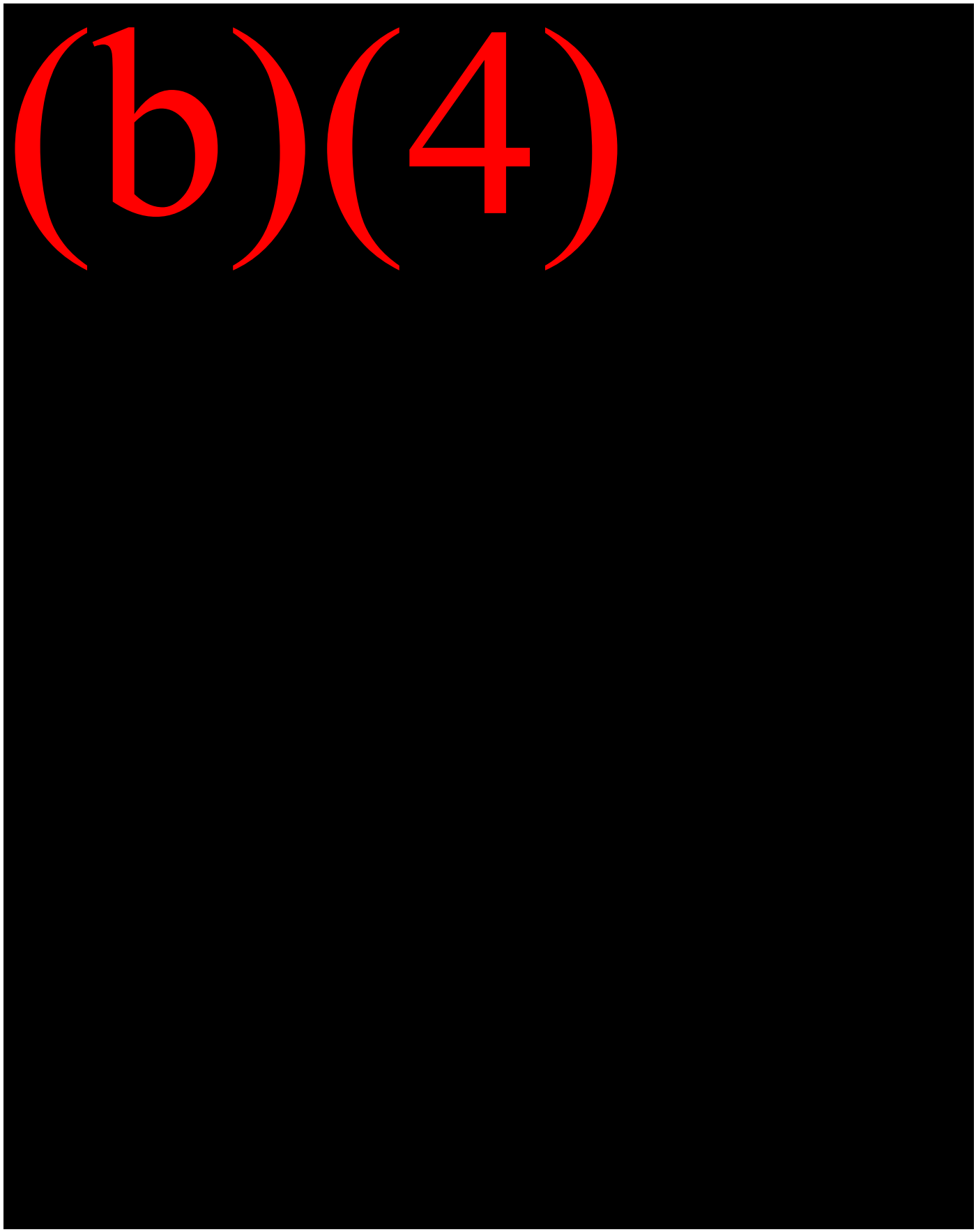
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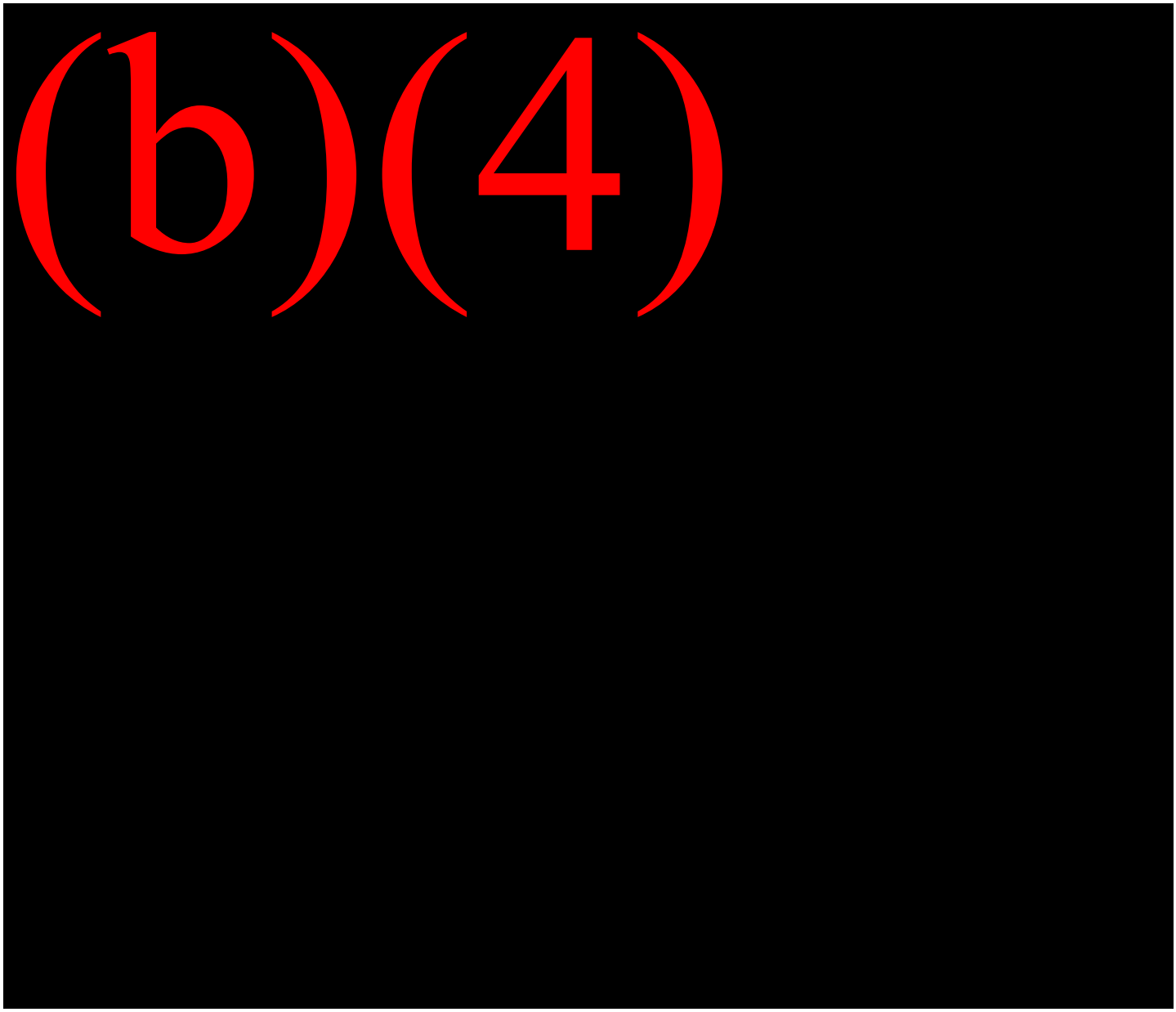
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Section 21: Other

There are no documents in this section. All information and data are presented in Sections 1 – 20.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Coramed Technologies, LLC
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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 21, 2015

RE: 510(k) #K150041 Amendment: Response to Hold Letter

The enclosed documentation and eCopy (on CD) is being submitted as an amendment to 510(k) #K150041 for Coramed's CORA® System. The eCopy is an exact duplicate of the paper copy, except that data line listings and statistical data were only provided in the eCopy "Statistical Data" folder. This cover letter provides references connecting appropriate sections of the paper copy back to the Statistical Data folder in the eCopy for information supporting those sections.

This amendment is in response to the FDA's letter of February 27, 2015 ("Hold Letter") requesting additional information. The format of this cover letter follows the content and structure of the Hold Letter.

1. Intended Use and Indications for Use – CORA Hemostasis System
   a. User's Manual and analyzer label updated as requested.
   b. Intended Use and Indications for Use updated for use of venous blood source.
   c. Intended Use and Indications for Use updated for use of 3.2% Citrated blood.
2. Intended Use and Indications for Use – Citrated Multichannel Cartridge
   a. An explanation has been added to the CRT paragraph of the Indications for Use to clarify that the CRT MA parameter is compared to the TEG 5000 Kaolin MA parameter.
   b. User's Manual and analyzer label updated as requested.
   c. Intended Use and Indications for Use updated for use of venous blood source.
   d. Intended Use and Indications for Use updated for use of 3.2% Citrated blood.
   e. Requested information is already included – no change is necessary.
3. Intended Use and Indications for Use – Abnormal Quality Control Material
   a. User's Manual and analyzer label updated as requested.
4. Claim for Citrated RapidTEG (CRT) Assay MA Parameter
   FDA has agreed that this section of the Hold Letter does not apply, but clarifications have been added to the Indications for Use for the CM cartridge, as well as section 5 (510(k) Summary) and section 20 (Clinical Testing) of the 510(k). Also, as requested by FDA in the

(b)(4) [redacted]

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Reader Study Protocol have been included. These documents provide details regarding the CORA System CRT MA parameter comparison to the TEG 5000 CK MA parameter (slides 37 & 38 of the training document, and page 5 of the protocol document).

5. Cleaning and Disinfection, Validation and Robustness Testing
   a. In an email on 3/17/2015, FDA clarified that performing cleaning, disinfection and robustness testing is not required, but requested that specific wording and additional instructions be added to user documentation. The requested wording and instructions have been added to the User's Manual.
   b. User instructions to switch gloves after completion of testing have been added to the User Manual and the Citrated Multichannel Cartridge Product Insert.
6. Precision Study for the Assay Reagents
   As agreed with FDA and confirmed in an email on 4/28/2015, additional precision studies were performed in accordance with the revised "Citrated Reagent Precision Protocol" document. This document, previously submitted to FDA as part of Q150295/S002, is included in this AI Response Package. Also, test results for testing performed under this (b)(4)
   Precision information in the Citrated Multichannel Product Insert, 510(k) Section 18 (Bench Testing), and the 510(k) Summary have been updated accordingly.
7. Method Comparison Study
   a. Section 20 (Clinical Testing) of the 510(k) has been updated to specify 3.2% sodium citrated blood samples.
   b. Only 3.2% sodium citrated samples were used in the clinical testing.
8. CKH Heparin Neutralization Protocol
   a. The CKH Heparin Neutralization protocol has been modified to include baseline tests (CKH samples without spiking and CK samples with spiking), and testing was performed using the revised protocol. The revised protocol and test results are included in this AI Response package.
9. CFF Linearity Study
   As agreed with FDA in the 3/31/2015 teleconference meeting minutes, Functional Fibrinogen linearity testing was performed using a revised protocol. A copy of this protocol and linearity test results are included in this AI Response Package. The Citrated Multichannel Product Insert and 510(k) Section 18 (Bench Testing) CFF Linearity documentation has been updated accordingly.
10. Labeling
    a. User's Manual and analyzer label updated as requested.
    b. Citrated Multichannel Cartridge Product Insert updated as requested.
    c. CORA System SMS User Guide updated as requested.
    d. The Hold Letter requested clarification of what constitutes a "normal" donor. Also requested were end user instructions in device labeling on the inclusion and exclusion criteria for selecting and establishing "normal" donors. In the previous F140421 submission evaluation, FDA accepted the use of the Abnormal WQC material to represent an abnormal sample. The example proposed by FDA in the cover letter instead mentions the establishment of a "known abnormal quality control using blood drawn from adults with platelet dysfunction (e.g. due to antiplatelet therapy)". As previously discussed with FDA, antiplatelet drugs will not change the MA of any of the citrated channels because the citrated blood samples contain thrombin, which will keep the MA at the same level even in

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the presence of antiplatelet therapy drugs. Also, in the normal population, only approximately 2-3% of donors would be expected to have naturally-occurring abnormally low MA, making it very difficult for laboratories to identify and use abnormal donor blood samples. Coramed's response to Section 10 (d) of the Hold Letter uses the FDA suggested example, modified for the use of Abnormal WQC material and removal of platelet function as a related element. These instructions are included in the revised Citrated Multichannel Product Insert and the CORA System User's Manual.

11. Real-Time/Accelerated (Shelf Life) and In-Use Stability Studies
    a. For Coramed's internal records, the Stability Study will be re-run using in-process production Citrated Multichannel cartridges to confirm and verify the stability data previously submitted to FDA for custom manufactured cartridges.
12. Reader Study
    a. The Reader Study report has been revised to include 95% Confidence Intervals (CI) for Average Positive Agreement (APA) and Average Negative Agreement (ANA). This report is included in this AI Response package.

Sincerely,



Norman E. Brunner
Director of RA/QA
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(847) 647-8800 ext. 16

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Coramed Technologies CORA® System 510(k) K150041 Amendment

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5. Updated Citrated Multichannel Product Insert
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7. Updated Bench Testing (Section 18 of 510(k))
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    c. Reader Study Test Report (revised to include 95% Confidence Intervals)
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    a. CKH Heparin Neutralization Protocol
    b. CKH Heparin Neutralization Test Report
12. CFF Linearity Documentation
    a. CFF Linearity Protocol
    b. CFF Linearity Test Report
13. Updated SMS User Guide

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Coramed Technologies, LLC
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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 21, 2015

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*
K150041

Device Name
CORA Hemostasis System

Indications for Use *(Describe)*
The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The CORA System records the kinetic changes in a venous sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*
K150041

Device Name
CORA Citrated Multichannel Cartridge

Indications for Use *(Describe)*
The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The Citrated Multichannel Cartridge, to be used with the CORA System instrument, contains four independent assays (CK, CRT, CKH and CFF), described below.

The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).
The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.
The CKH assay monitors the effects of heparin in 3.2% citrated whole blood specimens on the CORA System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests.
The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

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Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

Analyzer Label on back of unit



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017

CORA

CORA® System
USER'S MANUAL

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I: ABOUT THE CORA SYSTEM

PROPRIETARY NAME AND ESTABLISHED NAME

Proprietary Name: CORA® (Coagulation Resonance Analysis) System and the following citrated assays and reagents

CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent
Abnormal WQC material to be used for QC testing of citrated reagents

Established Name: Whole Blood Hemostasis System

INTENDED USE / INDICATIONS FOR USE

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The CORA System records the kinetic changes in a venous sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

USE OR FUNCTION

The CORA system consists of an analyzer and disposable cartridges. The following sections describe the use and function of these.

Analyzer Overview

The analyzer contains a user-friendly interface in the form of a color touch-enabled display. Through this interface, the operator can control all operations of the analyzer except turning it on and off, which is accomplished by accessing a switch at the rear of the analyzer. The system is designed to accept a disposable plastic cartridge, into which a blood sample can be placed. Once a test is started, the analyzer will process the sample and report results on the touchscreen display.

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The analyzer consists of the following features:

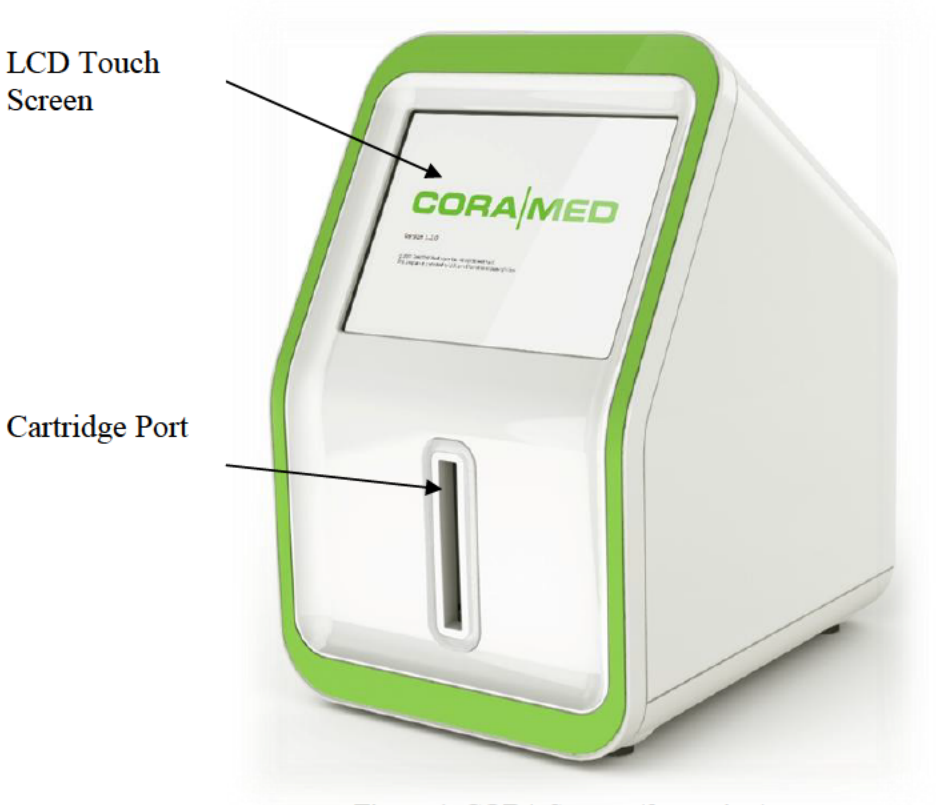


Figure 1. CORA System (front view)

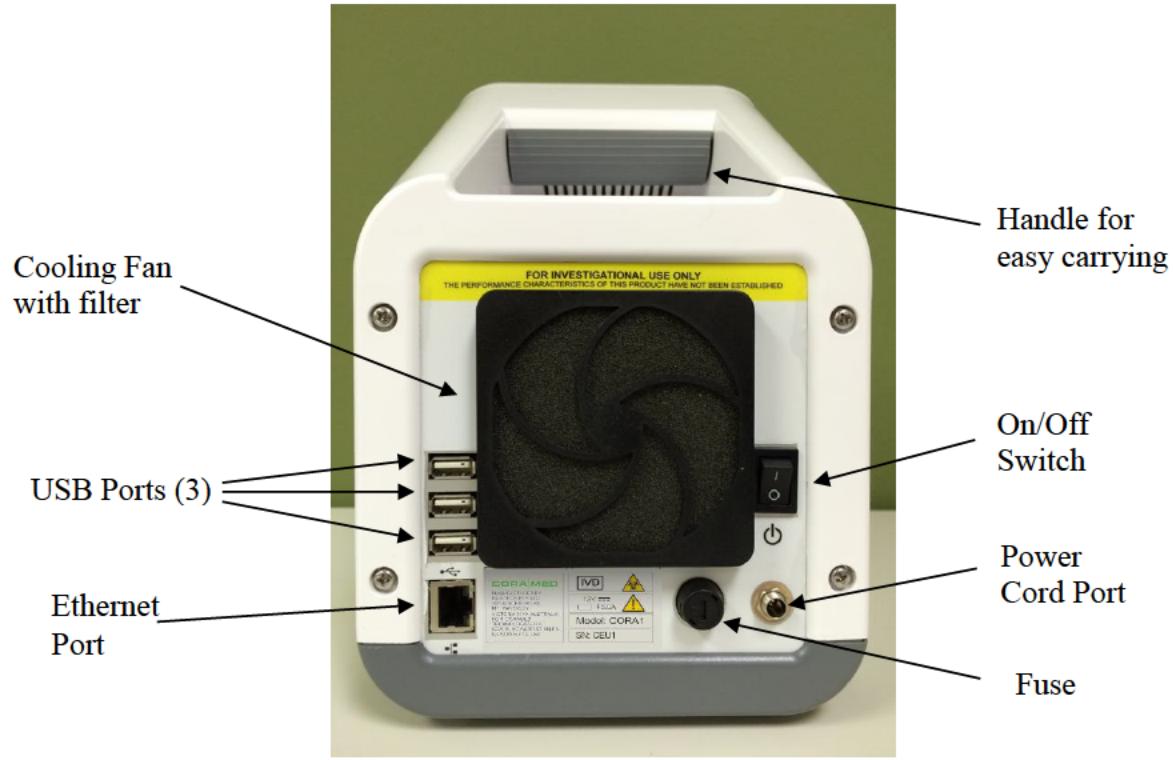


Figure 2. The CORA System (rear view)

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LCD Touch Screen: The primary user interface is a 6.5" color LCD touchscreen which displays instructions guiding the user through CORA System operations. All prompts, directions, selections, and results are displayed on this screen.

Power Input: The CORA system must be connected to a standard power outlet (100 – 240 volt 50/60 Hz) in order to function properly. Power cords appropriate for connection to local AC power mains are provided by Coramed or through distribution channels.

Ethernet Port: The device may be connected via Ethernet to a stand-alone computer (using a cross-over cable) or to an Ethernet switch or router for service, maintenance and setup, and for uploading patient data if desired. All communication through this port is encrypted.

Cooling Fan: A fan in the analyzer ensures that the internal temperature of the analyzer remains close to the ambient temperature. This allows the widest possible range of sample temperatures to be selected without requiring active cooling in the analyzer.

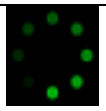
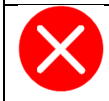
Carrying Handle: The CORA system has an integrated ergonomic carrying handle.

On/Off Switch: The power switch is located in the rear of the device, "I" indicates "on" and "O" indicates "off".

Cartridge Port: The cartridge port at the front of the analyzer accepts Coramed assay cartridges. Each cartridge contains all of the components necessary to allow the analyzer to prepare samples and perform hemostasis tests. During a test, the cartridge is locked in place. Both the unit and the cartridge are designed to prevent incorrect use.

Icons: Table 1 lists icons the user may encounter on the CORA system, along with their definitions. Figure 3 shows the location of all the icons on the display.

Table 1: CORA System user interface icons

	**Unit is Saving Data**		**Data is being collected (progress indicator)**
	**Critical Error**		**Remote User**
	**Error**		**Warning**
	**Unit is operating in Exclusive Mode**		

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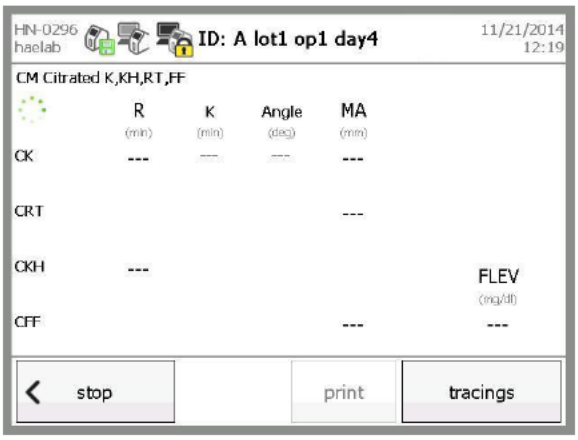


Figure 3. Locations of icons in the user interface

Icons in the top left corner of the screen indicate analyzer status (saving, locked, remote user). There is an icon below these for a progress indicator. When necessary, errors, critical errors and warnings are displayed in their own window.

Cartridge Overview

CORA disposable assay cartridges have a sample port at one end. This port is designed to accept an unmetered amount of blood, delivered by transfer pipette. Under analyzer control, the cartridge will pull this sample into up to four staging areas, mix the sample with reagents that have been dried in place, and then transfer a small amount into the test cells. Any excess blood is moved to a sealed waste area within the disposable.



Figure 4. CORA System disposable assay cartridge

Results Overview

Results of tests performed by the CORA system are designed to be easily read and understood. Up to four basic parameters are calculated during a test: R, K, Alpha, and MA. The following table describes each in more detail.

Table 2: CORA parameters and their meanings

R	The amount of time between the start of the test and the beginning of coagulation.
K	The speed of formation of the clot from R time to a specific clot strength
Alpha	The speed of clot strengthening.
MA	Maximum Amplitude is the ultimate strength of the clot.

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Test results are also plotted on a continuously-updated graph to view the progress of the test. Numerical parameters are determined over the course of a test (which can have a duration of up to 90 minutes), so at any given time there may be parameters that have not yet been finalized. In this case, those parameters are shown as dashed lines until they have been determined. Unused channels and parameters inappropriate for the assay being run will remain blank. Finalized parameters outside of the expected range will be highlighted in orange and an exclamation mark will appear next to the number. A typical results page looks similar to the following:

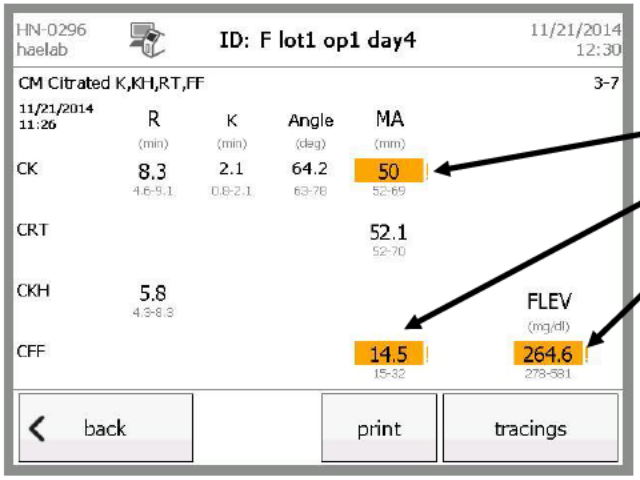


Figure 5. A typical results page for a four-channel assay. Values outside normal ranges are shown in orange with an exclamation point.

Quality Controls Overview

Wet quality control (WQC) consists of a vial with lyophilized biological material for use with the Citrated Multichannel cartridge. When a cartridge is inserted into the CORA device, it triggers a script to access the performance of the system as an Abnormal sample. WQC is described in more detail in Section V of this manual.

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SECTION II: GETTING STARTED WITH THE CORA SYSTEM

INSTALLATION PROCEDURES AND SPECIAL REQUIREMENTS

The CORA system is designed for the rigors of the hospital environment. When installing the device, try to find a location that is reasonably flat and level where the analyzer will be protected from accidental damage. Once a location has been determined, connect the unit's AC power adapter to an outlet using the supplied electrical cord. Then connect the smaller cord to the analyzer, making sure that the plug is screwed into the receptacle on the analyzer. There are no other special requirements.

PRINCIPLES OF OPERATION

Hemostasis is the physiological control of bleeding and is a complex process incorporating vasculature, platelets, coagulation factors (FI-FXIII), fibrinolytic proteins, and coagulation inhibitors. Normal hemostasis is a delicate balance between hemorrhage and thrombosis. The CORA System is an In Vitro Diagnostics (IVD) device that can be used to quantify the hemostatic function of a blood sample.

The CORA System and the Citrated Multichannel Cartridge are used to test the hemostasis properties of citrated blood samples using four different assays/reagents simultaneously, one in each of the four cartridge channels. For the CK assay, Kaolin-activated test methods are used to reduce variability and to reduce the running time of a native whole blood sample. The CRT assay maximally accelerates the clotting process by simultaneously activating the intrinsic and extrinsic coagulation pathways, allowing for the maximum clot strength to be reached more quickly. CKH is similar to CK but with the addition of heparinase, to neutralize the effects of heparin in the blood. If there is heparin present, the R time for CK will be significantly longer than the R time for CKH. The CFF assay fully inhibits all the platelets, thereby excluding their contribution to clot strength, and therefore measures only the functional fibrinogen contribution to clot strength.

PERFORMANCE CHARACTERISTICS AND SPECIFICATIONS

Analyzer Specifications

Dimensions	Width: 175mm
	Length: 257mm
	Height: 270mm
Weight	9.4 lbs (4.2 kg)
Voltage Rating	100V to 240V AC
Power Supply Output Voltage	12 volts DC

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Output Power / Current Rating	5 A, 60 W (max)
Supply Frequency	50/60 Hz
Replaceable Fuse – 5 Amp	Manufacturer: SIBA, P/N GZ179021-5A, 5mm x 20mm, Quick-Action Ceramic, UL Recognized E167295
Display	Backlit color LCD, 640x480 resolution, integrated 4-wire touch screen
Operating Temperature	10° to 32°C
Operating Pressure	0 to 2000 m above sea level
Operating Humidity	20 to 80% RH (non-condensing)
Shipping/Storage Temperature	-20° to +50°C
Shipping/Storage Humidity	20% to 80% RH (non-condensing)

Analytical Measurement Ranges

The following table gives the Analytical Measurement Ranges for the CORA System. It describes how parameter values are displayed and printed for values within the range, above the range and below the range.

Analytical Measurement Ranges (AMR)								
Reagent	Parameter	Low	High	Within AMR	Below AMR		Above AMR	
				Display & Print	Display	Print	Display	Print
CK	R (min)	0.4	17	Actual value	< 0.4 !	< 0.4 !	> 17 !	> 17 !
	K (min)	0.5	5	Actual value	< 0.5 !	< 0.5 !	> 5 !	> 5 !
	Angle (degrees)	39	83	Actual value	< 39 !	< 39 !	> 83 !	> 83 !
	MA (mm)	40	75	Actual value	< 40 !	< 40 !	> 75 !	> 75 !
CRT	MA (mm)	40	75	Actual value	< 40 !	< 40 !	> 75 !	> 75 !
CKH	R (min)	0.3	17	Actual value	< 0.3 !	< 0.3 !	> 17 !	> 17 !
CFF	MA (mm)	4	52	Actual value	< 4 !	< 4 !	> 52 !	> 52 !
	FLEV (mg/dl)	130	950	Actual value	<130 !	<130 !	> 950!	> 950!

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SECTION III: OPERATING INSTRUCTIONS

To turn on the device, move the power switch located at the lower corner of the rear of the analyzer from the "O" position to the "I" position. After a brief startup sequence, an initialization screen will appear as shown in figure 6. At this point, the device will execute a Power-On Self-Test (POST). Following a successful POST, the login screen will be presented, as shown in Figure 7. In this screen, the user can enter their username and password using the touch screen keyboard. To move from username to password, select the "return" key or touch the "password" box. When finished, pressing either the "return" key or the "login" button will complete the login.

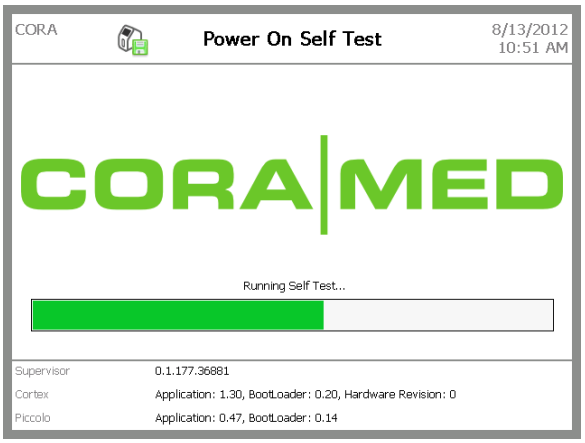


Figure 6. Initialization and POST screen



Figure 7. Login screen

Failed login attempts will result in a page similar to figure 8, requiring the user to reenter their username and password. The unit can safely be shut down from this screen by using the On/Off switch at the rear of the unit.

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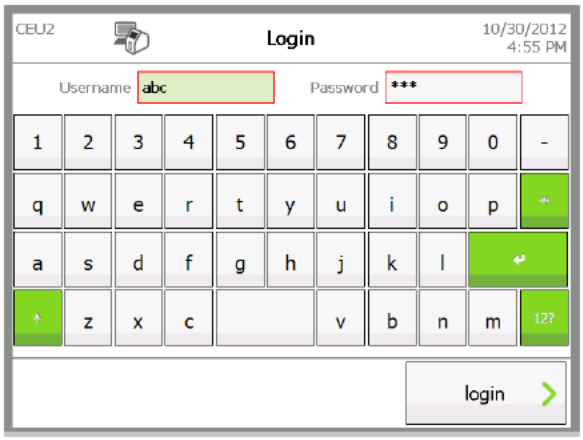


Figure 8. An incorrect login has been entered. Note the username and password fields bordered in red.

A successful login will bring up the analyzer's main menu, as shown in Figure 9.

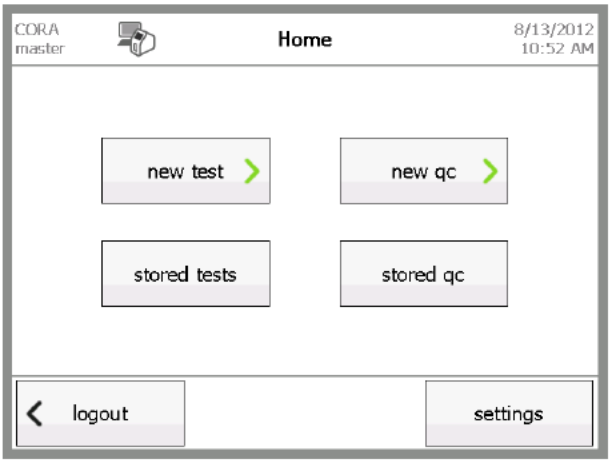


Figure 9. The main menu of the analyzer allows the operator to run new diagnostic and WQC tests or review results from earlier tests. It also provides access to analyzer settings and a method for logging out.

CORA System Operation Overview

The CORA System has been designed to be intuitive and easy to use. During all analyzer operations a button at the lower right of the screen will take the user forward to the next step of the workflow, while a button at the lower left will return to the previous step. Detailed guides for the running of assays, WQC's, and viewing results are discussed in later sections of this manual.

Settings

To change any analyzer settings from their default, select the "Settings" key from the main menu. In order to change settings, you must be logged in with Administrator credentials.

Once in the settings screen, it is possible to change the data and time along with the format used to display the date and time. To change date or time press the up or down arrow for the field you wish to change. Each press will increase or decrease the value by one. When the values are correct, press the Apply button in the bottom corner of the screen to save the changes. For the changes to take effect, the analyzer must be powered

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off and back on again. Altering the date and time has no effect on previously run tests. Always verify that the correct date and time are displayed before running new tests.

To change the date or time style, select the appropriate box and choose any of the available options from the drop-down list. An example of the currently selected date and time format is displayed to the right of the "Time Style" box.

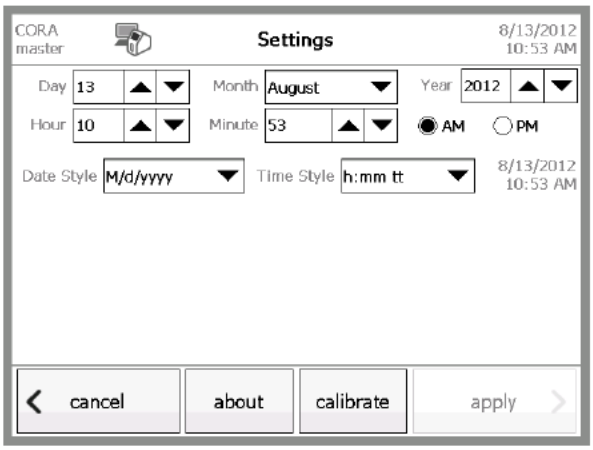


Figure 10. Settings page

To calibrate the touchscreen, select the "calibrate" button. The analyzer will prompt you to press several locations on the screen (figure 11). After completing this process, tap anywhere on the screen to move back to the settings page.

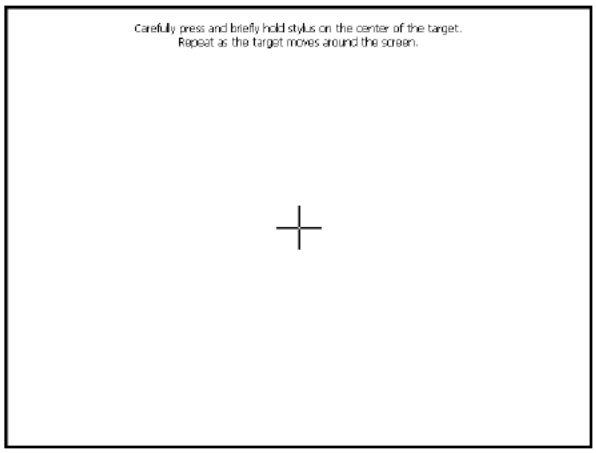


Figure 11. Calibration Screen

Information about the analyzer can be found by selecting the "about" button on the settings screen. Doing so will display a screen similar to Figure 12, where you determine which version of the analyzer software is currently installed, as well as the IP address of the analyzer. Pressing "back" will return you to the settings menu.

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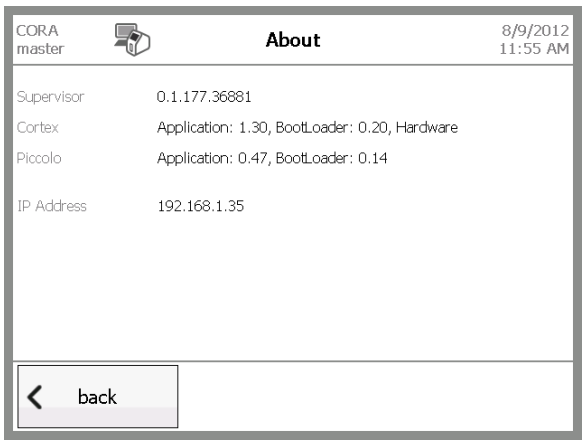


Figure 12. About Screen

Note: To save changes made to any of the settings, return to the main menu by pressing the "apply" button and cycle the analyzer power as noted above. Pressing "cancel" will discard changes and return to the main menu.

Running an Assay on the CORA system (Quick Guide)

1. From the main menu select "new test".
2. Select the patient ID you wish to use. If the patient is not listed, you may add a new patient by selecting the "+" option and entering a patient ID on the screen. Then press "next".
3. Insert the cartridge into the slot as indicated on the screen with the bar code on the left side.
4. After the cartridge pretest is completed and you have verified that the assay is what you intended to run, press "next". If the cartridge is not the desired assay, press "stop" and start over.
5. Add blood to the cartridge sample port to above the level indicated.
6. After loading the sample press "next".
7. The test will run and results will be displayed as they become available.
8. To see a graphical display of the test results thus far, press "tracings".
9. To cycle through individual channel results, press "next tracing" until the desired channel is displayed.
10. When the test is completed, the analyzer will prompt you to remove the cartridge and will return to the table of results.
11. Remove the used cartridge from the slot as shown on the LCD display.
12. Press "done" from the results screen to return to the home page.

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Performing a New Assay (Detailed Guide)

1. From the main menu select “new test,” as shown in Figure 13.

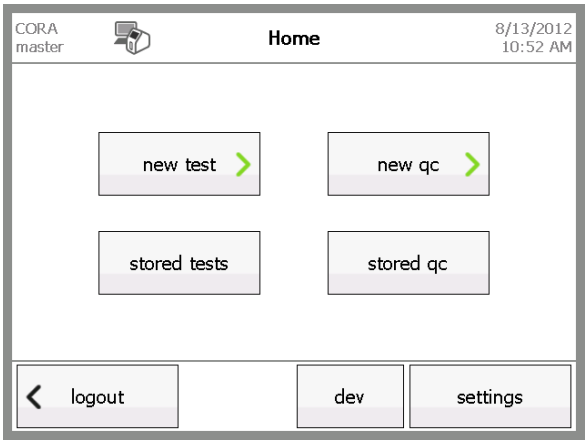


Figure 13: Main menu

2. Using the touchscreen and scroll bars as necessary, select the patient ID you wish to use (Figure 14).

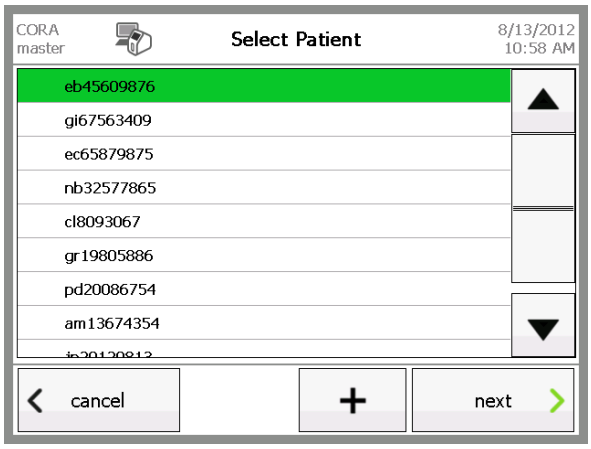


Figure 14. Patient Select screen

If the patient is not listed, a new patient ID can be added by selecting the “+” option to bring up the Add Patient screen. (Figure 15) Entering a patient ID# on this screen, followed by the “ok” or the return key, will add a new patient ID to this analyzer. To return to the main screen without entering a new patient, press “cancel”. Once you have added a patient, select them from the list as shown in Figure 14.

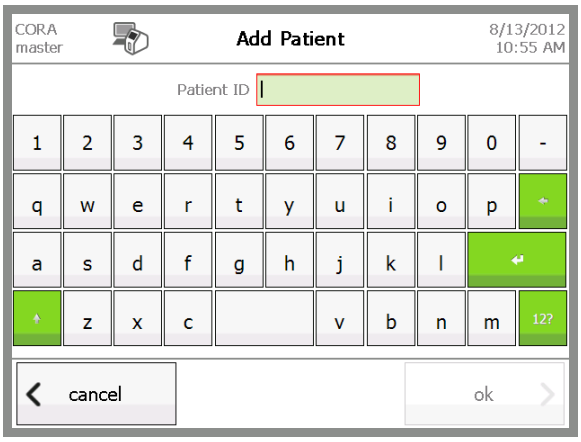


Figure 15. Add New Patient screen

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3. Insert the cartridge into the slot as indicated on the screen with the barcode on the left side, as shown in Figure 16.

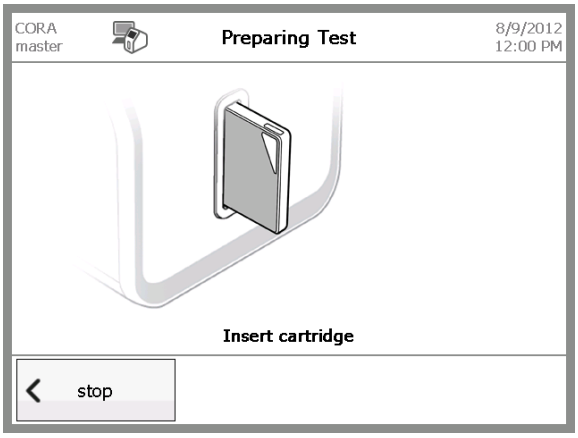


Figure 16. Insert Cartridge screen

IMPORTANT: Cartridges should be kept in their sealed pouches and in the specified storage conditions (2° to 8° C) until just before use. Cartridges can be used straight from the refrigerator – they do not have to be allowed to come to room temperature.

Before opening the cartridge pouch**,** verify that you have the proper cartridge for the assay you wish to run. Tear the pouch at the provided notch to remove the cartridge and then place the cartridge in the analyzer.

Inserting the cartridge triggers a barcode scanner and QC pretest of the cartridge. At the successful completion of the pretest, the analyzer will prompt you to verify that the assay being run is what was intended, as shown in Figure 17. If the assay is correct, press next, otherwise press stop to go back to the main menu. In the event that the cartridge pretest fails, the analyzer will prompt you to insert a new cartridge or contact service personnel if the problem persists.

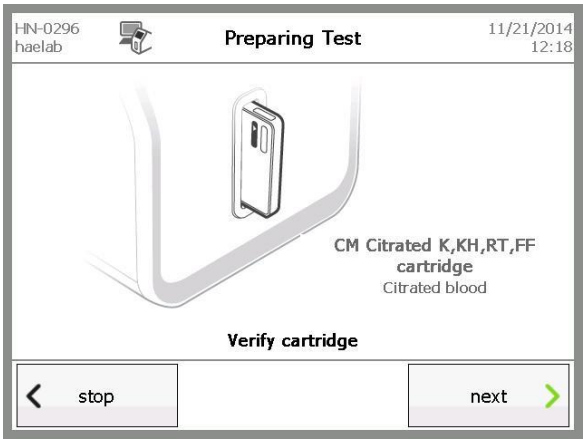


Figure 17. Verify Cartridge Screen

4. The analyzer will prompt you to load a sample of blood by transfer pipette or syringe into the cartridge sample well (Figure 18). Ensure that the blood reaches above the indicated line on the side of the cartridge. Precise measurement is unnecessary, as the analyzer will abort the test if too little blood is present.

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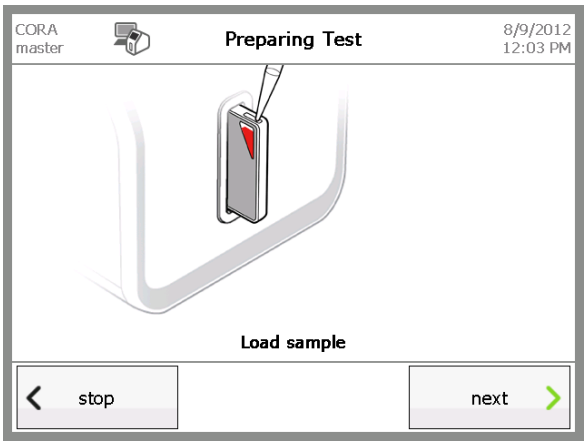


Figure 18: Load Blood Sample Screen

NOTE: Blood should be drawn by a trained phlebotomist following proper techniques and standards. For the citrated assays, citrated blood should be drawn into matching evacuated venous collection tubes. Citrated samples should be tested no earlier than fifteen minutes after being drawn.

5. Press "next" to proceed or "stop" to cancel the test.

6. The CORA analyzer then processes and runs the assay, with the display switching to a table of results. Over the course of the test, results will be updated as parameters are finalized, as shown in Figure 19.



Figure 19. Test results (in process)

The device automatically draws the blood into the active area of the cartridge, meters the exact amount required for the test, mixes it with the reagents spotted in the cartridge, and begins mapping the results as described below. DO NOT attempt to remove the cartridge during the test at any time until the completion of the assay or selecting to halt the test.

While the assay is running, you may access the graphical display of test results by pressing the "tracings" button. From the tracing screen, the user may select "next tracing" to cycle through superimposed, offset and single-tracing views, as shown in Figures 20-22. At any point you can return to the results table by selecting "results".

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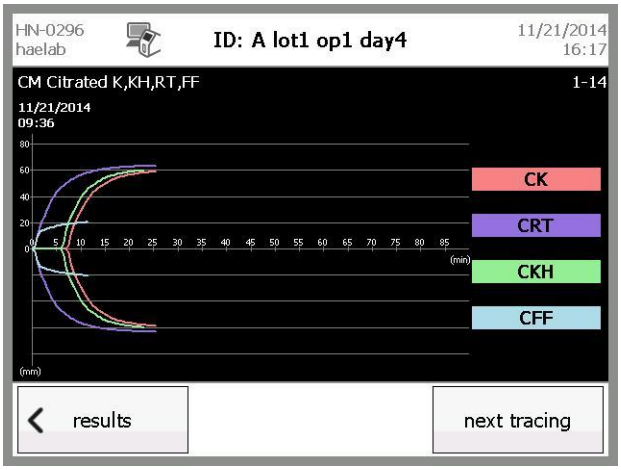


Figure 20. Superimposed Tracings screen

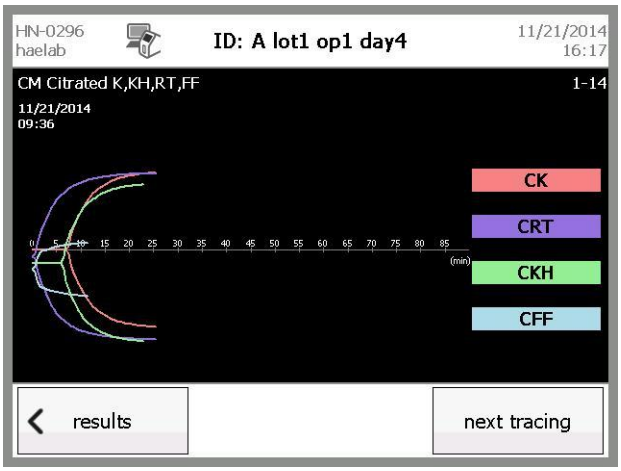


Figure 21. Offset Tracings screen

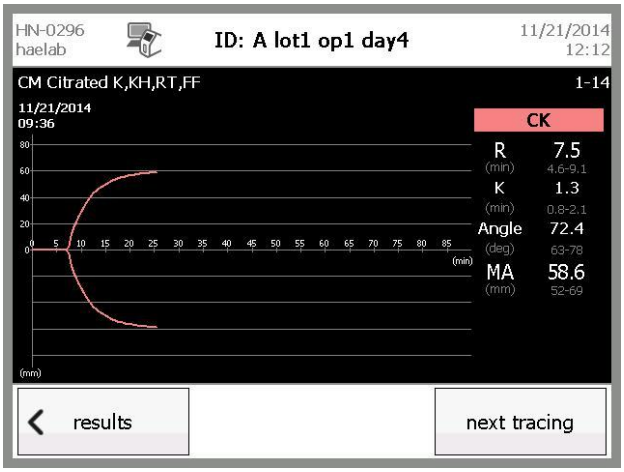


Figure 22. Single Tracing screen

If at any time you wish to discontinue the test, pressing "stop" from the Results screen will cause the system to prompt you to save the collected data. See Figure 23. Select "discard" to delete the test and return to the main menu, "save" to store the partial test and "cancel" to continue the test. If partial results are saved, the test record will show that the run was aborted by the user.

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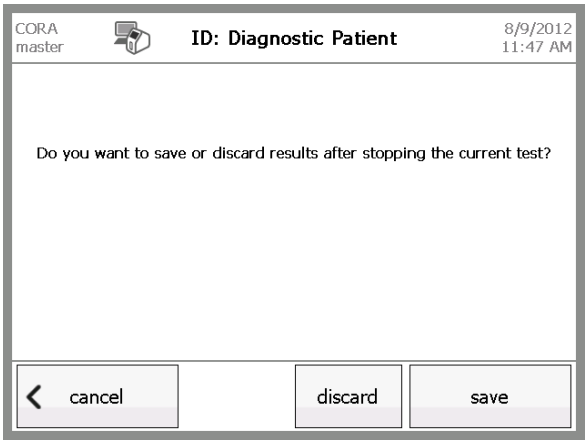


Figure 23. Stopped Test screen, showing the option of saving or discarding partial test results.

When the assay is finished the "stop" button will become a "done" button, as shown in Figure 24. The user may then view the tracings with the "tracings" button, print test results with the "print" button, or return to the main menu by pressing "done."

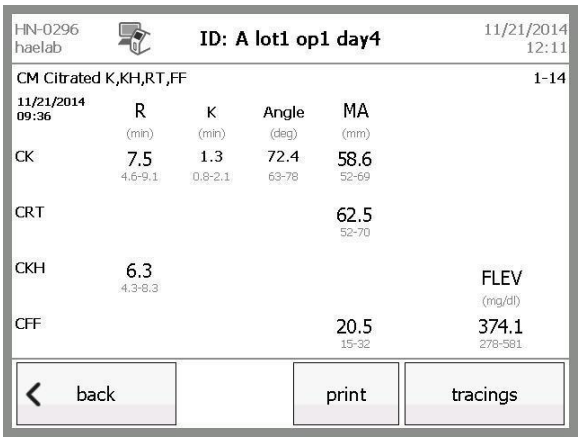


Figure 24. Complete Results screen

When a test has been completed or aborted, the analyzer will prompt you to remove the cartridge. This prompt will be in the form of an image and instructions on the touchscreen, shown in Figure 25, and a flashing light at the cartridge entry slot. Do not remove the cartridge until prompted. Immediately dispose of the cartridge properly in marked biohazard container.

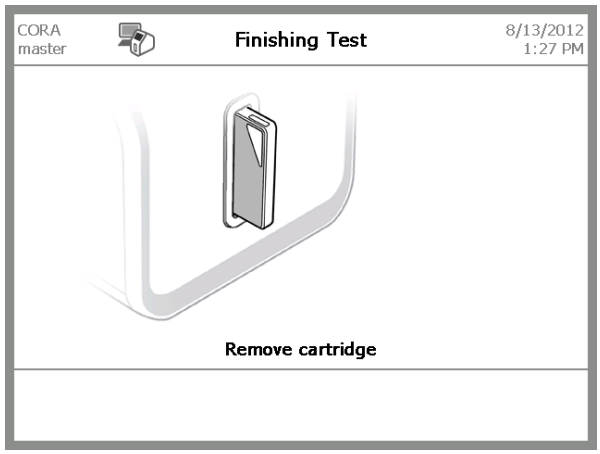


Figure 25. Remove Cartridge screen

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Recalling Patient Data (Quick Guide)

1. From the main menu select “stored tests.”
2. Highlight the desired test by selecting it then press “results” press “home” to return to the main menu.
3. To view the tracings press “tracings”.
4. To cycle through tracings from overlap to off-set to individual channels one through all collected channels select “next tracing”.
5. Return to the results page by selecting “results”.
6. Press “back” to return to the data selection page.
7. Press “home” to return to the main menu.

Recalling Patient Data (Detailed Guide)

1. From the main menu select “stored tests”.

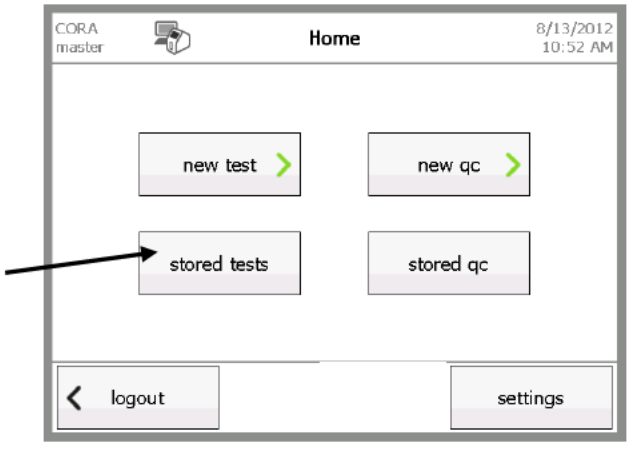


Figure 26: Main Menu

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2. Highlight the desired test by selecting it and pressing "results" (figure 27). To return to the main menu without selecting a test, press the "home" button.

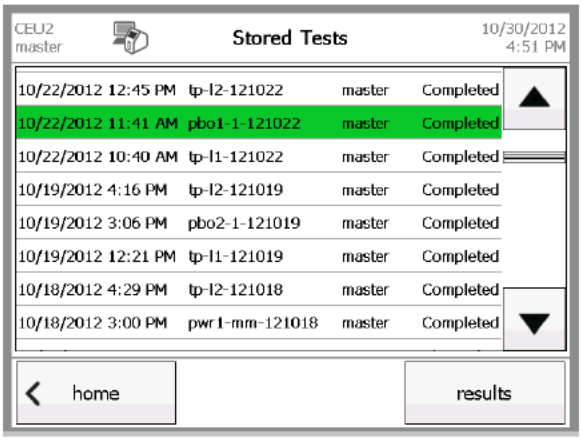


Figure 27. Stored Patient Results screen

When a record has been selected, the table of results for that record will be displayed, as shown in Figure 28.

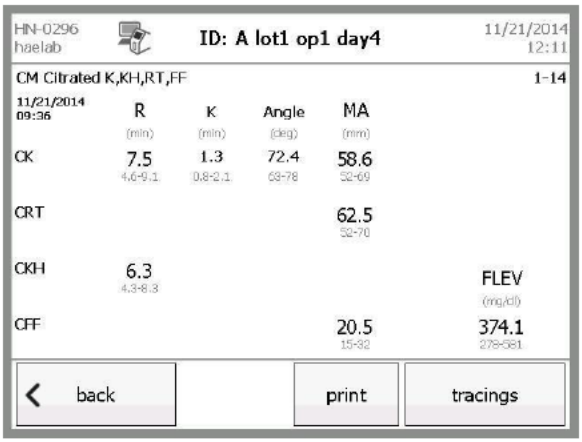


Figure 28: Results Screen

3. To view the tracings associated with a test record, press the "tracings" button.

4. To cycle through each tracing from superimposed, to offset, to each individual tracing, press "next tracing" (See Figures 20, 21, and 22).

5. To return to the list of stored tests, press "back".

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SECTION IV: QUALITY CONTROL PROCEDURES AND MATERIALS

This section contains instructions for testing wet quality control materials in the CORA System. Below is a handy **Quick Guide** to be used as a reference.

Quick Guide for Running a Wet Quality Control (WQC)

1. From the main menu select "new qc".
2. Insert the cartridge into the slot as indicated onscreen with the bar code on the left side.
3. Once the cartridge has passed pretest and you have verified it as the intended assay, press "next." If the cartridge is not the desired one, press "stop" and start over.
4. Prepare the WQC sample according to instructions on the package insert accompanying the WQC materials.
5. Deliver the WQC sample to the cartridge, filling to the line on the cartridge.
6. After loading the sample press "next."
7. The test will run and results will be displayed on the results page as they are available.
8. To see real time tracings press "tracings."
9. To cycle through superimposed, offset and single-channel tracings, repeatedly press "next tracing."
10. Press "results" to return to the results table.
11. When prompted to remove the cartridge, dispose of it properly.
12. Press "done" to return to the main menu.

Performing a WQC (Detailed Guide)

1. From the main menu select "new qc" as shown in Figure 29. Analyzer operation for WQC tests is very similar to running normal assays. As a result, figures in this section are very similar to those for patient assays.

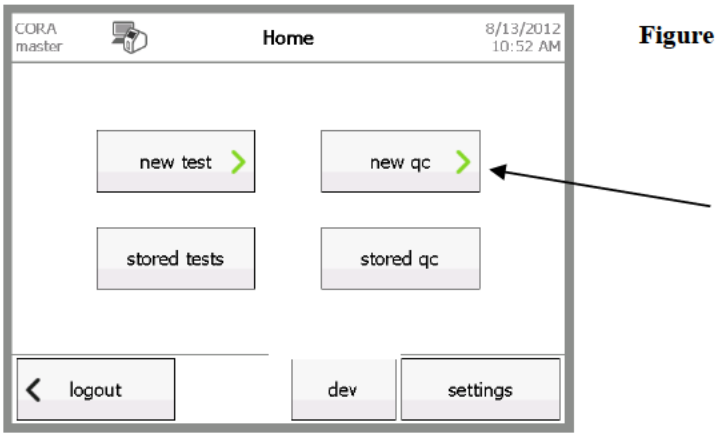


Figure 29. Main Menu

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2. Insert the cartridge into the slot as indicated on the screen with the bar code on the left side (see Figure 16).

Inserting the cartridge triggers a barcode scanner and QC pretest of the cartridge. At the successful completion of the pretest, the Analyzer will prompt you to verify that the WQC assay being run is what was intended, as shown earlier in Figure 17. If the assay is correct, press next, otherwise press stop to go back to the main menu. In the event that the cartridge pretest fails, the Analyzer will prompt you to insert a new cartridge or contact service personnel if the problem persists.

3. Press "next" if the card type is correct.

4. Prepare the WQC sample according to instructions on the package insert accompanying the WQC materials.

5. Using a transfer pipette, place the prepared WQC sample into the cartridge sample port, filling to the line marked on the cartridge. Press "next" to proceed.

NOTE: Each WQC vial, once reconstituted, contains 1ml of WQC material, which is sufficient for two WQC assays.

6. The CORA system runs the WQC, automatically drawing the WQC material into the active area of the cartridge. DO NOT remove the cartridge until prompted to do so, either after normal completion of the test or as a result of choosing to abort the test.

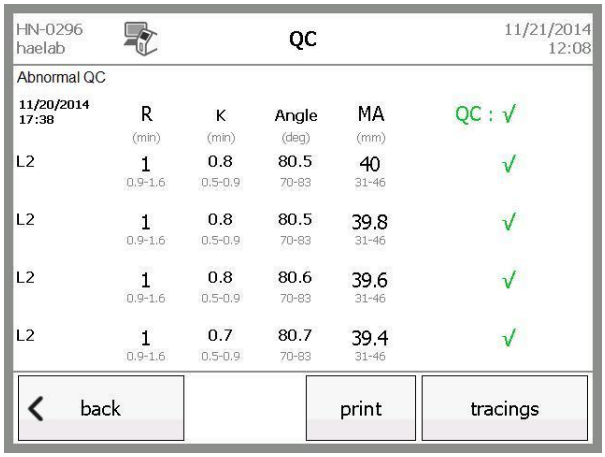


Figure 30. Running WQC

If at any time you wish to discontinue the test, pressing "stop" will cause the system to prompt you to save the collected data. Select "discard" to delete the test and return to the main menu, "save" to store the partial test and "cancel" to continue the test. If partial results are saved, the test record will show that the run was aborted by the user.

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As the WQC is running, you may access the tracings by pressing the "tracings" button. From the tracing screen, the user may select "next tracing" to cycle through superimposed, offset and individual-channel tracings (see Figures 20-22).

7. When the assay is finished the "stop" button will become a "done" button, as shown in Figure 24. You may then view the tracings with the "tracings" button or return to the main menu by pressing "done."

8. Remove the used cartridge when prompted to do so and immediately dispose of it in the proper marked biohazard waste receptacle. See notation on Page 3.

Recalling Stored WQC Data (Quick Guide)

1. From the main menu select "Stored tests".

2. Highlight the desired test by selecting it then press "results" press "home" to return to the main menu.

3. To view the tracings press "tracings".

4. To cycle through tracings from overlap to off-set to individual channels one through all collected channels select "next tracing".

5. Return to the results page by selecting "results".

6. Press "back" to return to the data selection page.

7. Press "home" to return to the main menu.

Recalling Stored WQC Data (Detailed Guide)

1. From the main menu select "stored qc."

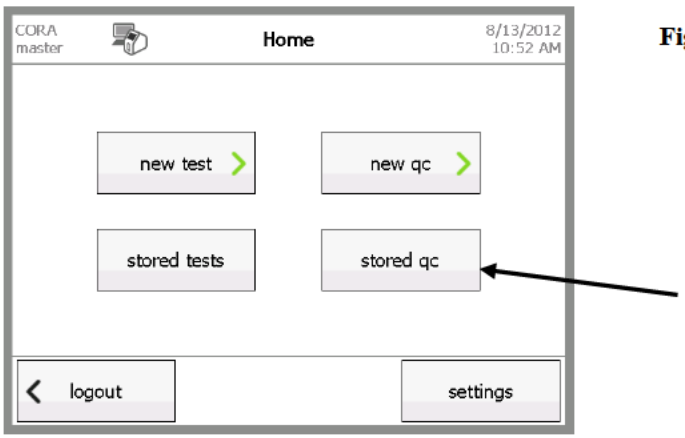


Figure 31: Main Menu

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2. Highlight the desired test by selecting it and then pressing “results.” Selecting “home” will return to the main menu (figure 32).

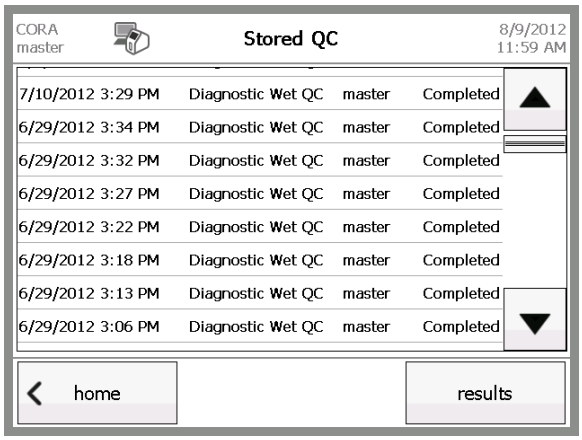


Figure 32. Stored QC Results screen

The entire results will then appear on the LCD screen as the parameters (as shown in the patient assay results of Figure 28).

3. To view the tracings, press “tracings”.

4. To cycle through superimposed, offset and single-tracing views, press ”next tracing” until the desired view is shown (see Figures 20-22).

5. To return to the data selection page, press “back”.

6. Select other WQC data to view, or press “home” to return to the main menu.

Citrated Reagent QC

The CORA analyzer performs internal QC checks during a pretest when the cartridge is inserted. This verifies that all electromechanical and pneumatic functions of the analyzer-cartridge combination are operating satisfactorily. Whereas the internal QC of the analyzer effectively tests analyzer functions, a QC methodology is required to verify that reagents in cartridges are still viable at time of use. This ensures that cartridges have not been mishandled between production and arrival at the lab, or have not been subject to adverse environmental conditions or otherwise mishandled while in lab storage. This can supplement the laboratory’s development of its own Individualized Quality Control Plan (IQCP) based on the lab’s risk analysis, in accordance with CLSI EP23. This risk analysis would take into account the lab’s specific situations that could affect reagent quality, such as environmental storage controls.

Coramed recommends that normal and abnormal donor control checks be performed for each new shipment of citrated multichannel assay cartridges. Additional QC checks may be performed on a monthly, weekly, daily or shift basis based on the laboratory’s quality control policies. The end user should follow the recommendations of local and state regulatory agencies as well as facility policies.

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Coramed recommends that the lab perform two levels of QC testing whenever indicated by the IQCP using the following procedure.

i. Establish a known normal quality control using blood drawn from healthy adults.
ii. The normal donor control should not have taken any medication known to affect coagulation levels and should have prior citrated multichannel cartridge tests that have fallen within the established normal reference ranges.
iii. Prepare an abnormal quality control using Abnormal WQC material, representing an abnormal sample, following instructions in the Abnormal QC Material Product Insert, #01-182.
iv. The "normal" donor should have test results that fall within established reference ranges. For the Abnormal WQC sample, reagent performance is verified if parameters fall within the following Reference Ranges

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (degrees)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563 - 873

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SECTION V: OPERATIONAL PRECAUTIONS AND LIMITATIONS

General

Read and understand the entire contents of this manual before operating the CORA system – especially precautionary information and specifications.

Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.

The CORA system is to be operated by professionally trained healthcare workers only.

If this equipment is used in a manner inconsistent with this manual, protections provided by the device may be impaired.

Use only Coramed parts and accessories with the CORA system. Third-party accessories may cause improper performance.

DO NOT use malfunctioning equipment. Have the unit repaired by an authorized Coramed service representative.

Common Errors and How to Correct Them

The CORA system is designed such that should any error appear on the screen, there will be clear instructions as to how to correct the error. If the problem persists after performing the recommended solution, call a customer service technician.

Errors require some form of action on the part of the operator, whereas warnings only require acknowledgement, after which the analyzer may continue to be used. Every report of an error generated on the CORA system will provide the user with a description of the error, an error code number, and response actions to the error. Please follow the response actions exactly to prevent further errors. There should be no need to refer to the user manual for error solutions. The typical error screen will look like figure 33 and a typical warning screen will look like figure 34. An error will cause the test to stop and require the analyzer to be power-cycled in an attempt to clear the error, and may ultimately require the assistance of Service personnel. A warning occurs when the device encounters a problem which is not critical to operation of the analyzer. A warning does not require any action by the user (other than pressing the acknowledge button).

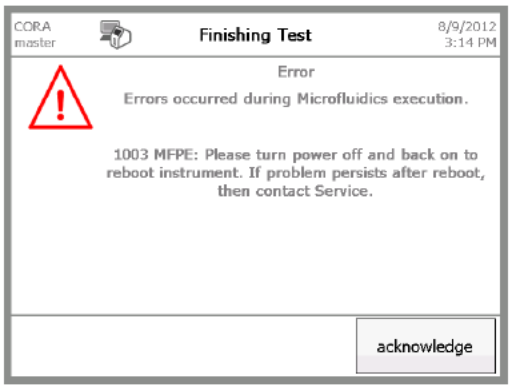


Figure 33: Typical Error Screen

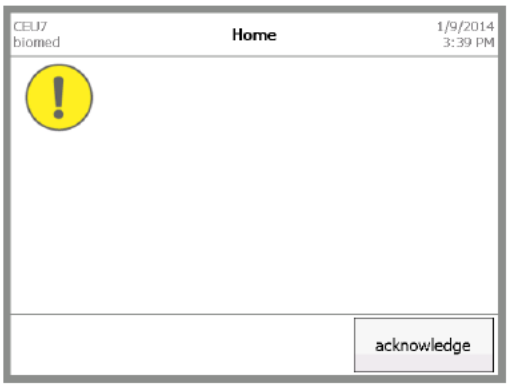


Figure 34: Typical Warning Screen

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If at any point the user encounters a message that reads "Please turn power off and back on to reboot analyzer. If problem persists after reboot, then contact customer service", the user should follow the given instructions. If the problem does persist after a successful power off followed by a power on then a call to the customer service number, 847-647-8800 should be initiated. Make sure you report the error code that appears on the screen next to the error information. NOTE: When an error occurs during data collection, the data is NOT saved.

Warnings require no action to be taken by the user; they simply alert the user to an occurring event which the user must then acknowledge. NOTE: When a warning occurs no data is lost.

If the error is triggered by a faulty cartridge, simply remove the cartridge and rerun the test with a new cartridge. DO NOT attempt to repair or reuse the old, faulty cartridge.

Below are examples of errors which may be encountered by the user, including the error and warning numbers, probable cause, and recommended solution in order of code number. For error codes reported that are not on this list, please contact customer service.

Error Code	LCD Display Reading	Probable Cause	Solution
1016	Bubble detected in channel	Bubbles have been detected in one or more channels.	Remove cartridge and use new cartridge. Verify that quantity of blood sample is sufficient for test. If problem persists, call customer service.
1030	Pretest Fault - Pressure Leak in analyzer	Pressure leak in analyzer	Contact Service
1031	Pretest Fault - Pressure Leak in cartridge	Pressure leak in cartridge	Remove cartridge and rerun test with new cartridge. If problem persists, contact Service.
1032	Pretest Fault - Vacuum Leak in analyzer	Vacuum leak in analyzer	Contact Service
1033	Pretest Fault - Vacuum Leak in cartridge	Vacuum leak in cartridge	Remove cartridge and rerun test with new cartridge. If problem persists, call Service.
2001	LED Error	Front panel LED failure	The analyzer will continue to operate OK, but the failure should be reported to customer service.
2003	Unexpected Reset while Running a Test	The analyzer has unexpectedly been reset during a Test	Please turn power off and back on to reboot analyzer. Discard cartridge and result. If problem persists after reboot then contact Service.
3000	Temperature out of range - Set point above 30°C	Sample temperature out of range for one or more channels	Remove cartridge and call Service

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Error Code	LCD Display Reading	Probable Cause	Solution
3019	Firmware Update Cortex Failed	Firmware update failed.	Reset the system to the previous firmware revision. This requires administrator access; if no administrator is available or if the problem persists, contact Service.
3020	Firmware Update Piccolo Failed	Firmware update failed.	Reset the system to the previous firmware revision. This requires administrator access; if no administrator is available or if problem persists, contact Service.
3027	POST Fault - Diskspace is critically low	Power-On-Self-Test Fault - Diskspace is critically low	Delete unneeded test results from analyzer, then turn power off and back on to reboot analyzer. NOTE: This requires administrator access, if no administrator is available Contact Service
3032	Cortex Firmware Not Found	Analyzer program error.	Update the System firmware. NOTE: This requires administrator access, if no administrator is available or If the problem persists, contacts Service.
3033	Piccolo Firmware Not Found	Analyzer program error.	Update the System firmware. NOTE: This requires administrator access; if no administrator is available or If problem persists, contact Service.

Basic Cleaning and Disinfecting Requirements

Because the CORA system is a self-contained device, the analyzer exterior should be cleaned and disinfected weekly, or more frequently as needed according to laboratory medical disinfecting procedures, to prevent contamination of the analyzer and limit potential exposure of bloodborne pathogens to operating personnel. Products containing a 70% Isopropyl Alcohol solution are recommended, and commonly-used germicidal disposable wipes (PDI Super Sani-Cloth or equivalent) are effective and will not cause damage to the CORA analyzer when used according to manufacturer's instructions. The Laboratory Administrator or Supervisor may contact Coramed or an authorized distributor concerning questions about the compatibility of decontamination or cleaning agents with parts of the equipment. For thorough cleaning and disinfecting, all external surfaces, including the touch screen display, must be wiped with the solution, taking care to avoid getting liquid into the cartridge slot at the front of the analyzer or into connectors on the rear panel. In general, the users should clean and disinfect according to the state and local regulatory bodies and laboratory policy.

The CORA system must also be cleaned and disinfected prior to return shipment if servicing is necessary. For further information, refer to "Packaging the CORA system for return" below.

All materials used for the disinfecting should be disposed of in the proper biohazard waste receptacles.

CAUTION: Do not steam-sterilize or autoclave the analyzer or any cartridge. Do not immerse the analyzer or cartridge in any solution. Do not clean the analyzer or cartridge with acetone or any other plastic solvent or abrasive cleaner.

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The CORA analyzer has a filter assembly mounted at the rear of the unit to filter air as it is drawn into the unit by the fan (see figure 2). This filter should be periodically removed and cleaned if required.

Unpacking the CORA System

The CORA system is packaged to reduce the risk of damage during shipment. Remove all Styrofoam inserts and carefully remove the CORA system from the box. The power adapter and cables are wound up and packaged separately. Save the packing materials for future use since it is required for the safe return of the analyzer for service or repair.

Simply place the CORA system on a flat surface, e.g. table or lab bench. Attach all of the cables to the appropriate inputs on the device, and the appropriate inputs for successful operation, e.g. power cable to a wall outlet.

Placement of the CORA system

Care should be taken in the placement of the CORA analyzer, so that it is not positioned in such a way as to make it difficult to reach and operate the power switch and power cord disconnection.

Storage and Handling of the CORA system

Safe and successful operation depends in part on the proper routine handling of the CORA system, disposables, and blood samples. The operator should be aware of the problems that could result if these items are stored, installed, or used incorrectly. Whenever the user is using the CORA system he or she should be wearing latex or nitrile gloves.

The CORA Analyzer needs only to be placed on a flat surface and operated at room temperature (10° to 32°C). The analyzer may be stored at a temperature between -20°C and +50°C, however, prior to use the unit must be brought to operating temperature. The CORA system is designed for indoor use only.

Storage and Handling of the CORA system cartridges

The storage and handling of CORA® system Citrated Multichannel cartridges and WQC materials may differ depending on the type of reagent or control. Refer to each product insert for storage and handling instructions.

Transporting the CORA system

To transport the CORA system, remove all plugs, cords, and cartridges from the device. The CORA System must also be cleaned and disinfected prior to moving the analyzer to a new location, or for return shipment if servicing is necessary.

Product Return Guidelines

Should the user need to return the CORA system or any of its component parts for service, the following procedures should be followed to ensure no further damage comes to the device and to ensure personnel safety.

- Make sure the system and any component parts have been thoroughly cleaned and disinfected according to the cleaning and disinfecting guidelines above to prevent biohazard contamination during shipment.

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- Use the original packing material, as appropriate.
- Use only the Styrofoam originally provided in the original packaging.
- Place the CORA system in the CORA box exactly as when you received it.

Power Outlet Connection

Do not power the device using a power cord other than the one originally supplied by Coramed or an authorized Coramed distributor for the CORA system. Always ensure the power cord is connected to an appropriately grounded power source per your institution's policy.

Caution: *Grounding reliability can only be achieved when the equipment is connected to a properly grounded outlet.*

Caution: *Do not unplug the male single-pin connector end of the power cord from the analyzer while leaving the power cord connected to a live power source. Electrical shorting and power supply damage may occur.*

FCC Compliance

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case users will be required to correct the interference at their own expense.

Warning: Any changes or modifications not expressively approved by Coramed Technologies could void the user's authority to operate this equipment.

Warranty

Coramed Technologies warrants its manufactured products (excluding disposable or consumable supplies) to be free from defects in materials or workmanship for one year from the original date of purchase subject to these terms and conditions. Returns will not be accepted without authorization from a Coramed Representative. Products must show no evidence of improper handling or operation, including unauthorized repairs.

At its discretion, Coramed Technologies may repair or replace defective products covered by this warranty. Even if Coramed Technologies cannot repair or replace, its entire liability shall in no event exceed the purchase price. Coramed Technologies expressly disclaims all other warranties, whether express, implied, or statutory, including the warranty of merchantability and fitness of use. In no event will Coramed Technologies be liable for consequential, incidental, or special damages arising out of the use of its products.

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SECTION VI: HAZARDS

Electrical Shock Hazards

The CORA system operates at a low-rated voltage. The risk of electrical shock is, therefore, minimal. However, the operator should never remove the CORA system's covers. Maintenance that requires the removal of these covers remains the responsibility of a Coramed-trained service technician.

Blood Borne Pathogens

Users should adhere to Standard Precautions when handling or using this device. All parts of the Coramed Hemostasis System should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. Although the CORA system does not present a significant biohazard risk in itself, the unit is used to analyze human blood, so care must be taken to properly handle, clean, and disinfect the equipment as appropriate.

Warning: Special cleaning needs, such as a blood spill, should be dealt with promptly. Follow local standard operating procedure for blood precautions when cleaning up a blood spill or dealing with blood contaminated components. Dispose of all cleaning materials as biohazardous waste.

While operating the CORA system, wear powder-free examining gloves and wash hands immediately after removing the gloves. Also, operators should switch gloves between patients and after completion of testing, and wear fluid-resistant clothing.

Proper Handling of Blood Contaminated Material

Even though the only working surfaces that routinely come into contact with blood are the internal surfaces of the disposable cartridge, any CORA system surface that could be contaminated by a blood spill should be properly cleaned and decontaminated with an appropriate disinfectant (refer to above "Basic Cleaning and Disinfecting Requirements"). This should only need to be done as required by laboratory protocol and immediately after any blood spill.

Precautions must be taken to eliminate or reduce the hazards involved with removing the CORA system from its point of use, transporting it from one place to another, or disposing of the analyzer. If any blood-contaminated material must be returned to Coramed for further inspection, see "Product Return Guidelines" above for instructions.

Warning: Coramed products must be properly cleaned and packaged prior to their return. It remains an important responsibility of the customer to reduce potential health hazards by being aware of the risks involved in the shipping, handling and testing of this material. Units returned to Coramed for repair may be subject to biohazard charges if any component is contaminated with blood or blood products.

Proper Disposal of Biologically Contaminated Materials

Any disposable material used during a procedure is considered to be biologically contaminated and biohazardous. It must be disposed of according to local standard operating procedures for the removal of such material and should not be mixed with non-biohazardous waste.

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External Symbols on the Analyzer

	***CAUTION: BIOHAZARD*** *Turn off and lock out power before servicing.*	IVD	In-vitro Type Medical Device
	***CAUTION: Risk of danger*** *Consult documentation for information relating to potential HAZARDS and actions to be taken*	RX Only	Prescription Use Only

NAME AND PLACE OF BUSINESS OF MANUFACTURER



Coramed Technologies
6225 W Howard St
Niles, IL 60714 USA

DATE OF ISSUANCE OF LAST LABELING REVISION:

May 21, 2015

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Proprietary Name and Established Name

Proprietary Name: CORA® (Coagulation Resonance Analysis) System and the following citrated assays and reagents

CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent

Established Name: Whole Blood Hemostasis System

Intended Use

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The Citrated Multichannel Cartridge, to be used with the CORA System analyzer, contains four independent assays (CK, CRT, CKH and CFF), described below.

The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).

The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CKH assay monitors the effects of heparin in 3.2% citrated whole blood specimens on the CORA System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests.

The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Summary and Explanation of the Test

The CORA System and the Citrated Multichannel Cartridge are used to test the hemostasis properties of citrated blood samples using four different assays/reagents simultaneously, one in each of the four cartridge channels. For the CK assay, Kaolin-activated test methods are used to reduce variability and to reduce the running time of a native whole blood sample. The CRT assay maximally accelerates the clotting process by simultaneously activating the intrinsic and extrinsic coagulation pathways, allowing

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for the maximum clot strength to be reached more quickly. CKH is similar to CK but with the addition of heparinase, to neutralize the effects of heparin in the blood. If there is heparin present, the R time for CK will be significantly longer than the R time for CKH. The CFF assay fully inhibits all the platelets, thereby excluding their contribution to clot strength, and therefore measures only the functional fibrinogen contribution to clot strength.

Principles of the Procedure

CK Principle

Kaolin is a standardized reagent consisting of dry Kaolin and 0.85% Saline solution. Kaolin-activated test methods are used to reduce variability and to reduce the running time of a native whole blood sample. Use of these particles of hydrated aluminum silicate shortens coagulation time because Kaolin acts as a contact surface activator (intrinsic pathway), which activates Factor XII and platelets and stimulates the reserve clotting ability of a blood sample. Kaolin is combined with $CaCl_2$ to neutralize any sodium citrate in the blood.

CRT Principle

RapidTEG maximally accelerates the clotting process by simultaneously activating the intrinsic and extrinsic coagulation pathways using a high concentration of Kaolin and Tissue Factor (TF). This closely reflects the physiological clotting process and yields results significantly faster than a native, Kaolin, and/or TF activated test. $CaCl_2$ is included to neutralize any sodium citrate in the blood.

CKH Principle

Heparin is commonly used as an anticoagulant in surgical procedures. Even very low concentrations of Heparin, fractions of IU/mL of blood, can noticeably increase the R time and can even completely anticoagulate the blood, making it difficult if not impossible to monitor developing coagulopathies that are masked by high levels of therapeutic Heparin. The Kaolin with Heparinase assay will rapidly and specifically neutralize the anticoagulant property of Heparin. $CaCl_2$ is included to neutralize any sodium citrate in the blood

CFF Principle

The Functional Fibrinogen reagent activates the extrinsic pathway using tissue factor and inhibits platelet aggregation using a platelet inhibitor that binds to GPIIb/IIIa receptors. The Functional Fibrinogen reagent fully inhibits all the platelets, thereby excluding their contribution to clot strength (MA), and therefore measures only the functional fibrinogen contribution (MA_{PI}) to clot strength. Functional Fibrinogen is combined with $CaCl_2$ to neutralize any sodium citrate in the blood. Determining the independent contribution of platelets and fibrinogen further improves the use of the CORA System in helping to detect and diagnose hemostasis defects.

Reagents

CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
Dried Kaolin and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 35.45% Kaolin (concentration 0.011896% w/w), 21.97% water, and 42.58% Calcium Chloride 2 M solution.

CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
Dried Kaolin, Tissue Factor and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 11.73% Kaolin (concentration 14.098 % w/w), 46.92% Tissue Factor (concentration 3.88 µg/mL), and 41.35% Calcium Chloride 2M solution.

CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
Dried Kaolin and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 57.42% Kaolin (concentration 0.012854% w/w) and 42.58% Calcium Chloride 2 M solution; dried Heparinase,

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900 nL spot in blood well of channel, consisting of 23.66% Heparinase (concentration 0.38 IU) and 76.34% water.

CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent
Dried Tissue Factor and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 58.65% Tissue Factor (concentration 0.00055 µg/mL) and 41.35% Calcium Chloride 2 M solution; dried ReoPro®, 900 nL spot in blood well of channel, consisting of 100% ReoPro®.

Warnings or Precautions:

For In-Vitro Diagnostic Use

Sources of Reagent Error

Cartridges should be refrigerated (2° C to 8° C) when not in use.

Sources of Procedural Error

Use only citrated tubes. Do not collect blood samples into heparin tubes or any other tubes not specifically recommended.

Instructions for reconstitution, mixing, dilution, etc.

None required.

Handling Instructions:

While operating the CORA system, wear powder-free examining gloves and wash hands immediately after removing the gloves. Also, operators should switch gloves between patients and after completion of testing, and wear fluid-resistant clothing.

Storage instructions

CORA Citrated Multichannel cartridges are for single use only and should be stored refrigerated at 2°C to 8°C prior to removal from storage for use. Cartridges should be discarded after use.

Analyzer

Refer to CORA System User's Manual

Specimen Collection and Preparation for Analysis

Use only citrated tubes for blood draws. No additives or preservatives are necessary to maintain the integrity of the sample, but samples must be used within 2 hours of draw to maintain in-use stability.

Known Interfering Factors

CK assay was tested for interference factors according to CLSI EP7-A2. Potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Only Hemolysis, and Hemodilution levels above 20%, were found to be interferents.

CRT assay was tested for interference factors according to CLSI EP7-A2. Potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). All except EACA and Absence of a Discard Tube were found to be interferents, with Hemodilution being an interferent above 20% concentration.

CKH assay was tested for interference factors according to CLSI EP7-A2. The potential interferent tested was Protamine. Results show that Protamine is an interferent at concentrations above 0.062 mg/mL.

CFF assay was tested for interference factors according to CLSI EP7-A2. Potential interferents tested were Heparin and Hemodilution. Heparin was found to be an interferent for Functional Fibrinogen above Heparin concentrations of 1 IU/mL, and Hemodilution was found to be an interferent above hemodilution levels of 30%.

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Procedure

Materials Provided

One (1) Citrated Multichannel cartridge sealed with desiccant pack in foil pouch. Cartridge contains the following dried reagents: Kaolin, RapidTEG, Kaolin with Heparinase and Functional Fibrinogen, all with Calcium Chloride.

Materials Required (but not supplied)

CORA® Analyzer (Coramed Technologies) – see User's Manual for instructions for use.
Transfer pipette(s) (Samco Scientific #212 or equivalent)
Blood drawing supplies (any medical supplier)

Test Procedure

1. Remove the cartridge from refrigerated storage.
2. Tear open the pouch, remove the cartridge and discard the pouch and desiccant pack.
3. From the main menu on the CORA analyzer, select "new test".
4. Select the patient ID you wish to use. If the patient is not listed, you may add a new patient by selecting the "+" option and entering a patient ID on the screen. Then press "next".
5. Insert the cartridge into the slot as indicated on the screen with the bar code on the left side.
6. After the cartridge pretest is completed and you have verified that the assay is what you intended to run, press "next". If the cartridge is not the desired assay, press "stop" and start over.
7. Add blood to the cartridge sample port to above the level indicated on the cartridge.
8. After loading the sample press "next".
9. The test will run and results will be displayed as they become available.
10. When the test is completed, the analyzer will prompt to remove the cartridge and will return to the table of results.
11. Remove the used cartridge from the slot as demonstrated on the LCD display, and discard the cartridge.
12. Press "done" from the results screen to return to the home page.

Calibration

The CORA analyzer does not require routine calibration.

Quality Control Procedures

The CORA analyzer performs internal QC checks during a pretest when the cartridge is inserted. This verifies that all electromechanical and pneumatic functions of the analyzer-cartridge combination are operating satisfactorily. Laboratories should perform additional QC testing as required by their laboratory's procedures. Coramed provides Abnormal WQC materials to be used for this purpose.

Whereas the internal QC of the analyzer effectively tests analyzer functions, a QC methodology is required to verify that reagents in cartridges are still viable at time of use. This ensures that cartridges have not been mishandled between production and arrival at the lab, or have not been subject to adverse environmental conditions or otherwise mishandled while in lab storage. This can supplement the laboratory's development of its own Individualized Quality Control Plan (IQCP) based on the lab's risk analysis, in accordance with CLSI EP23. This risk analysis would take into account the lab's specific situations that could affect reagent quality, such as environmental storage controls.

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Coramed recommends that normal and abnormal donor control checks be performed for each new shipment of citrated multichannel assay cartridges. Additional QC checks may be performed on a monthly, weekly, daily or shift basis based on the laboratory's quality control policies. The end user should follow the recommendations of local and state regulatory agencies as well as facility policies.

Coramed recommends that the lab perform two levels of QC testing whenever indicated by the IQCP using the following procedure.

i. Establish a known normal quality control using blood drawn from healthy adults.
ii. The normal donor control should not have taken any medication known to affect coagulation levels and should have prior citrated multichannel cartridge tests that have fallen within the established normal reference ranges.
iii. Prepare an abnormal quality control using Abnormal WQC material, representing an abnormal sample, following instructions in the Abnormal QC Material Product Insert, #01-182.
iv. The "normal" donor should have test results that fall within established reference ranges. For the Abnormal WQC sample, reagent performance is verified if parameters fall within the following Reference Ranges

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (degrees)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563 - 873

Results

No calculations are necessary to obtain test results; these are displayed on the CORA analyzer display, and may be printed if a printer is attached.

CK Test Results

The R, K, Angle and MA parameters are measured and displayed at the conclusion of the test, along with the corresponding reference ranges established for these parameters.

CRT Test Results

The MA parameter is measured and displayed at the conclusion of the test, along with the corresponding reference ranges established for these parameters.

CKH Test Results

The R parameter is the only one of importance for this test. It is measured and displayed at the conclusion of the test, along with the corresponding reference range established for the R parameter for Kaolin with Heparinase.

CFF Test Results

The MA parameter and the estimated Functional Fibrinogen Level (FLEV) are measured and displayed at the conclusion of the test.

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Limitation of the Procedure

Use of Results

CORA results should always be considered within the clinical context of the individual patient's case. In the event of inconsistencies with the patient's clinical status, samples should be repeated or supplemented with additional clinical information and/or data.

Expected Values

Expected values for test results are within the Reference Ranges for a reference population that were established according to CLSI C28-A3c. The following tables contain the reference range data for each reagent and parameter. It is recommended that customers validate reference ranges based on their local population.

CK Reference Ranges

Citrated Blood Parameter	N	Range
R (min)	157	4.6 – 9.1
K (min)	157	0.8 – 2.1
Angle (deg)	155	63 - 78
MA (mm)	151	52 - 69

CRT Reference Ranges

Citrated Blood Parameter	N	Range
MA	152	52 - 70

CKH Reference Ranges

Citrated Blood Parameter	N	Range
R	155	4.3 – 8.3

CFF Reference Ranges

Citrated Blood Parameter	N	Range
MA	151	15 - 32
FLEV	152	278 - 581

Specific Performance Characteristics

CK Precision

The precision of the CORA Kaolin test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the Kaolin Assay was CV less than 15% for the R parameter, less than 10% for the MA parameter, less than 10% for the Angle parameter and less than 25% for the K parameter.

CK Sensitivity and Specificity

The Kaolin reagent is often used in conjunction with tests performed on blood samples from patients administered with heparin, with the goal of either determining heparin effect (titration of dose) or determining full reversal (post-protamine) of heparin administered. It is, therefore, important that the Clinical Sensitivity and Specificity for the presence of heparin be determined. Five different heparin spiked samples were examined, with concentrations spread across the heparin therapeutic ranges (0.2 to

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6.0 IU/mL). 0.2 IU/mL is the lowest therapeutic dose typically used and 6.0 IU/mL represents a typical dose of heparin used when patients are fully heparinized during cardio-pulmonary by-pass. In addition, five (5) non-heparin spiked samples were analyzed. Kaolin's sensitivity to Heparin was 100%, with the R parameter elongated and out of range for all concentrations. Specificity was also 100%, with all un-spiked samples having an R parameter within normal range.

CRT Precision

The precision of the CORA RapidTEG test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the RapidTEG Assay was less than 10% for the MA parameter.

CKH Precision

The precision of the CORA Kaolin with Heparinase test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the Kaolin with Heparinase Assay was CV less than 15% for the R parameter.

CKH Neutralization

The Kaolin with Heparinase assay was tested to verify that 6 IU of Heparinase per 1 mL of blood will effectively neutralize the effects of both Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) on Kaolin-activated citrated whole blood samples. This is the amount of Heparinase used in the Kaolin with Heparinase assay. Tests were performed using UHF and LMWH spiked samples and un-spiked samples. All tests reported R parameter values within the normal range, confirming the neutralization effectiveness of the assay.

CFF Precision

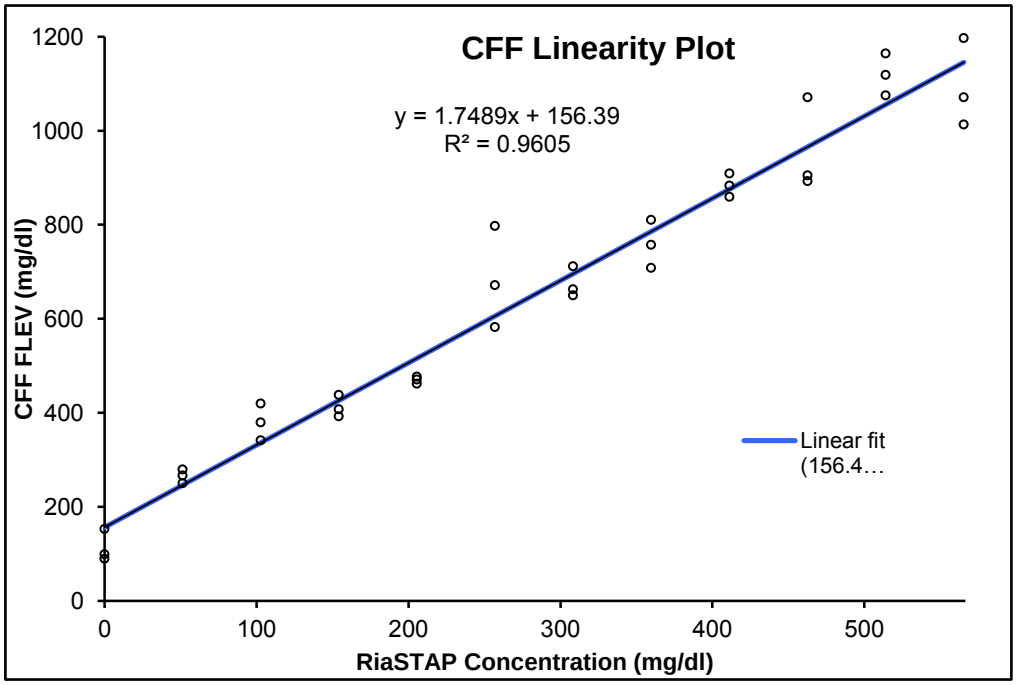
The precision of the CORA Functional Fibrinogen test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the Functional Fibrinogen Assay was CV less than 10% for the MA and FLEV parameters.

CFF Linearity

The Function Fibrinogen assay was tested for linearity according to CLSI EP6-A. Linearity with respect to Fibrinogen concentration levels is shown below.

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Clinical Performance - Method Comparison and Reader Studies

Method Comparison studies were conducted at three clinical sites on patient samples following CLSI EP09-A3 Guideline. The subjects enrolled were patients undergoing cardiovascular surgery or cardiology procedures, with blood samples drawn pre- and post-surgery and in the ICU. In order to broaden the range of comparison, up to 10% contrived samples were added. Summary statistics are presented below.

Method Comparison Statistics Summary – All Clinical Sites					
Parameter	**R**	**Intercept**	**95% CI**	**Slope**	**95% CI**
CK – R (min)	0.868	-0.325	-0.425	1.069	1.034
			-0.225		1.103
CK – K (min)	0.740	-0.097	-0.292	0.906	0.769
			0.098		1.042
CK – Alpha (deg)	0.680	7.305	-13.160	0.940	0.640
			27.769		1.240
CK – MA (mm)	0.924	2.351	0.166	0.948	0.912
			4.536		0.983
CKH – R (min)	0.812	-0.329	-0.393	1.057	1.026
			-0.265		1.089
CRT|CK – MA (mm)	0.929	-0.126	-1.909	0.978	0.948
			1.656		1.007
CFF – MA (mm)	0.938	-0.774	-1.836	1.126	1.072
			0.289		1.180
CFF – FLEV (mg/dl)	0.928	-12.495	-36.810	1.127	1.059
			11.819		1.194

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In addition, a Reader Study was conducted to assess the comparison of CORA System and TEG 5000 results based on reading printed test outcomes. The study was performed at three sites, using three experienced TEG 5000 doctors as readers at each site, for a total of nine readers. 30 test outcomes were compared for each of the reagent test categories, for a total of 270 reading comparisons per reader. Excellent agreement between the two devices was demonstrated.

In both the Method Comparison Study and Reader Study, the CORA RapidTEG (CRT) MA parameter was compared to the TEG 5000 Kaolin (CK) MA parameter, to demonstrate that the CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

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Date of Issuance of Last Labeling Revision: May 21, 2015

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CORA® System 510(k) Summary

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Date that Summary was prepared: May 21, 2015

DEVICE INFORMATION

Trade name (proprietary name): CORA® (Coagulation Resonance Analysis) System and the following assays and reagents

- Citrated Assays and Reagents
  - CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
  - CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
  - CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
  - CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent

Common name (usual name): Whole Blood Hemostasis System

Classification Name: 21CFR 864.5425 Multipurpose System for *in vitro* Coagulation Studies

PREDICATE DEVICE

- Thrombelastograph® Coagulation Analyzer (TEG®) – 5000 Series, K002177, Product Code JPA (System, Multipurpose, for In Vitro Coagulation Studies), Haemoscope Corporation

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DESCRIPTION OF THE DEVICE

System Description

The CORA System consists of a four-channel diagnostic analyzer with integrated computer module, system reagents (CK, CRT, CKH, and CFF), and Abnormal Quality Control material and microfluidic test cartridges. See below for a description of system reagents. Reagents are dried-in-place within the cartridges during manufacturing. Abnormal Quality Control material is lyophilized and can be reconstituted with water as needed for WQC testing with reagent cartridges.

To perform a test, a disposable CORA Cartridge is inserted into the analyzer. Blood or WQC material is added to an entry port on the cartridge and drawn into the cartridge under analyzer control. The amount of the sample drawn into the cartridge is automatically determined by the volume of the blood chambers in the cartridge. Once in the disposable, the sample is metered into as many as four separate analysis channels, depending upon the assays being performed. Reconstitution of reagents dried within the cartridge is accomplished by moving the sample back and forth through reagent chambers, under the control of microfluidic valves and bellows (pumps) within the cartridge. After each sample has been mixed with reagent, it is delivered to a test cell where it is monitored for visco-elastic changes due to coagulation. Excess sample material is moved under microfluidic control into an enclosed waste chamber within the cartridge.

The CORA Measurement Technique

The CORA technology is based on a disposable containing up to four independent measurement cells. Each cell consists of a short vertically-oriented injection molded tube (ring) with a diameter of 2.5mm and a length of 4.5mm. Detection of clotting in the CORA System is performed optically. Under control of the analyzer, approximately 20µl of prepared sample is delivered to the tube, where a meniscus naturally forms at each end of the tube. The tube is positioned so that the lower meniscus partially blocks light traveling from a collimated source toward a photodiode.

During testing, a piezoelectric actuator drives the measurement cell(s) through a motion profile composed of summed sinusoids at different frequencies. The profile has a maximum amplitude of under 10µm and contains frequencies from 10-500Hz. Some, but not all, of the measurement cell motion will induce motion in the sample meniscus, which will be detected by the photodiode. The resulting motion of the meniscus is monitored optically and recorded by the analyzer to calculate the resonant frequency and modulus of elasticity (stiffness) of the sample. By performing a Fast Fourier Transform (FFT) on meniscus motion data, it is possible to determine the frequencies of input motion that caused the greatest deflection of the sample (these are called the resonant frequencies).

Resonance is the tendency of a material or structure to oscillate with greater amplitude at some frequencies than others. The exact frequencies at which resonance occurs will depend on the stiffness and mass of the sample. Stiffness, in turn, is a function of a material's modulus of elasticity and the boundary conditions to which the material is exposed, such as the geometry and materials of a test cell. By holding these boundary conditions and sample mass constant from run to run, the CORA System allows direct comparison of elasticity between samples.

In a typical test, blood that has been delivered to the measurement cell will not clot for several minutes. During this time the sample has no inherent stiffness except that provided by surface tension, and since this remains constant the measured resonant frequencies will not change. Once clotting begins, however, the elastic modulus and thus the resonant frequencies increase rapidly. During fibrinolysis, the process is reversed, with elastic modulus and resonant frequencies decreasing. In tests where clotting does not occur, the resonant frequency of the sample will not change. During coagulation, however, a clot will bind to the test tube (ring) and the resonant frequency will rise with increasing firmness of the clot. The

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CORA Analyzer collects meniscus motion data, tracks changing resonant frequencies and analyzes the frequency data to provide semi-quantitative parameters describing the clot. Results are presented in a format similar to the TEG 5000.

Both the TEG 5000 and CORA System monitor the elastic modulus of clots. Method Comparison testing has been performed, yielding data from approximately 300 patients from three sites (Mayo Clinic, University of Pittsburgh Medical Center, and Sinai Hospital, Baltimore). These data include all applicable parameters from the four citrated tests (CK, CKH, CRT and CFF). The TEG 5000 measures the changes of the linkage forces of the clot between the cup and pin over time, while the CORA System measures the changes of the resonant frequency of the clot over time. Despite the difference in the way the two analyzers measure the changes in the modulus of elasticity of the clot over time, they measure the same physical phenomenon and produce the same result when converted from their specific units of measurement (forces for the TEG5000 and frequency for the CORA System) to millimeters. The fact that these results are similar across all reagents used in both technologies is demonstration that the two technologies measure the same phenomenon, the changes in elastic modulus.

The following definitions apply to calculated parameters in the CORA System:

CORA Parameter	Definition	Parameter Relation to Hemostasis
R	R is the time from the start of the test until initial fibrin formation. This represents the enzymatic portion of coagulation.	Normal / reduced / increased speed of coagulation initiation
K	K is the time after R needed to reach a certain level of clot strength. This represents clot kinetics.	Normal / reduced / increased speed of coagulation amplification and propagation
Alpha α (angle)	Alpha is the angle representing the rate increase in the clot strength and the rapidity of fibrin build-up and cross-linking.	Normal / reduced / increased speed of coagulation amplification and propagation
MA	MA, or Maximum Amplitude, represents the maximum firmness of the clot during the test.	Normal / reduced / increased clot elasticity/strength
FLEV	FLEV is an estimate of the fibrinogen level in the blood sample.	Estimated Functional Fibrinogen Level

Citrated Assays

The CK assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle), and Maximum Clot Strength (MA). K and Alpha are complementary parameters and should be used in conjunction with Clotting Time (R) and Maximum Clot Strength (MA).

The CRT assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via both the intrinsic and extrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CFF assay is a semi-quantitative *in vitro* diagnostic assay for monitoring hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. CFF is used in conjunction with CK and clotting characteristics are described by the functional parameter Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

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The CKH assay is a semi-quantitative *in vitro* diagnostic assay used in conjunction with the CORA System to monitor the effects of heparin in the blood stream of a patient. CKH is used in conjunction with CK and heparin influence is determined by comparing Clotting Times (R) between the two tests.

Wet Quality Control (WQC)

Abnormal Wet Quality Control (WQC) material consists of bovine plasma with buffers and stabilizers, and is used instead of hypocoagulable blood, in conjunction with the Citrated Multichannel system cartridge. When used with the Citrated Multichannel cartridge, this material provides consistent and repeatable values for CORA parameters to confirm reagent quality and viability.

INTENDED USE AND INDICATIONS FOR USE`

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The CORA System records the kinetic changes in a sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARING THE CORA SYSTEM TO THE TEG 5000 PREDICATE DEVICE

Table of Similarities

Item	TEG® 5000 Predicate	CORA® System
Analyzer		
Technological Purpose	Monitoring the response of a clot to low levels of applied strain	Monitoring the response of a clot to low levels of applied strain
What is measured	Changes in clot elasticity over time	Changes in clot elasticity over time
Initial Warm Up Time	5 min	5 min
Time to Complete a Test	Varies with assay	Same as TEG 5000
Assays and Reagents		
Intrinsic Contact Activation Reagent (CK)	Kaolin and $CaCl_2$	Kaolin and $CaCl_2$, same materials as TEG 5000
Intrinsic Contact Activation Reagent with Heparinase for heparin reversal (CKH)	Kaolin and $CaCl_2$ with Heparinase	Kaolin, Heparinase and $CaCl_2$, same materials as TEG 5000
Citrated RapidTEG (CRT) (Tissue Factor and Kaolin Activation)	Tissue Factor (TF), Kaolin and $CaCl_2$	Tissue Factor (TF), Kaolin and $CaCl_2$, same materials as TEG5000

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Item	TEG® 5000 Predicate	CORA® System
Citrated Functional Fibrinogen (CFF) / Platelet-Blocked (Tissue Factor Activation)	ReoPro® ,Tissue Factor and $CaCl_2$, same materials as CORA	ReoPro®, Tissue Factor and $CaCl_2$, same materials as TEG 5000
Calcium Chloride Reagent (CC) (for re-calcification)	$CaCl_2$ reagent	$CaCl_2$ same materials as TEG 5000
Quality Control Material (WQC Abnormal Control)	TEG coagulation control – Level II	TEG coagulation control – Abnormal, same materials as TEG 5000

Table of Differences

Item	TEG® 5000 Predicate	CORA® System
Analyzer	Thrombelastography analyzer, separate computer and software	Fully integrated Thrombelastography analyzer
Measuring Technique	Direct-contact measurement of shear elasticity of a coagulating sample	Non-contact measurement of shear elasticity of a coagulating sample
Measuring Channels	Two, each independent and interchangeable (can be used with any approved reagent)	Four, each independent and interchangeable (can be used with any approved reagent)
Signal Transducer	Electromechanical detection (rotary variable inductive transformer) of rotary motion of a pin suspended in the sample	Optical detection (silicon photodiode) of the motion of a free surface of the sample
Temperature Control	20° to 40°C	20° to 50°C
Sample Volume (per channel)	360-380 µl	63 µl
Total Reaction Volume (single channel)	360-380 µl	20 µl
Mains Supply Voltage	120V, 60Hz and 220V, 50Hz model available	100-240V, 50-60Hz (international power supply)
Analyzer Input Voltage	24 volts AC, 30 watts max	12 volts DC, 60 watts max
Environment	Level and vibration free position, no solar radiation Operating temperature: 10° to 35 °C Storage Temperature: -30° to +50 °C (analyzer only) Relative humidity 20-80% (non-condensing)	Stable and level surface. Operating Temperature 10° to 32°C Storage Temperature: -20° to 50°C (analyzer only) Relative humidity 20 to 80% (non-condensing)
Sample Preparation	Performed by the operator using pipettes to reconstitute reagents and mix reagents with the sample	Performed under analyzer control within the disposable cartridge

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Item	TEG® 5000 Predicate	CORA® System
Pipetting	Manual accurate pipettes (10, 20, 50, 100, 340, 360, 500, 1000µl)	Unmetered transfer pipette or syringe; blood sample is added until it fills to a level above the line marked on the blood intake well of the cartridge
Consumables	Cups & Pins (acrylic plastic)	Carrier (acrylic plastic) with microfluidics laminate and test rings (acrylic plastic)

SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Analytical Precision

Testing was performed in Coramed's laboratory for precision, using CLSI EP5-A2 as guidance. Acceptance criteria for all reagents are: CV ≤ 15% for the R parameter, CV ≤ 25% for the K parameter, and CV ≤ 10% for the Alpha and MA parameters. Three types of donor citrated whole blood (CWB) were used in this precision testing:

- Hypo (donors with natural coagulation levels of R parameter near the upper limit of the reference range and MA parameter near the lower limit of the reference range);
- Normal (donors with natural coagulation levels of R and MA parameters near the center of the reference ranges):
- Hyper (donors with natural coagulation levels of R parameter near the lower limit of the reference range and MA parameter near the upper limit of the reference range

Testing was performed with blood draws from three donors (one Hypo, one Normal, and one Hyper) on each of five days (non-consecutive). Testing was performed by two operators using three reagent lots and twelve analyzers, two replicates. The structure of this precision test is shown below.

Sample Type (Hypo, Normal or Hyper)												
	Day 1 (Total of 5 days)											
Operator	Operator 1						Operator 2					
Reagent lot	1		2		3		1		2		3	
Analyzer	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2

Structure of Precision Testing

Precision test estimates by test, parameter and donor sample test level are shown in the table on the following page. All acceptance criteria were met.

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Test	Parameter	Level	n	Mean	Reagent Lot		Operator*		Analyzer (within Operator, Reagent Lot)		Day (within Analyzer, Operator, Reagent Lot)		Repeatability		Total		Total without Day (Within Day)	
					SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
CFF	FLEV	Hypo	120	269.8	2.36	0.9%	0	0.0%	0	0.0%	5.32	2.0%	5.87	2.2%	8.27	3.1%	6.33	2.3%
CFF	FLEV	Normal	120	376.8	0	0.0%	2.25	0.6%	0	0.0%	5.49	1.5%	3.98	1.1%	7.15	1.9%	4.57	1.2%
CFF	FLEV	Hyper	120	597.4	0	0.0%	0	0.0%	0	0.0%	49.38	8.3%	9.62	1.6%	50.31	8.4%	9.62	1.6%
CFF	MA	Hypo	120	14.8	0.11	0.8%	0	0.0%	0	0.0%	0.29	2.0%	0.33	2.2%	0.45	3.0%	0.35	2.3%
CFF	MA	Normal	120	20.6	0	0.0%	0.13	0.6%	0	0.0%	0.3	1.5%	0.22	1.1%	0.39	1.9%	0.25	1.2%
CFF	MA	Hyper	120	32.7	0	0.0%	0	0.0%	0	0.0%	2.71	8.3%	0.53	1.6%	2.76	8.4%	0.53	1.6%
CKH	R	Hypo	120	8.2	0	0.0%	0	0.0%	0.18	2.2%	0.36	4.3%	0.76	9.2%	0.86	10.0%	0.78	9.5%
CKH	R	Normal	120	6.0	0	0.0%	0.05	0.9%	0.09	1.6%	0.14	2.3%	0.42	7.1%	0.46	7.7%	0.44	7.3%
CKH	R	Hyper	120	4.9	0	0.0%	0.05	1.1%	0	0.0%	0.28	5.7%	0.5	10.0%	0.58	12.0%	0.5	10.0%
CK	Angle	Hypo	120	68.7	0	0.0%	1.09	1.6%	0	0.0%	1.61	2.3%	3.01	4.4%	3.59	5.2%	3.2	4.7%
CK	Angle	Normal	120	72.1	0	0.0%	0	0.0%	0	0.0%	1.14	1.6%	1.73	2.4%	2.07	2.9%	1.73	2.4%
CK	Angle	Hyper	120	76.7	0	0.0%	0	0.0%	0	0.0%	1.84	2.4%	1.77	2.3%	2.56	3.3%	1.77	2.3%
CK	K	Hypo	120	1.8	0.03	1.9%	0.06	3.6%	0	0.0%	0.13	7.2%	0.18	10.0%	0.23	13.0%	0.19	11.0%
CK	K	Normal	120	1.4	0	0.0%	0	0.0%	0	0.0%	0.09	6.7%	0.16	12.0%	0.19	13.0%	0.16	12.0%
CK	K	Hyper	120	0.9	0	0.0%	0	0.0%	0	0.0%	0.12	12.0%	0.18	20.0%	0.22	23.0%	0.18	20.0%
CK	MA	Hypo	120	52.4	0.33	0.6%	0.55	1.0%	0.26	0.5%	0.83	1.6%	0.77	1.5%	1.33	2.5%	1.03	2.0%
CK	MA	Normal	120	59.4	0	0.0%	0.5	0.8%	0.48	0.8%	0.57	1.0%	0.86	1.4%	1.24	2.1%	1.1	1.9%
CK	MA	Hyper	120	68.0	0	0.0%	0.2	0.3%	0	0.0%	0.9	1.3%	0.52	0.8%	1.06	1.6%	0.56	0.8%
CK	R	Hypo	120	8.9	0	0.0%	0.29	3.3%	0	0.0%	0.64	7.1%	0.85	9.5%	1.1	12.0%	0.9	10.0%
CK	R	Normal	120	6.5	0	0.0%	0	0.0%	0	0.0%	0.28	4.3%	0.49	7.6%	0.56	8.7%	0.49	7.6%
CK	R	Hyper	120	5.2	0.13	2.5%	0	0.0%	0	0.0%	0.31	5.8%	0.66	13.0%	0.74	14.0%	0.67	13.0%
CRT	MA	Hypo	120	52.4	0.39	0.7%	0.22	0.4%	0	0.0%	0.92	1.8%	0.59	1.1%	1.18	2.3%	0.74	1.4%
CRT	MA	Normal	120	62.7	0	0.0%	0.15	0.2%	0.14	0.2%	0.37	0.6%	0.31	0.5%	0.52	0.8%	0.37	0.6%
CRT	MA	Hyper	120	69.4	0	0.0%	0	0.0%	0	0.0%	0.91	1.3%	0.2	0.3%	0.93	1.3%	0.2	0.3%

*Operator = Operator + operator-by-reagent lot interaction

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In addition, Coramed's Citrated Reagent Precision Protocol Rev. 02 was written to supplement precision data originally provided to FDA in 510(k) K150041. This protocol specifies testing to be performed outside of reference range values but within the Analytical Measurement Range (AMR) limits. This report presents data and statistics resulting from the execution of this protocol.

The following pages contain tables of precision statistics. Table 1 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from normal donors but spiked to achieve hypocoagulable (hypo) and hypercoagulable (hyper) results. Three donors for each reagent-parameter and spiking type were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each donor-reagent-parameter-hypo/hyper type, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B
Sample	Hypercoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

The focus of this study was on achieving values for the primary coagulation parameters R, MA and FLEV outside the reference ranges but within AMR limits, and taking the resulting K and Alpha (angle) values as is. Total Precision %CV values were all within pre-established limits, except for one CFF MA hypo outcome (11.6% for a limit of 10%) and 2 outcomes for Angle. The K and Angle parameters indicate the kinetics of the clotting process, and are not clinically significant as the main parameters representing coagulation, platelet and fibrinogen activities and abnormalities. The CFF MA CV% is higher because the MA value is small (mean of 6.5 mm) and although the Standard Deviation is very small (0.8mm) the resulting CV% is just over the limit. When the SD is so small there is no clinical significance for the differences making this CV% acceptable.

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Table 2 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from patients taking anticoagulants Dabigatran and Warfarin. Four Dabigatran patients and two Warfarin patients for each reagent-parameter were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each patient-reagent-parameter, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1		2		3		4		5		6	
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

Results for this testing were generally within limits, except for a few minor exceptions. As the data shows, all the MAs, for CK, CRT, and CFF, are within the specified expected CV% across the board while for the R parameter, there are no significant differences between lots, operators and devices and the only CVs (for CK and CKH – R parameter) somewhat exceeding 15% come from repeatability (16.9% for MH-DB003 for CK and 15.9% for MH-DB004 for CKH). Even though the, K and Angle are not parameters that are considered clinically significant the raw data indicates that the single angle CV% that is above the limit was due to an outlier while the K parameter has high CVs due to the fact that elongated coagulation results in higher CVs for that parameter.

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Test	Param	Spiking	Patient ID	N	Mean	Lot		Operator		Instrument		Repetition		Total	
						StDev	CV	StDev	CV	StDev	CV	StDev	CV	StDev	CV
CK	R	hyper	D101	12	2.1	0	0	0	0	0.1	4.5	0.1	3.1	0.1	5.5
CK	R	hyper	D108	12	2.7	0	0	0	1	0.1	3.5	0.1	2.4	0.1	4.3
CK	R	hyper	D169	12	2.2	0.1	2.8	0	0	0.1	3.1	0.1	2.5	0.1	4.6
CK	R	hypo	D141	12	16.1	0	0	1.1	6.9	1.3	8	0.7	4.3	1.7	10.8
CK	R	hypo	D169	12	15.3	0.8	5.3	0	0	1.6	10.2	1.1	7.1	2	13.2
CK	R	hypo	D108	12	12.1	0.1	1	0.1	0.9	0.9	7.2	0.7	5.6	1.1	9.3
CK	K	hyper	D101	12	0.5	0	0	0	0	0	3.9	0	4.1	0	5.7
CK	K	hyper	D108	12	0.4	0	3.8	0	3.8	0	7.2	0	6.5	0	10.7
CK	K	hyper	D169	12	0.5	0	0	0	0	0	8.2	0	8.2	0.1	11.6
CK	K	hypo	D141	12	3	0.2	5.2	0.2	6	0.3	9.9	0.2	8.2	0.4	14.6
CK	K	hypo	D169	12	3.1	0.5	16.4	0	0	0.5	14.8	0.3	10	0.7	22.7
CK	K	hypo	D108	12	2.2	0	0	0.1	6.4	0.3	12	0.1	6.2	0.3	14.6
CK	Angle	hyper	D101	12	80	0.8	1.1	1.5	1.8	7.2	9	6.9	8.7	10.1	12.6
CK	Angle	hyper	D108	12	85.1	0.1	0.2	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hyper	D169	12	84.3	0.1	0.1	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hypo	D141	12	54.7	0	0	0	0	8.4	15.4	5.4	9.9	10	18.3
CK	Angle	hypo	D169	12	42.7	1	2.4	1.9	4.5	1.8	4.3	1.6	3.7	3.1	7.2
CK	Angle	hypo	D108	12	66.7	3	4.4	0	0	4.8	7.2	3.3	5	6.3	9.5
CK	MA	hyper	D108	12	71.6	0	0	0.5	0.7	0.3	0.4	0.3	0.4	0.5	0.8
CK	MA	hyper	D169	12	70	0	0	0.1	0.1	0.2	0.2	0.1	0.2	0.2	0.3
CK	MA	hyper	D121	12	71.1	0	0	0	0	0.9	1.3	0.6	0.8	1.1	1.5
CK	MA	hypo	D141	12	42	0.2	0.6	0	0	1.5	3.5	0.9	2.1	1.7	4.1
CK	MA	hypo	D169	12	46.6	0	0	0	0	0.8	1.8	0.5	1.1	1	2.1
CK	MA	hypo	D108	12	45.4	0	0	0.8	1.8	1.2	2.7	0.9	2	1.7	3.7
CKH	R	hyper	D101	12	2	0.1	4.8	0	0	0	2.4	0.1	2.8	0.1	5.5
CKH	R	hyper	D108	12	2.6	0	0	0	0	0.1	2.6	0	1.6	0.1	3.1
CKH	R	hyper	D169	12	2.2	0	0	0	0	0	1.5	0	1	0	1.8
CKH	R	hypo	D141	12	15.7	0	0	1	6.4	0.7	4.5	0.6	4.1	1.3	8.2
CKH	R	hypo	D169	12	14.5	0	0	0.8	5.2	0.8	5.7	0.5	3.2	1.1	7.9
CKH	R	hypo	D108	12	12.3	0.6	5	0	0	0.8	6.3	0.5	4.4	1.1	8.8
CRT	MA	hyper	D108	12	70.8	0.2	0.3	0	0	0.1	0.2	0.1	0.2	0.2	0.3
CRT	MA	hyper	D121	12	72.5	0.2	0.3	0	0	0.4	0.5	0.4	0.5	0.5	0.8
CRT	MA	hyper	D145	12	73	0.2	0.2	0	0	0.2	0.3	0.2	0.2	0.3	0.4
CRT	MA	hypo	D141	12	41.3	0	0	0	0	0.7	1.8	0.5	1.2	0.9	2.2
CRT	MA	hypo	D169	12	44.4	0	0	0.3	0.7	0.6	1.3	0.4	0.9	0.8	1.7
CRT	MA	hypo	D108	12	45.5	0	0	0.4	0.9	1	2.1	0.5	1.1	1.1	2.5
CFF	MA	hyper	D101	12	49.9	0.1	0.1	0	0	0.5	0.9	0.3	0.5	0.5	1.1
CFF	MA	hyper	D141	12	44.3	0	0	0	0	0.5	1.2	0.3	0.6	0.6	1.3
CFF	MA	hyper	D145	12	47	0	0	0	0	0.7	1.4	0.5	1	0.8	1.7
CFF	MA	hypo	D101	12	10.2	0.2	1.5	0	0	0.3	3	0.2	1.7	0.4	3.6
CFF	MA	hypo	D125	12	9.5	0	0	0.2	1.8	0.4	4	0.3	2.7	0.5	5
CFF	MA	hypo	D169	12	6.5	0	0	0.7	10.1	0.3	4.9	0.4	6	0.8	11.6
CFF	FLEV	hyper	D101	12	910.7	1.2	0.1	0	0	8.6	0.9	5	0.5	10	1.1
CFF	FLEV	hyper	D141	12	809	0	0	0	0	9.6	1.2	5.2	0.6	10.9	1.3
CFF	FLEV	hyper	D145	12	858.1	0	0	0	0	11.9	1.4	8.5	1	14.7	1.7
CFF	FLEV	hypo	D101	12	186.4	2.9	1.5	0	0	5.5	3	3.1	1.7	6.8	3.6
CFF	FLEV	hypo	D125	12	173.4	0	0	3.1	1.8	7	4	4.6	2.6	8.7	5
CFF	FLEV	hypo	D169	12	157.5	1.8	1.2	1.1	0.7	2	1.3	1.7	1.1	3.2	2.1

Spiked Precision – Table 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Test	Param	PatientID	N	Mean	Lot		Operator		Instrument		Repetition		Total	
					StDev	CV	StDev	CV	StDev	CV	StDev	CV	StDev	CV
CK	R	MH-DB001	12	13	0	0	0	0	0.4	3.2	1.2	8.9	1.2	9.4
CK	R	MH-DB002	12	21.3	0	0	0	0	1	4.7	2.1	10.1	2.3	11
CK	R	MH-DB003	12	14.4	0	0	0	0	0	0	2.4	16.9	2.4	16.9
CK	R	MH-DB004	12	11.8	0.5	4	0.5	4.3	0	0	1.6	13.9	1.7	14.8
CK	R	MH-WR001	12	9.9	0.7	7	0.3	2.7	0.3	2.6	0.5	4.9	0.8	8.5
CK	R	MH-WR002	12	10.1	1	10.2	0	0	0.3	3.2	1	10	1.4	13.6
CK	K	MH-DB001	12	1.3	0	0	0	0	0	0	0.2	18.2	0.2	18.2
CK	K	MH-DB002	12	2.4	0	0	0	0	0.4	15.4	1	42	1	44.5
CK	K	MH-DB003	12	1.3	0	0	0	0	0	0	0.3	19.8	0.3	19.8
CK	K	MH-DB004	12	0.9	0.1	11.4	0	0	0	0	0.3	33	0.3	34.4
CK	K	MH-WR001	12	2.2	0	0	0	0	0	0	0.2	8.2	0.2	8.2
CK	K	MH-WR002	12	2	0	0	0	0	0	0	0.4	19.1	0.4	19.1
CK	Angle	MH-DB001	12	72.5	0	0	0	0	0	0	3.6	5	3.6	5
CK	Angle	MH-DB002	12	55.5	0	0	0	0	10.3	18.6	11.6	20.8	15.2	27.4
CK	Angle	MH-DB003	12	72.7	0	0	0	0	0	0	3.2	4.3	3.2	4.3
CK	Angle	MH-DB004	12	79.5	0	0	0	0	0	0	3.4	4.3	3.4	4.3
CK	Angle	MH-WR001	12	65	0	0	0	0	0	0	1.1	1.7	1.1	1.7
CK	Angle	MH-WR002	12	67.1	0	0	1.1	1.6	0	0	3	4.4	3.1	4.6
CK	MA	MH-DB001	12	60.2	0	0	0	0	0	0	0.9	1.5	0.9	1.5
CK	MA	MH-DB002	12	64.5	0	0	0.2	0.4	0	0	0.6	1	0.7	1
CK	MA	MH-DB003	12	64.1	0	0	0.4	0.7	0	0	0.5	0.8	0.7	1
CK	MA	MH-DB004	12	71.9	0.1	0.1	0.5	0.6	0	0	0.5	0.7	0.7	0.9
CK	MA	MH-WR001	12	60.6	0	0	0	0	0	0	0.9	1.4	0.9	1.4
CK	MA	MH-WR002	12	59.7	0	0	0	0	1	1.6	0.8	1.3	1.2	2
CKH	R	MH-DB001	12	12.2	0.8	6.8	0	0	0	0	0.7	5.8	1	8.2
CKH	R	MH-DB002	12	19.3	0	0	1.6	8.4	0	0	2.2	11.4	2.6	13.5
CKH	R	MH-DB003	12	13.5	0	0	0.5	4	0	0	1.4	10.6	1.5	11.1
CKH	R	MH-DB004	12	11.3	0	0	0	0	0	0	1.8	15.9	1.8	15.9
CKH	R	MH-WR001	12	8.4	0	0	0.1	0.8	0	0	0.8	9.7	0.8	9.8
CKH	R	MH-WR002	12	9.1	0.5	5.1	0	0	0	0	0.7	7.4	0.8	8.6
CRT	MA	MH-DB001	12	64.9	0.1	0.1	0	0	0.1	0.1	0.1	0.2	0.1	0.2
CRT	MA	MH-DB002	12	67.7	0.1	0.1	0	0	0	0	0.2	0.2	0.2	0.2
CRT	MA	MH-DB003	12	66	0	0	0	0	0	0	0.1	0.2	0.1	0.2
CRT	MA	MH-DB004	12	73.8	0.1	0.1	0	0	0.1	0.1	0.2	0.2	0.2	0.3
CRT	MA	MH-WR001	12	64	0.1	0.1	0	0	0	0	0.2	0.3	0.2	0.3
CRT	MA	MH-WR002	12	64.7	0	0	0	0	0	0	0.3	0.4	0.3	0.4
CFF	MA	MH-DB001	12	20.7	0.1	0.4	0	0	0.3	1.3	0.1	0.6	0.3	1.4
CFF	MA	MH-DB002	12	23.7	0.3	1.3	0.3	1.4	0	0	0.2	0.7	0.4	1.6
CFF	MA	MH-DB003	12	23.4	0.2	1	0	0	0	0	0.3	1.5	0.4	1.7
CFF	MA	MH-DB004	12	51.9	1.1	2.2	0	0	0	0	0.4	0.8	1.1	2
CFF	MA	MH-WR001	12	20.7	0	0	0	0	0	0	0.4	1.7	0.4	1.7
CFF	MA	MH-WR002	12	24.7	0.1	0.4	0.3	1.2	0	0	0.3	1.3	0.4	1.7
CFF	FLEV	MH-DB001	12	377.3	1.4	0.4	0	0	4.8	1.3	2.4	0.6	5.3	1.4
CFF	FLEV	MH-DB002	12	432.2	5.8	1.3	6.2	1.4	0	0	3	0.7	6.8	1.6
CFF	FLEV	MH-DB003	12	426.5	4.5	1	0	0	0	0	6.2	1.5	7.3	1.7
CFF	FLEV	MH-DB004	12	947.1	20.9	2.2	0	0	0	0	7.5	0.8	19.3	2
CFF	FLEV	MH-WR001	12	377.4	0	0	0	0	0	0	6.5	1.7	6.5	1.7
CFF	FLEV	MH-WR002	12	450	1.6	0.4	5.2	1.2	0	0	6	1.3	7.7	1.7

Patient-Derived Hypo Samples (Dabigatran and Warfarin) – Table 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Interference

Testing was performed in Coramed's laboratory for interference, using CLSI EP7-A2 as guidance.

For CK, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Only Hemolysis and Hemodilution were found to be interferents.

For CRT, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Short Draw, Hemolysis and Hemodilution were found to be interferents.

For CKH, Protamine was tested for interference. Protamine was found to be an interferent for CKH at concentrations above 0.062 mg/ml.

For CFF, potential interferents tested were Na Heparin and Hemodilution. Heparin was found to be an interferent for CFF above Heparin concentrations of 1 IU/ml, and Hemodilution was found to be an interferent above hemodilution levels of 30%.

Linearity

Testing was performed in Coramed's laboratory for linearity, using CLSI EP6-A as guidance.

CFF was tested and found to be linear with varying concentrations of Fibrinogen.

Sensitivity and Specificity

CK was tested for Sensitivity and Specificity with respect to Na Heparin, comparing R parameters of five blood samples with different clinically relevant concentrations of Heparin to five samples without heparin. Both Sensitivity and Specificity were found to be 100%.

Heparin Neutralization

Heparin Neutralization of CKH was tested using blood samples spiked with Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) and comparing these results to data obtained from testing CK with un-spiked blood samples. CKH was found to completely neutralize UFH levels of 6 IU/ml blood and LMWH levels of 0.016 mg/ml blood.

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SUMMARY OF CLINICAL PERFORMANCE DATA

Testing was performed at three clinical sites for Reference Ranges and Method Comparison.

Reference Ranges

Reference Ranges for the CORA assays were estimated using the CLSI C28-A3c Guideline on three reference sample groups. Blood samples from up to 55 normal volunteer subjects were taken at each of the three sites, for a total of 157 samples. There were at least 151 valid results for every parameter for all reagents. Samples were excluded on a per-parameter basis using standard outlier criteria. An alternative method would have been to exclude all parameters for any tests where one or more parameter results were determined to be outliers. However, it was decided to retain all valid parameter results in calculating reference ranges because a larger number of samples adds statistical credibility. Also, it does not appear that using the alternative approach would have any significant effect on the reference ranges. Subjects were chosen representing demographic populations of the three areas, regarding age, race and gender. These reference ranges are shown below.

Reagent ↓	N	R (min)	N	K (min)	N	Angle (deg)	N	MA (mm)	N	FLEV (mg/dl)
CK	157	4.6-9.1	157	0.8-2.1	155	63 - 78	151	52 - 69		
CRT							152	52 - 70		
CKH	155	4.3-8.3								
CFF							151	15 - 32	152	278-581

Reference Ranges for CKH are shown but not usually required because the only purpose is to neutralize the heparin in a patient's blood, regardless of the patient's hemostasis condition. Comparing results from the CK and CKH tests for the R parameter can assist in determining whether or not there is heparin in the blood sample.

Reference Ranges for Wet Quality Control (WQC) Abnormal material when used in CORA assay cartridges were estimated. Using three lots of Abnormal Quality Control and three citrated reagent lots, a total of over 135 test results were obtained.

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (deg)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563-873

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Method Comparison

Method Comparison studies were conducted at three clinical sites on patient samples following CLSI EP09-A3 Guideline. The subjects enrolled were patients undergoing cardiovascular surgery or cardiology procedures, with blood samples drawn pre- and post-surgery and in the ICU. In order to broaden the range of comparison, up to 10% contrived samples were added. Summary statistics are presented below.

Method Comparison Statistics Summary – All Clinical Sites					
Parameter	**R**	**Intercept**	**95% CI**	**Slope**	**95% CI**
CK – R (min)	0.868	-0.325	-0.425	1.069	1.034
			-0.225		1.103
CK – K (min)	0.740	-0.097	-0.292	0.906	0.769
			0.098		1.042
CK – Alpha (deg)	0.680	7.305	-13.160	0.940	0.640
			27.769		1.240
CK – MA (mm)	0.924	2.351	0.166	0.948	0.912
			4.536		0.983
CKH – R (min)	0.812	-0.329	-0.393	1.057	1.026
			-0.265		1.089
CRT|CK – MA (mm)	0.929	-0.126	-1.909	0.978	0.948
			1.656		1.007
CFF – MA (mm)	0.938	-0.774	-1.836	1.126	1.072
			0.289		1.180
CFF – FLEV (mg/dl)	0.928	-12.495	-36.810	1.127	1.059
			11.819		1.194

In addition, a Reader Study was conducted to assess the comparison of CORA System and TEG 5000 results based on reading printed test outcomes. The study was performed at three sites, using three experienced TEG 5000 doctors as readers at each site, for a total of nine readers. 30 test outcomes were compared for each of the reagent test categories, for a total of 270 reading comparisons per reader. Excellent agreement between the two devices was demonstrated.

In both the Method Comparison Study and Reader Study, the CORA RapidTEG (CRT) MA parameter was compared to the TEG 5000 Kaolin (CK) MA parameter, to demonstrate that the CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTING

The data and information provided in this submission support a substantial equivalence determination for the CORA System and the TEG 5000 predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

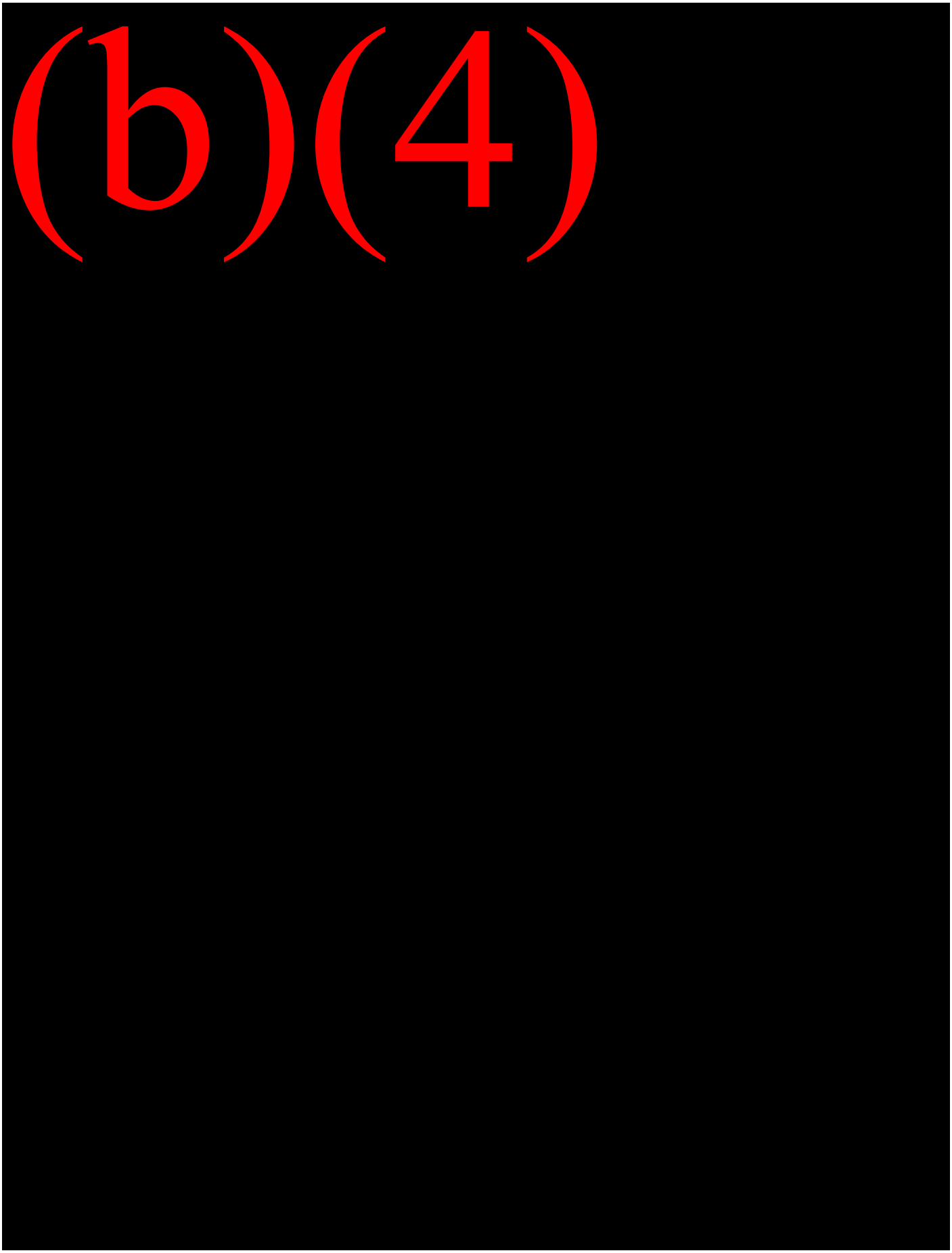
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Section 18: Performance Testing - Bench

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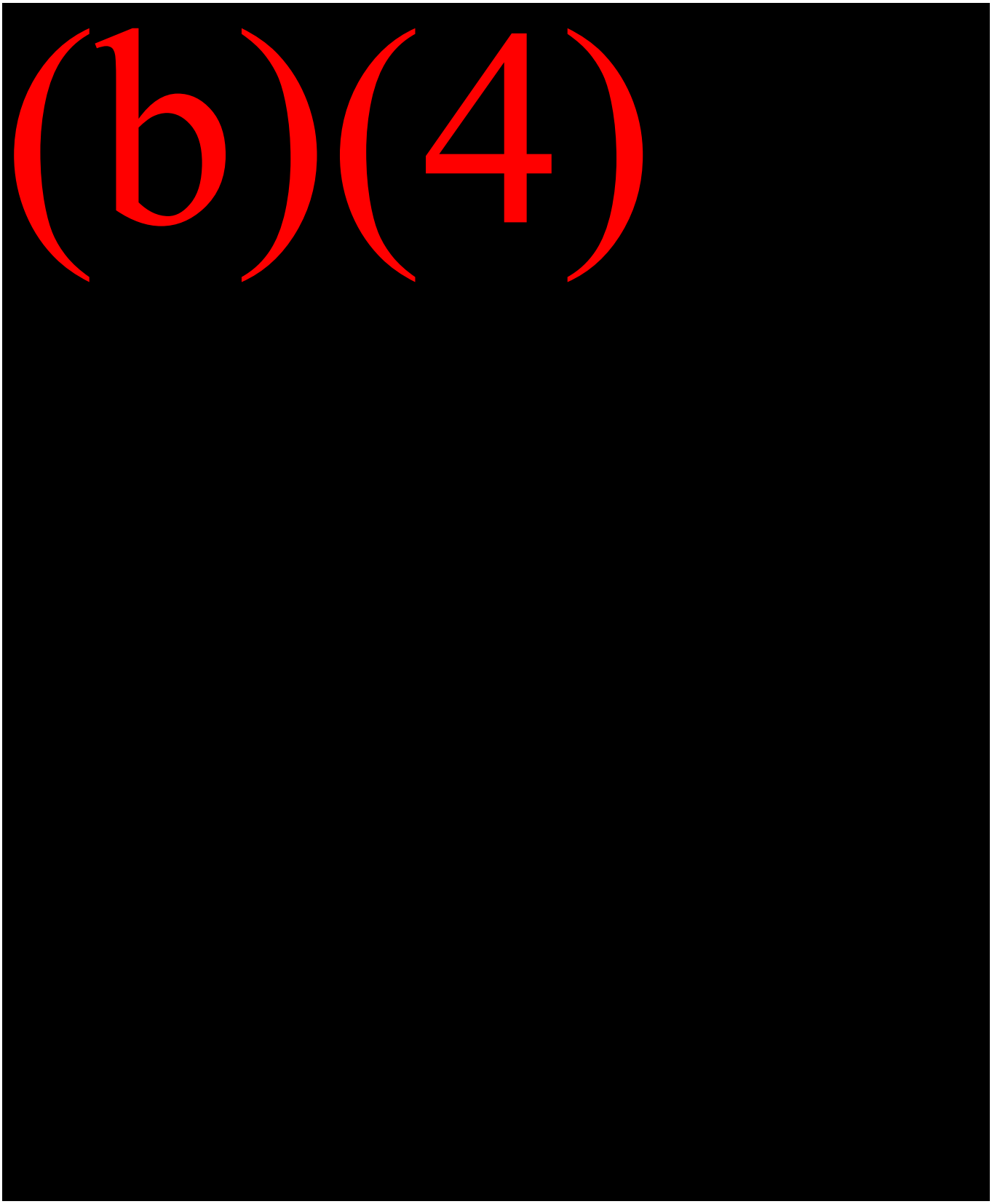
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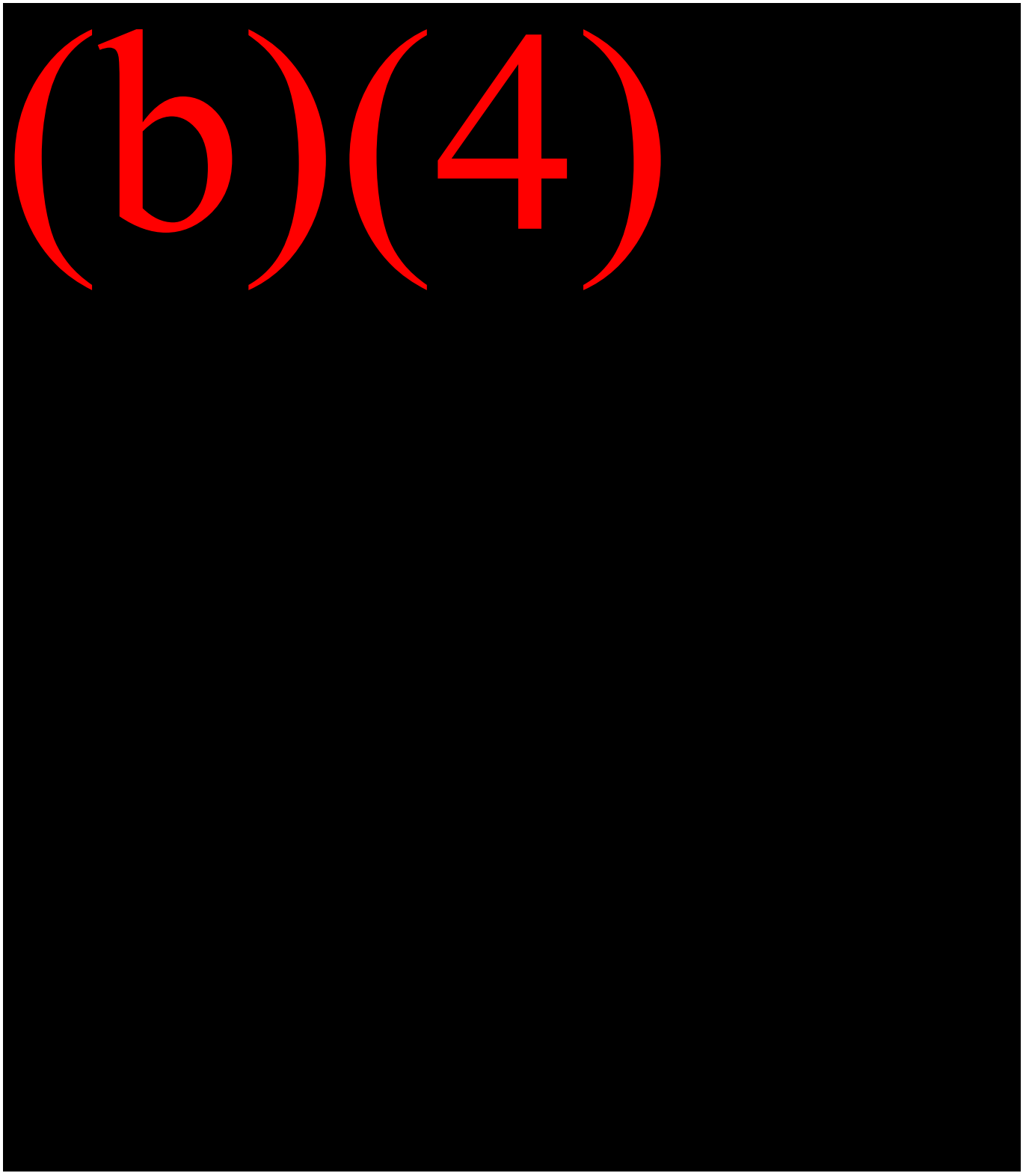
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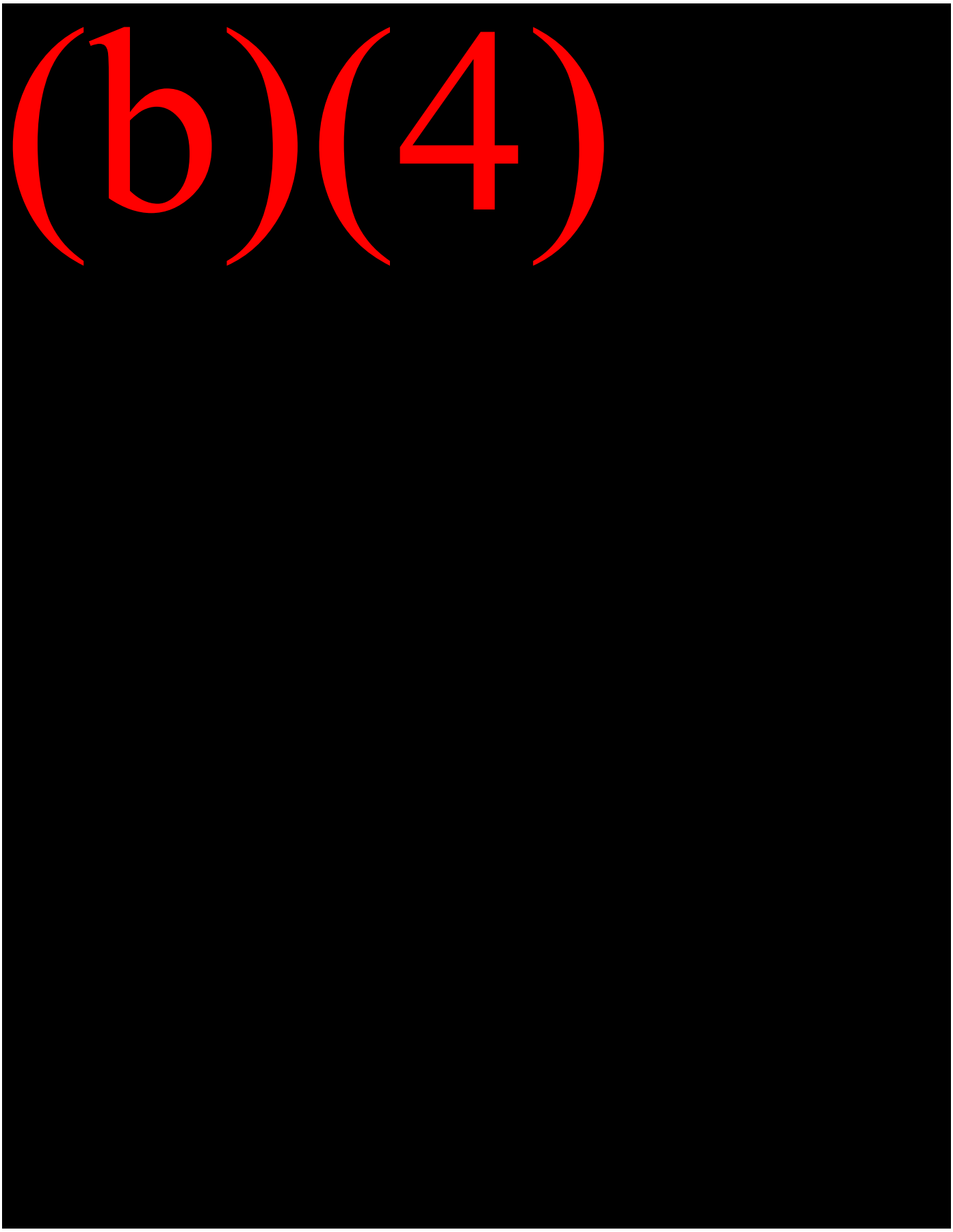
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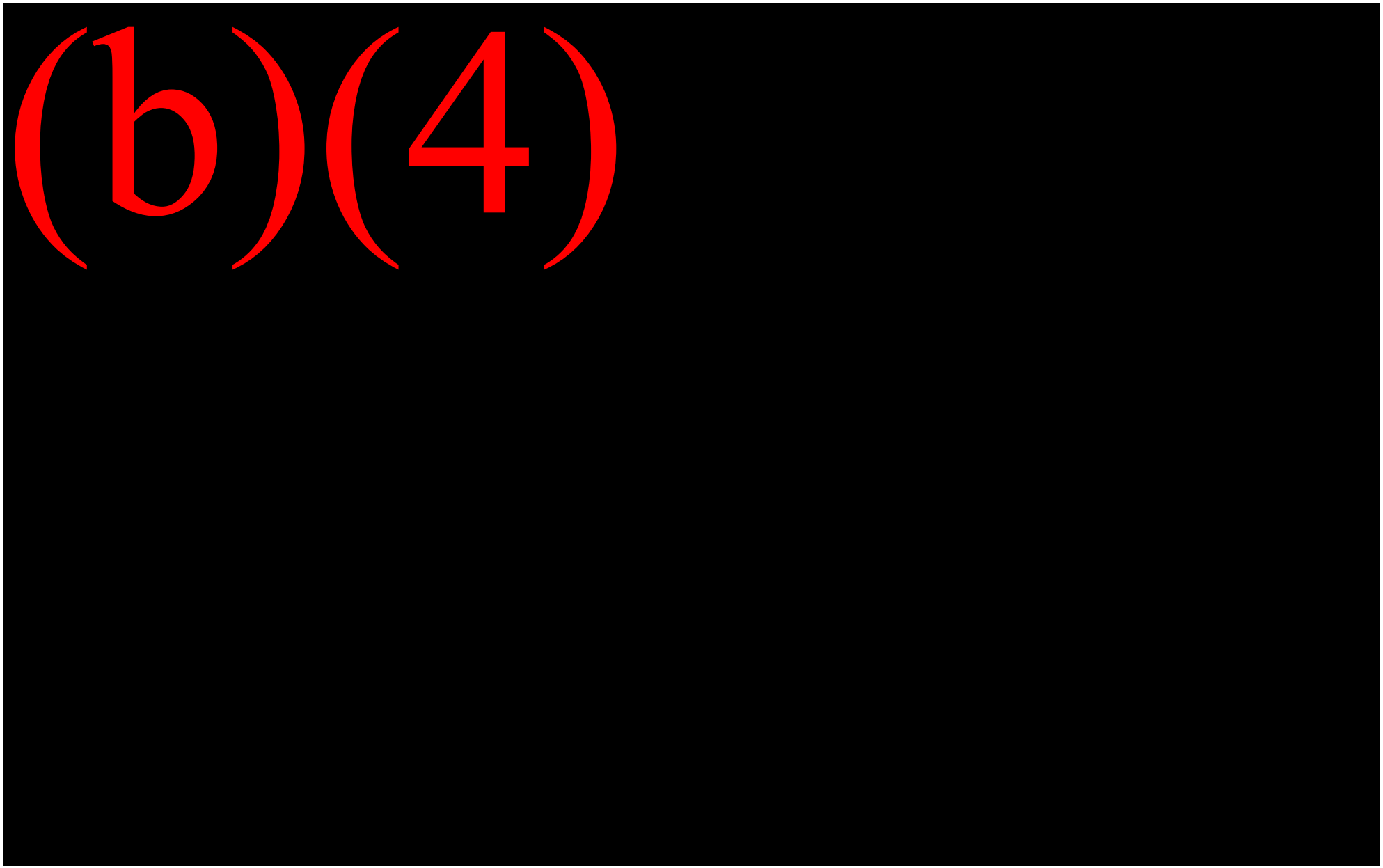
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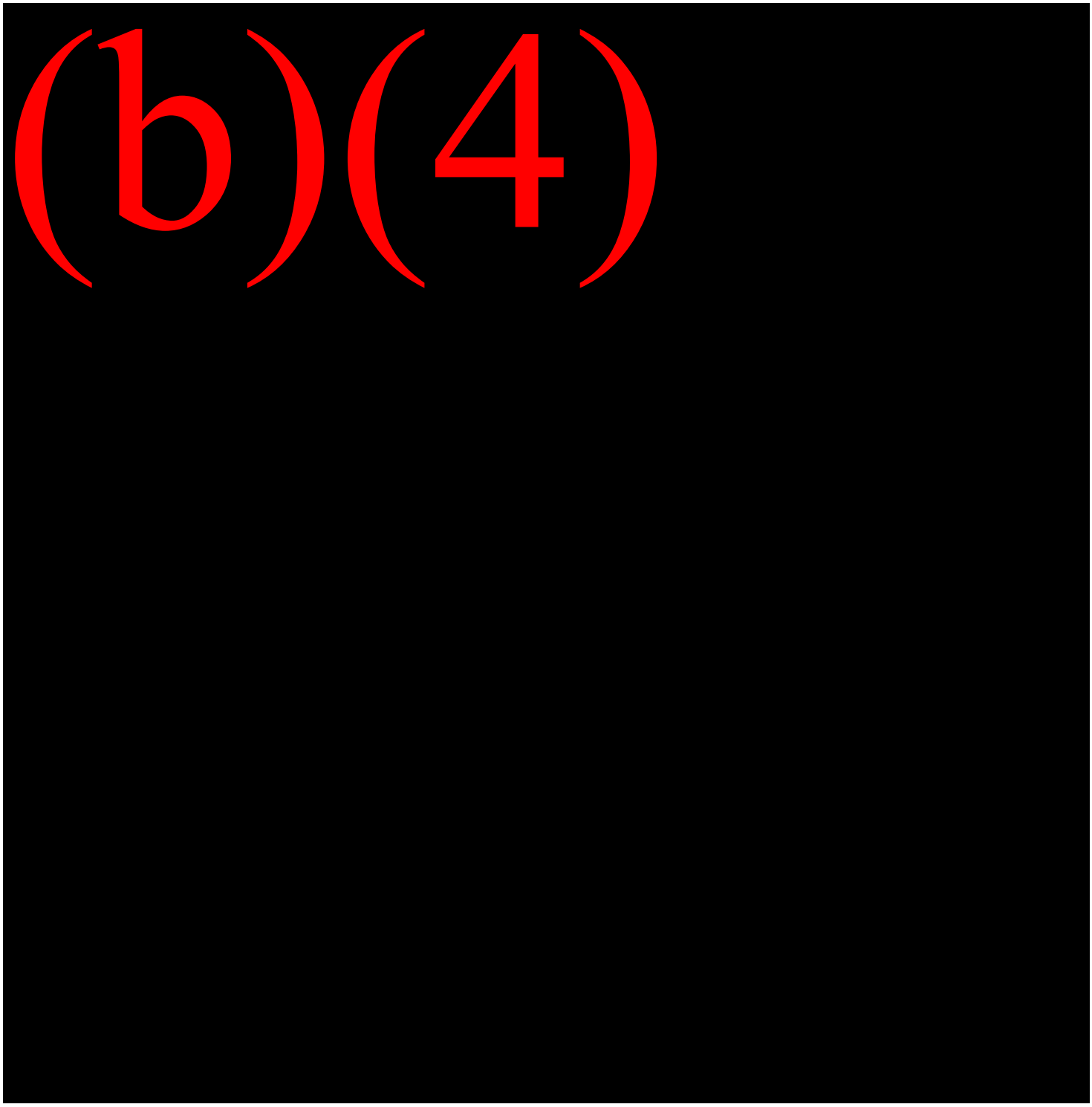
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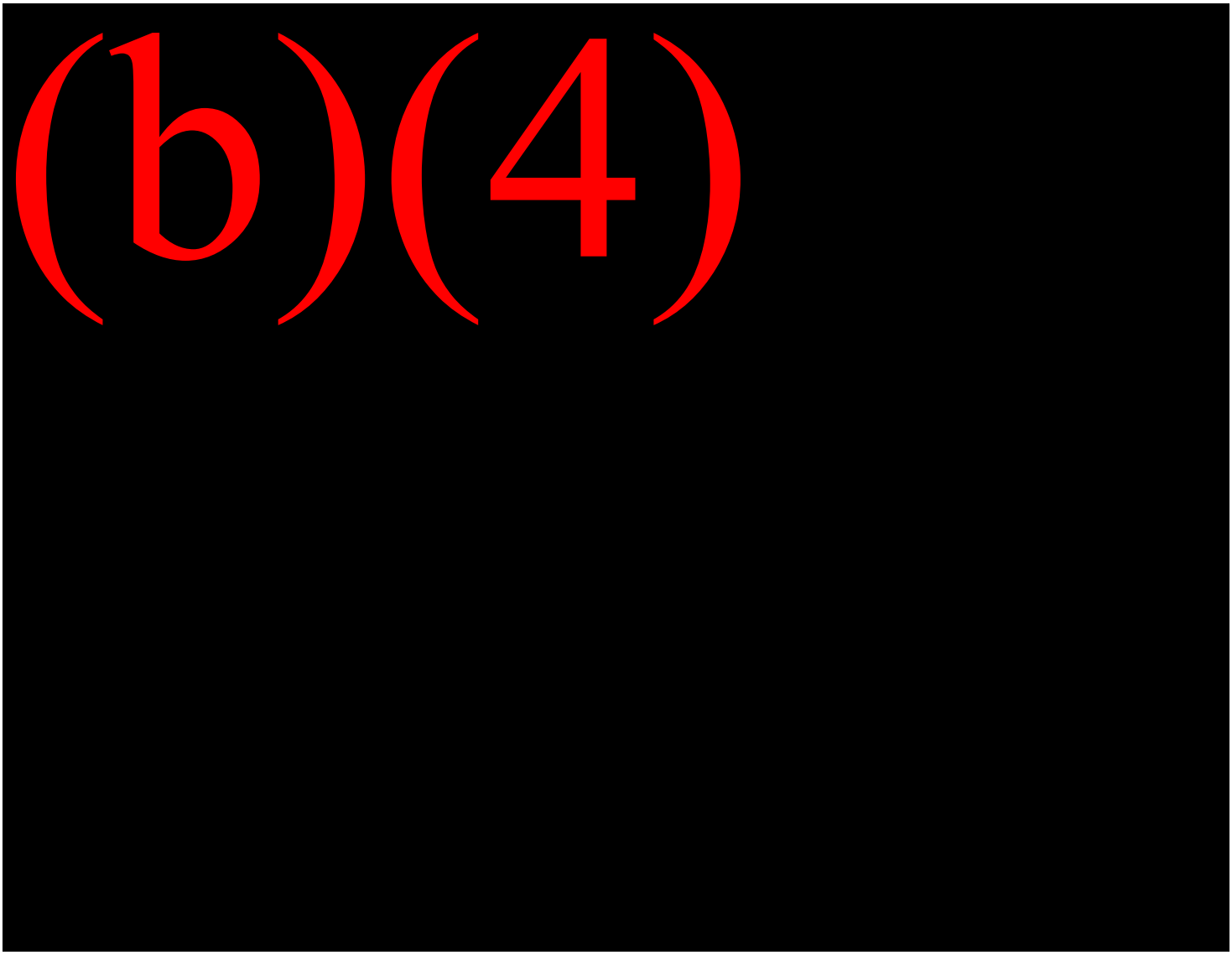


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Section 20: Performance Testing - Clinical

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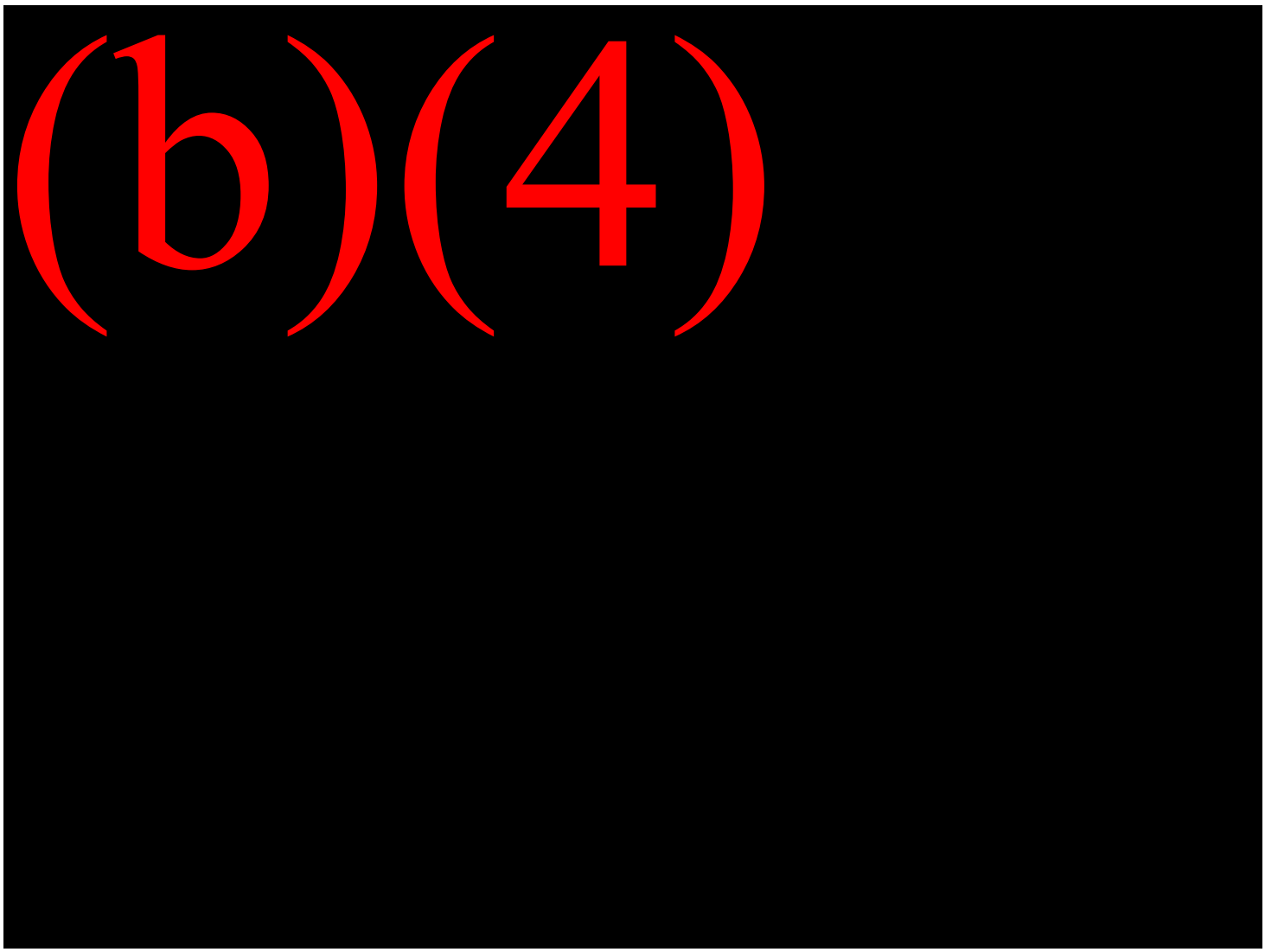
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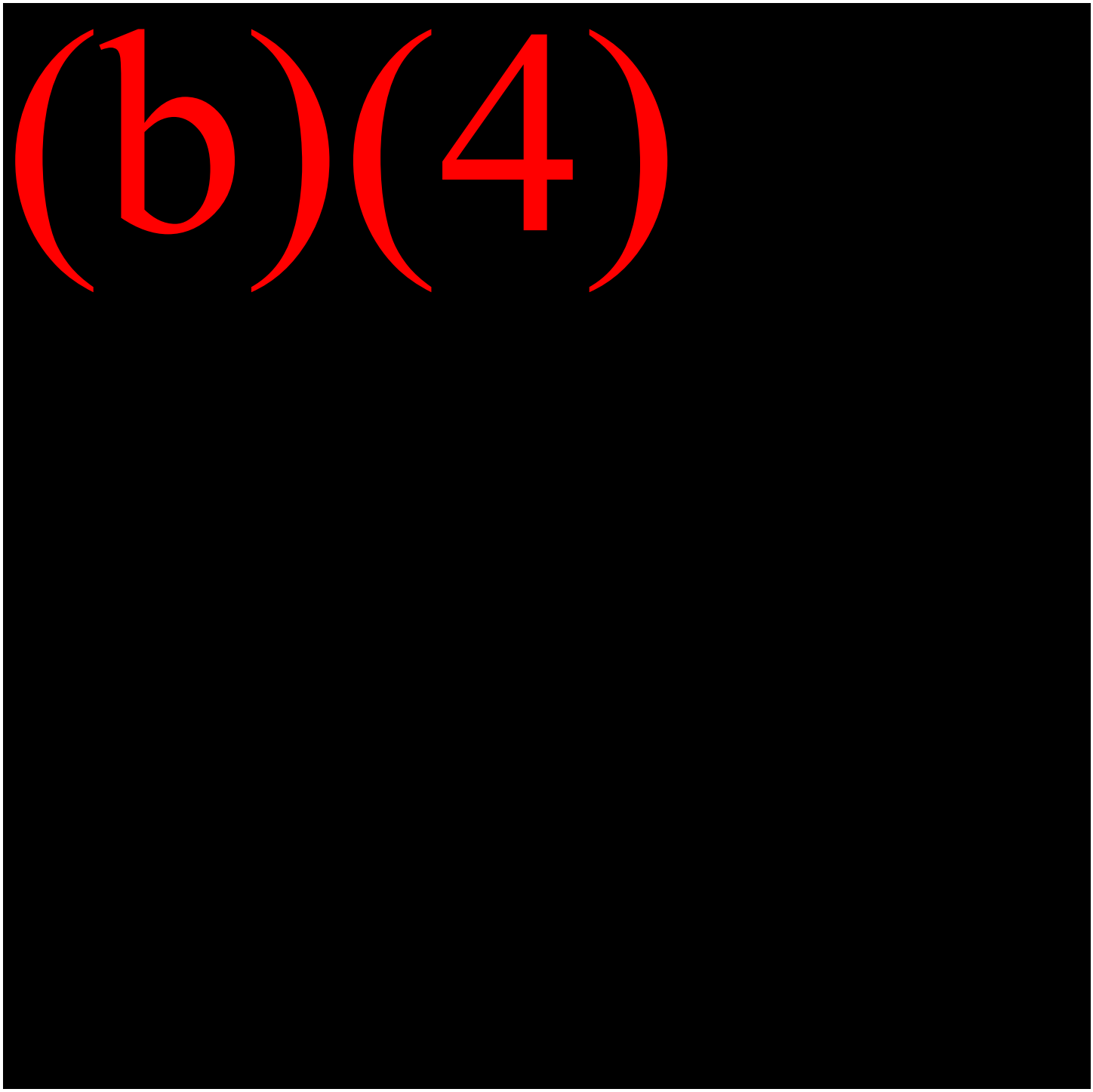
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Reader Study of the CORA® and TEG® 5000 Systems

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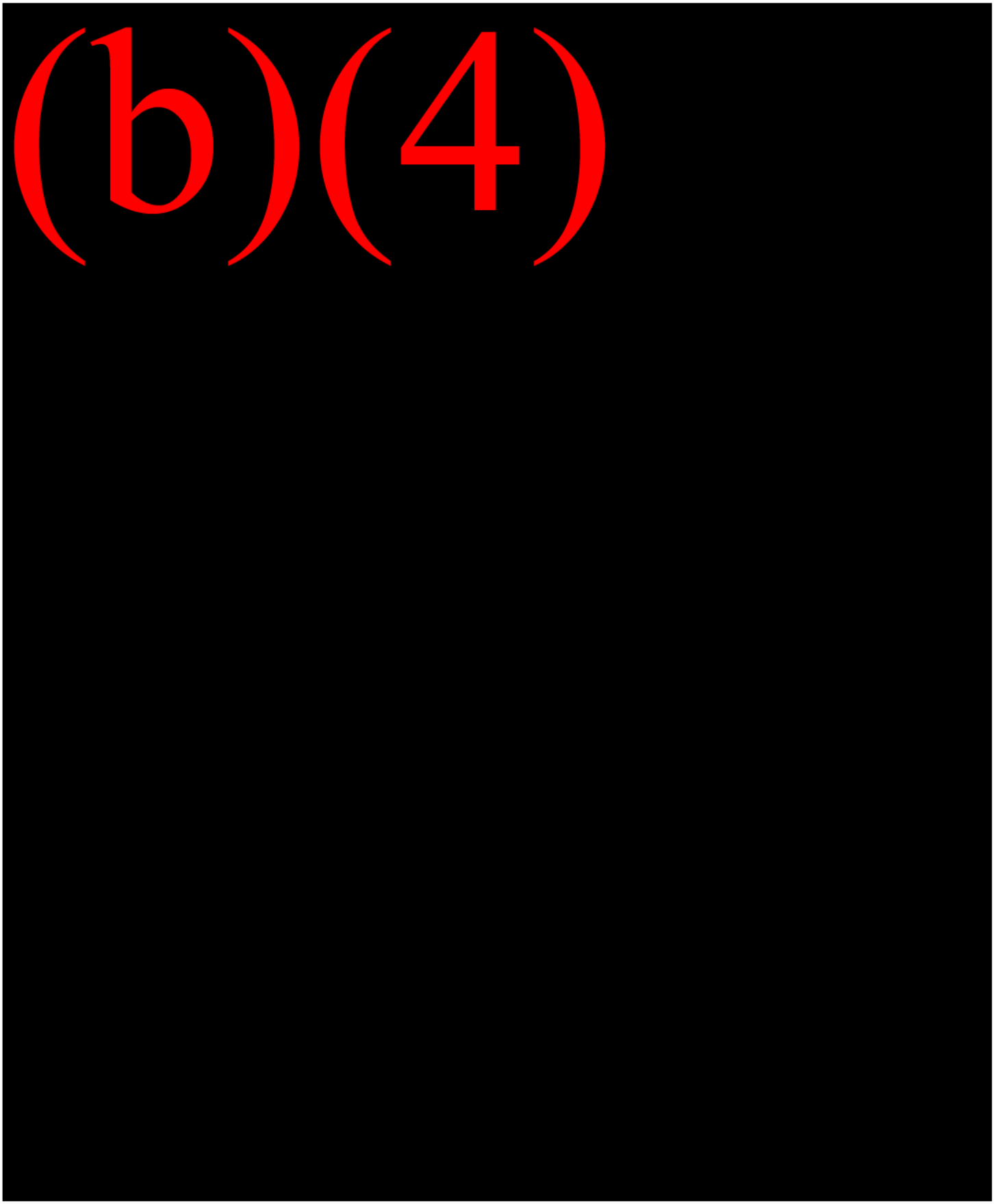
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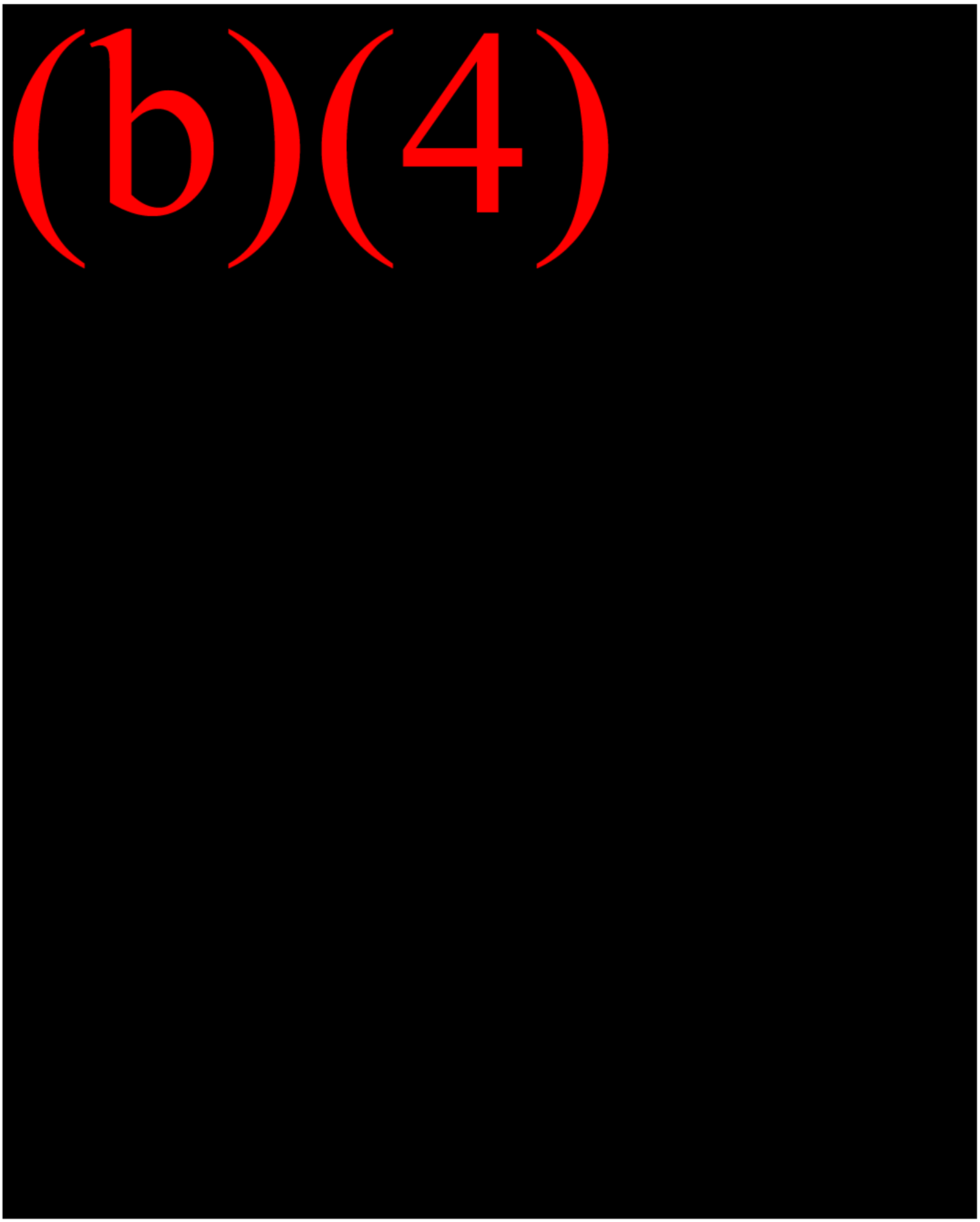
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CORA® and TEG® 5000 Hemostasis Systems – Hemostasis Status Determination

Training program for Coramed-sponsored Reader Study, Protocol (b)(4)

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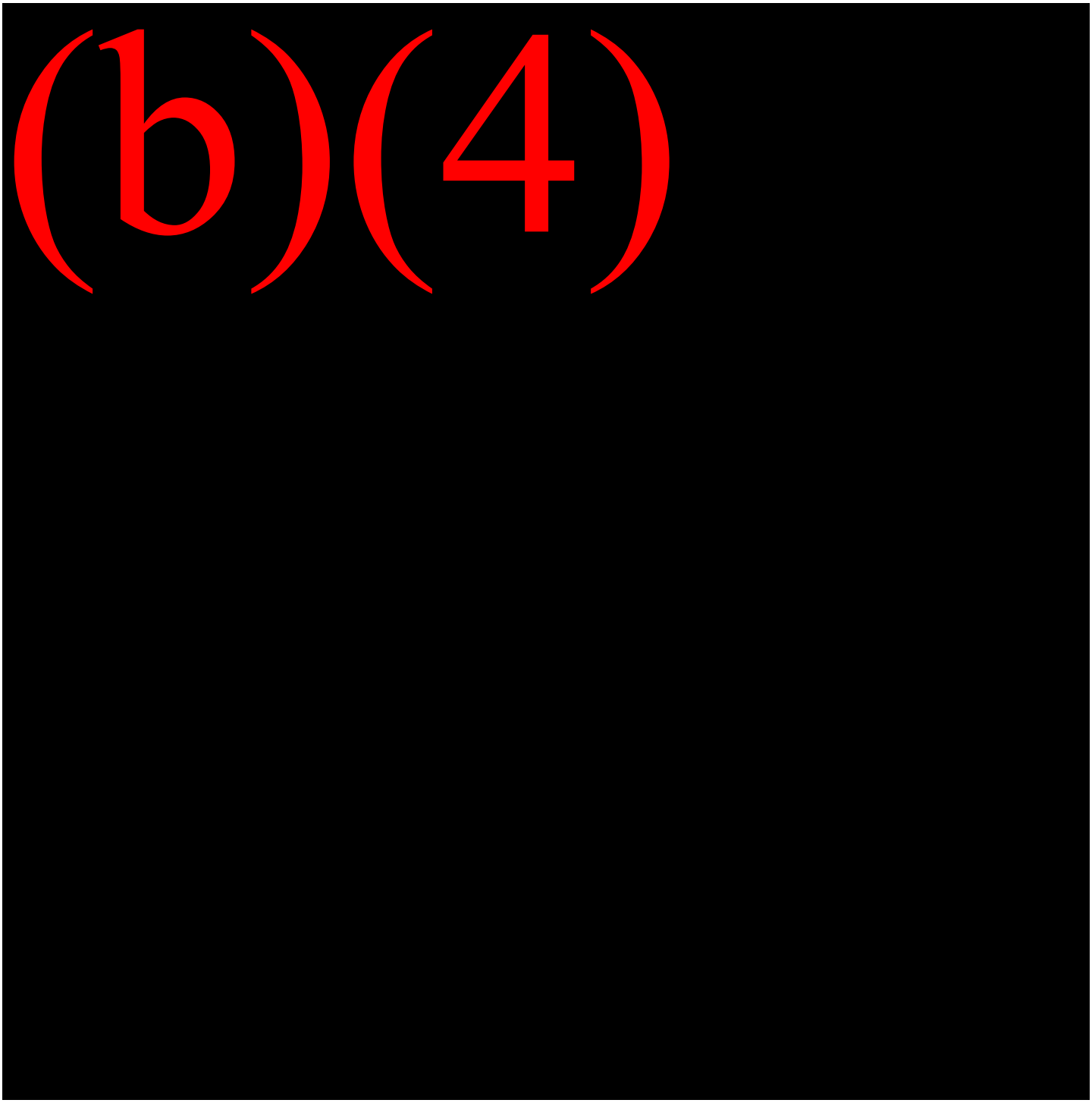
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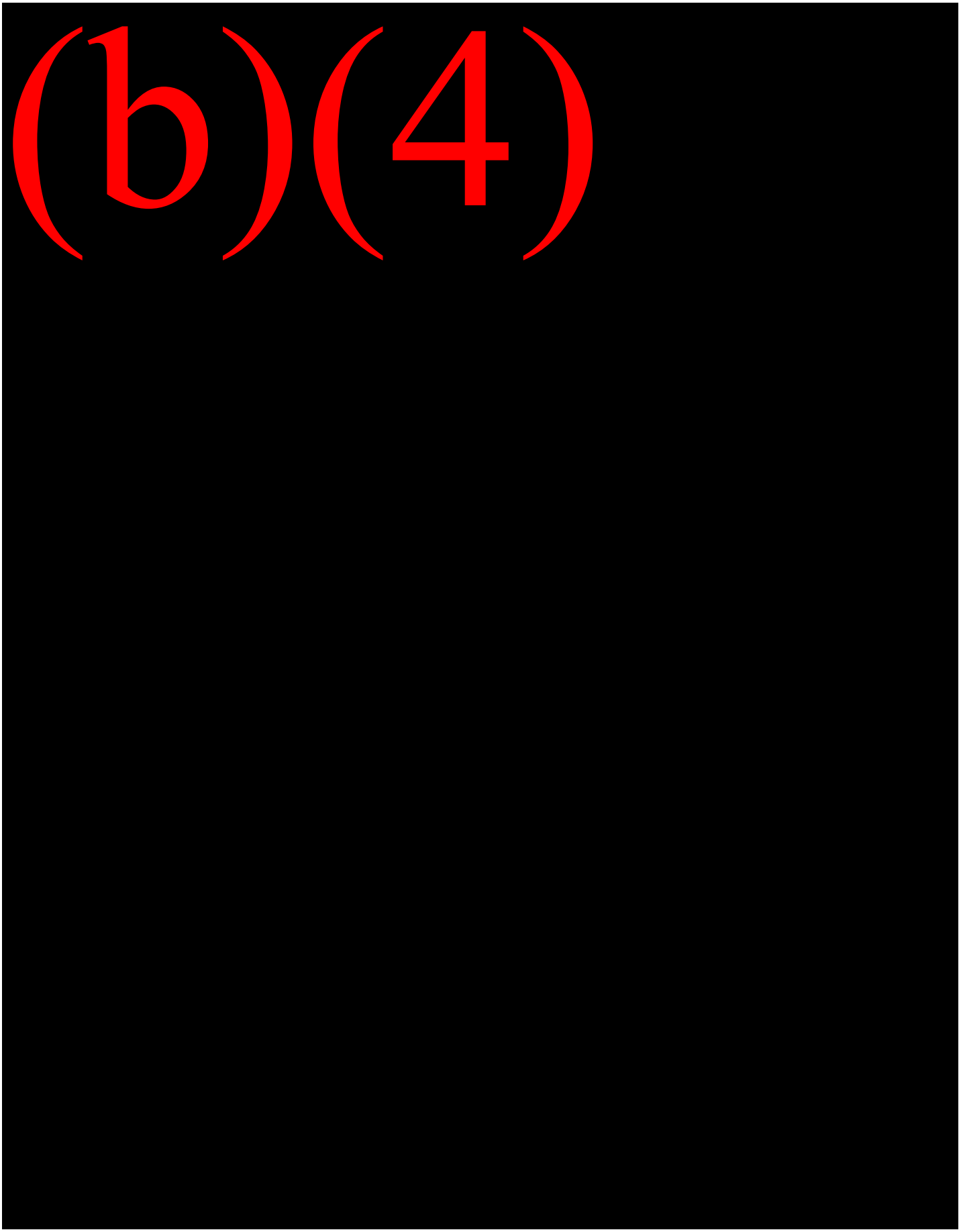
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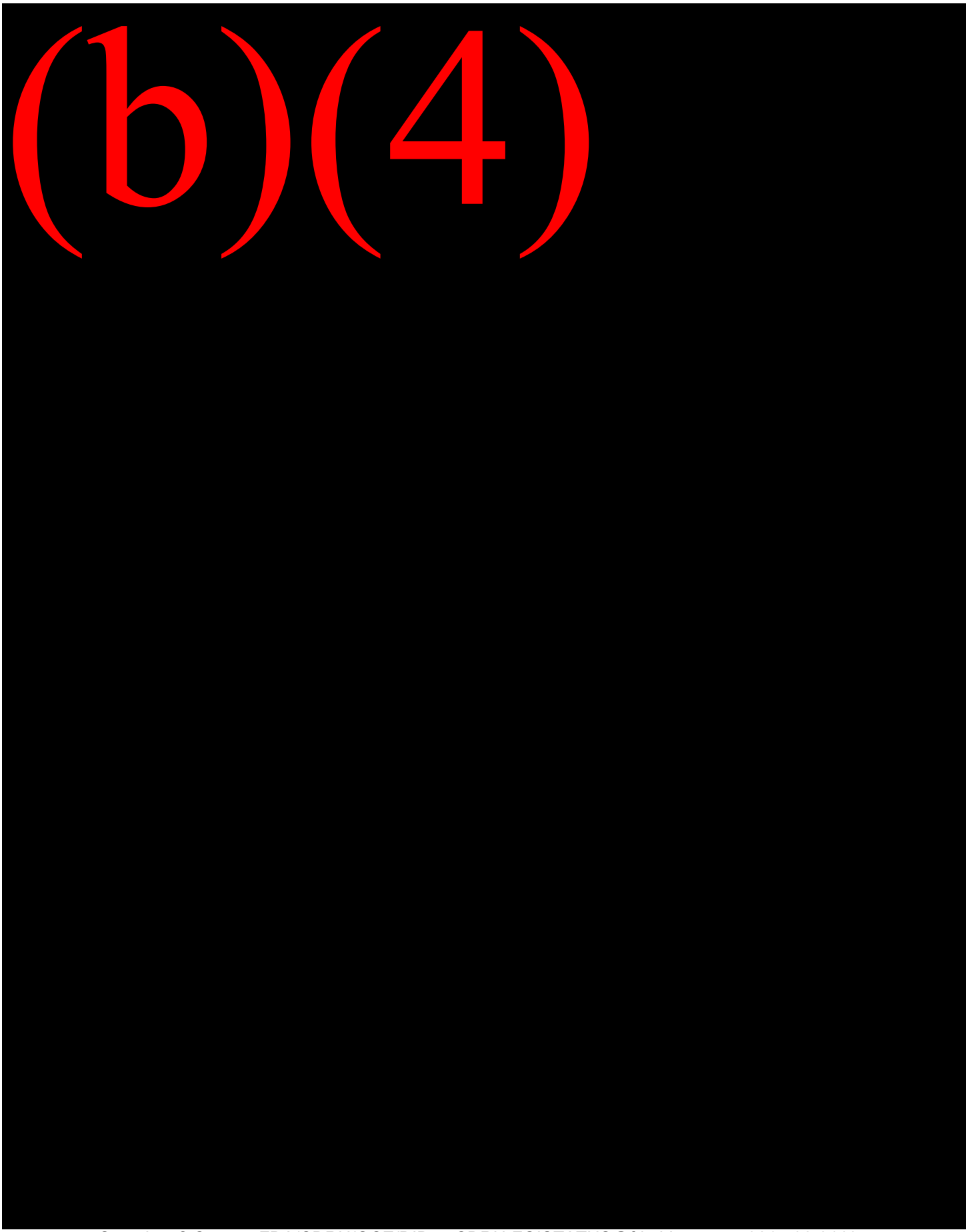
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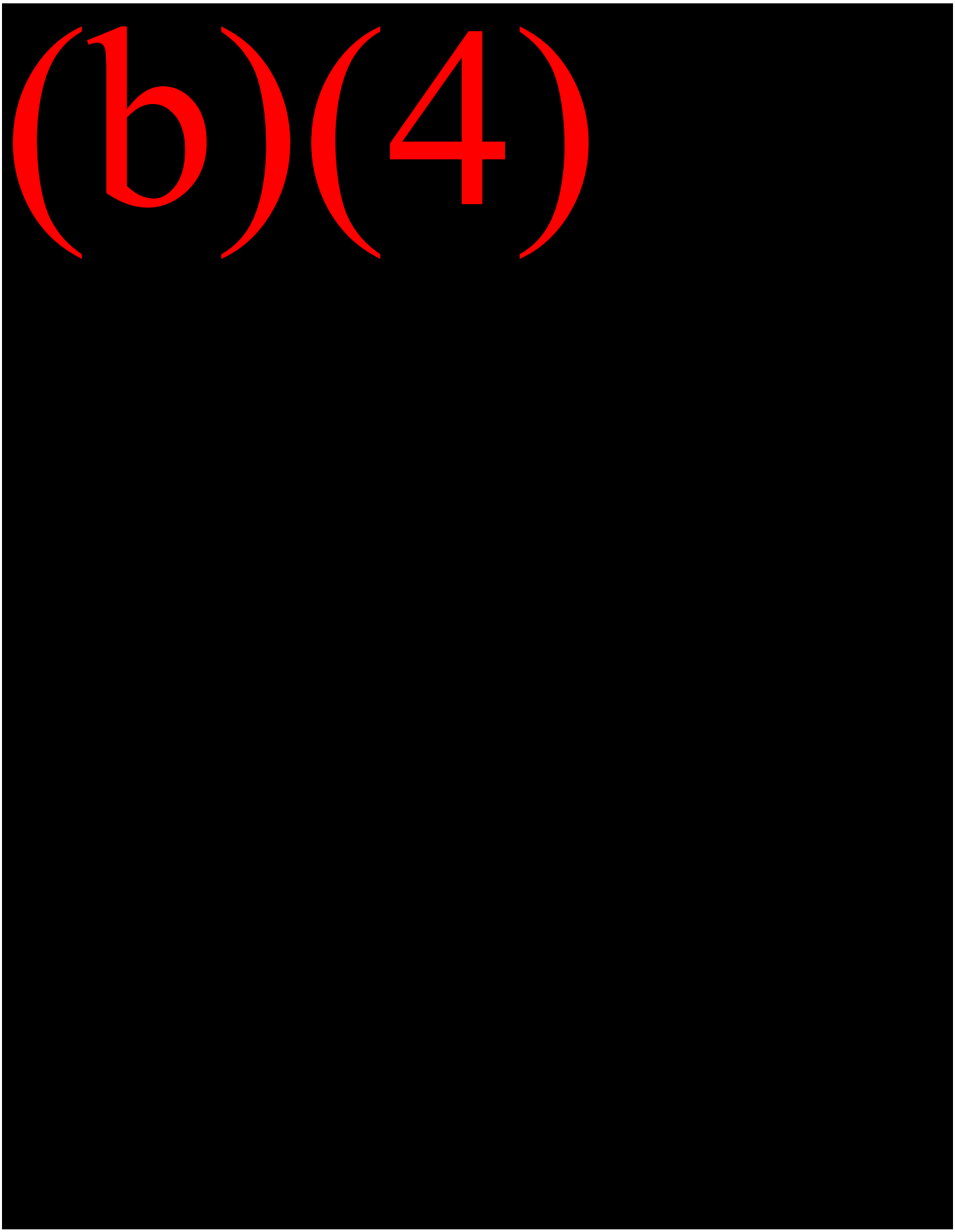
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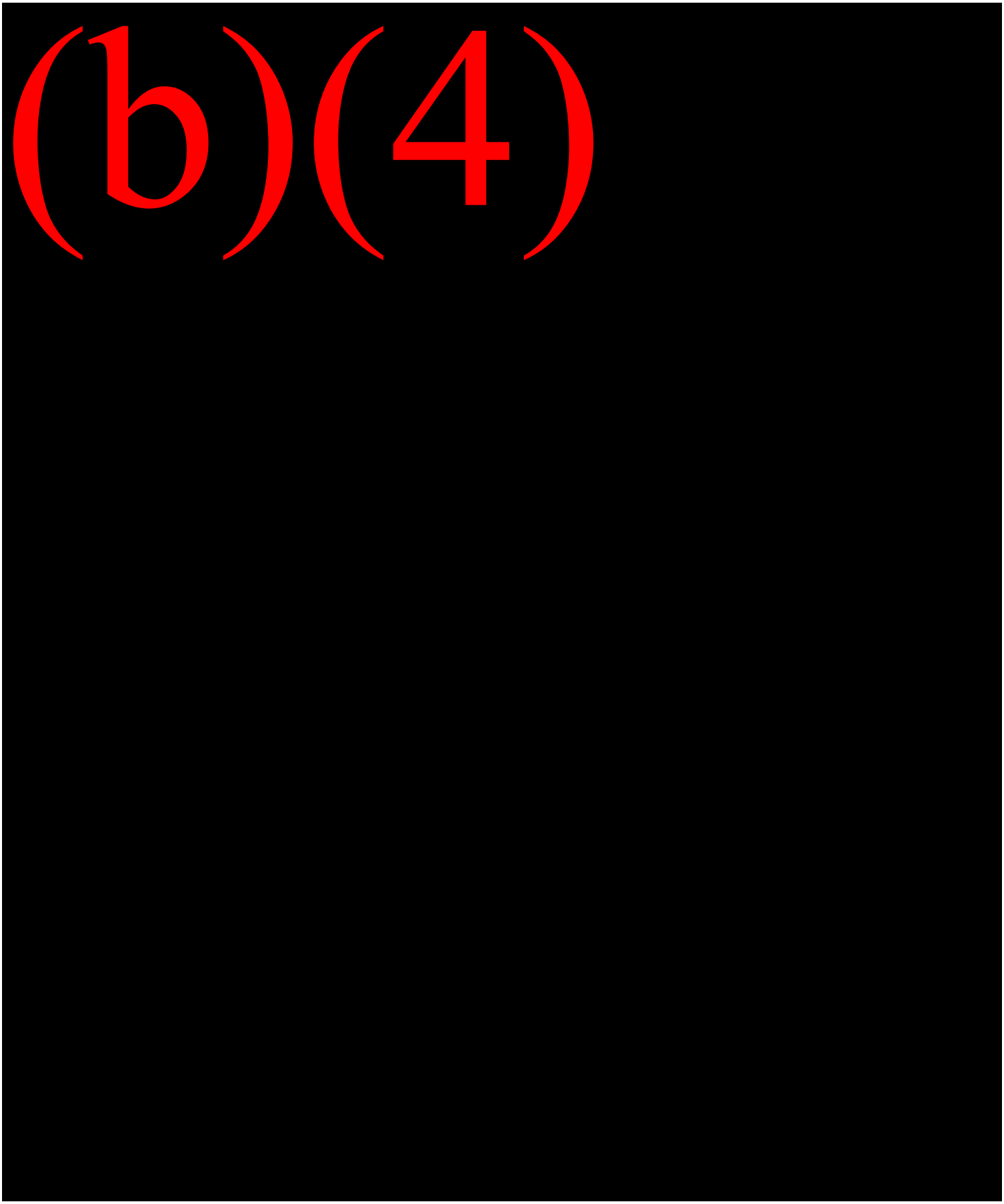
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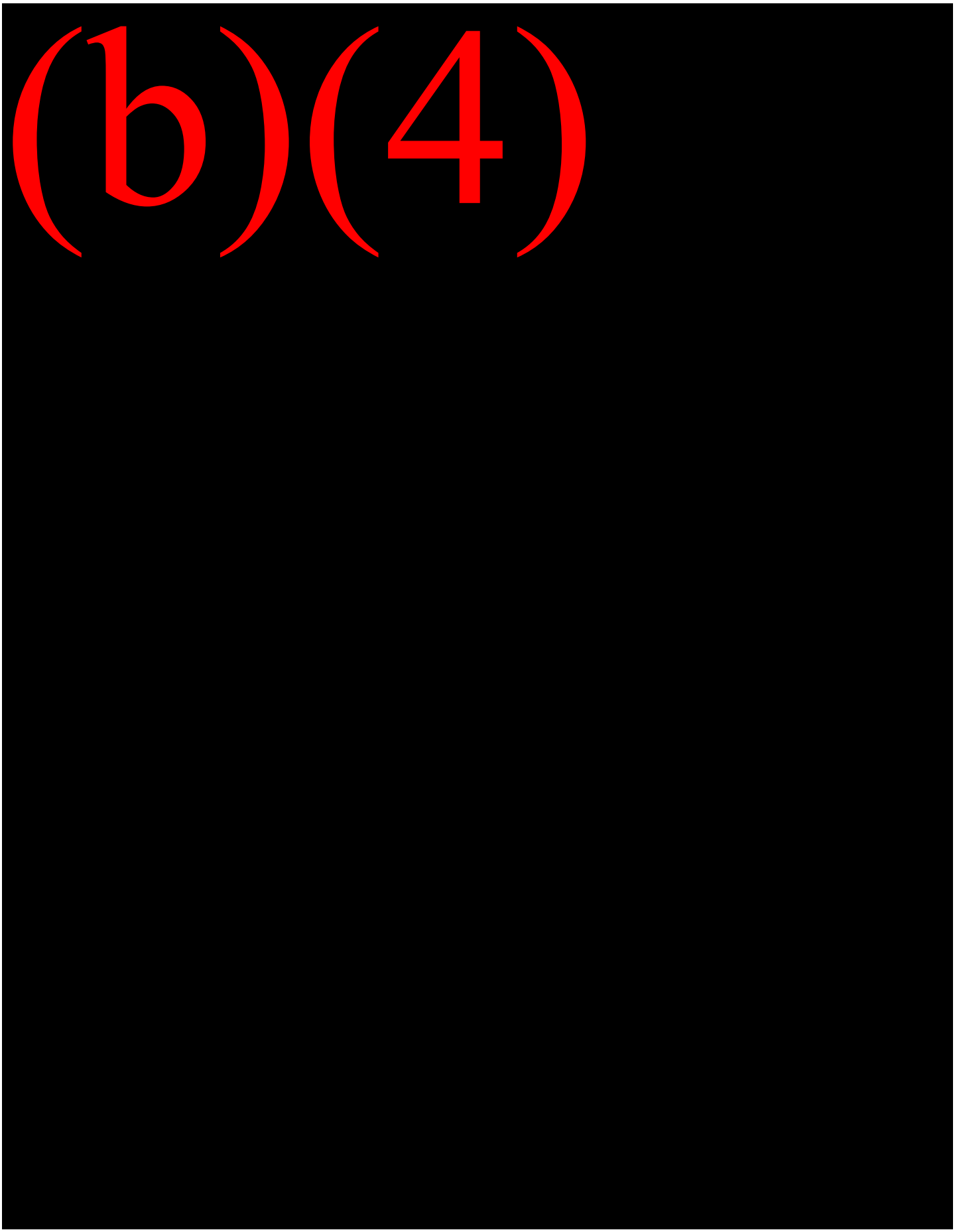
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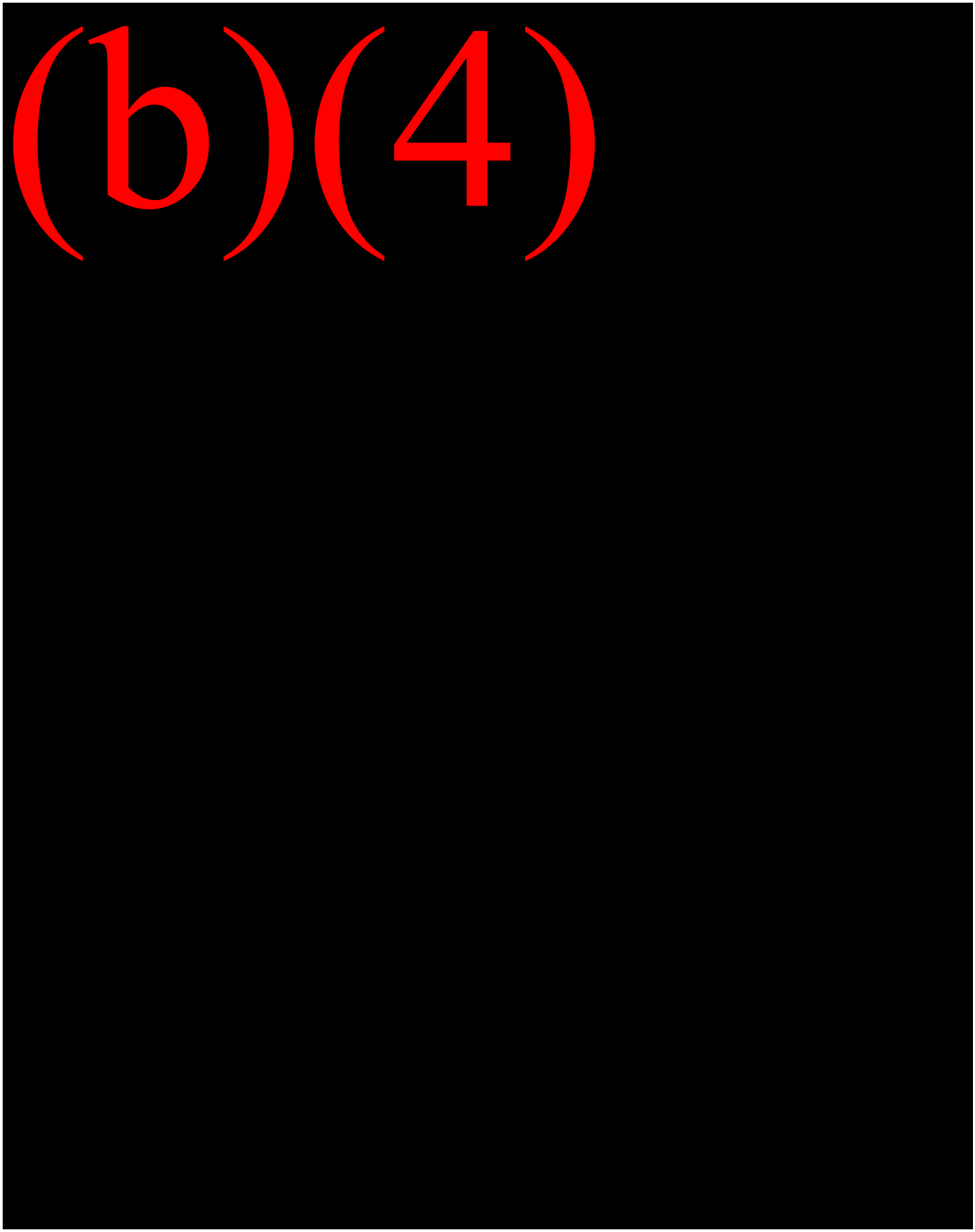
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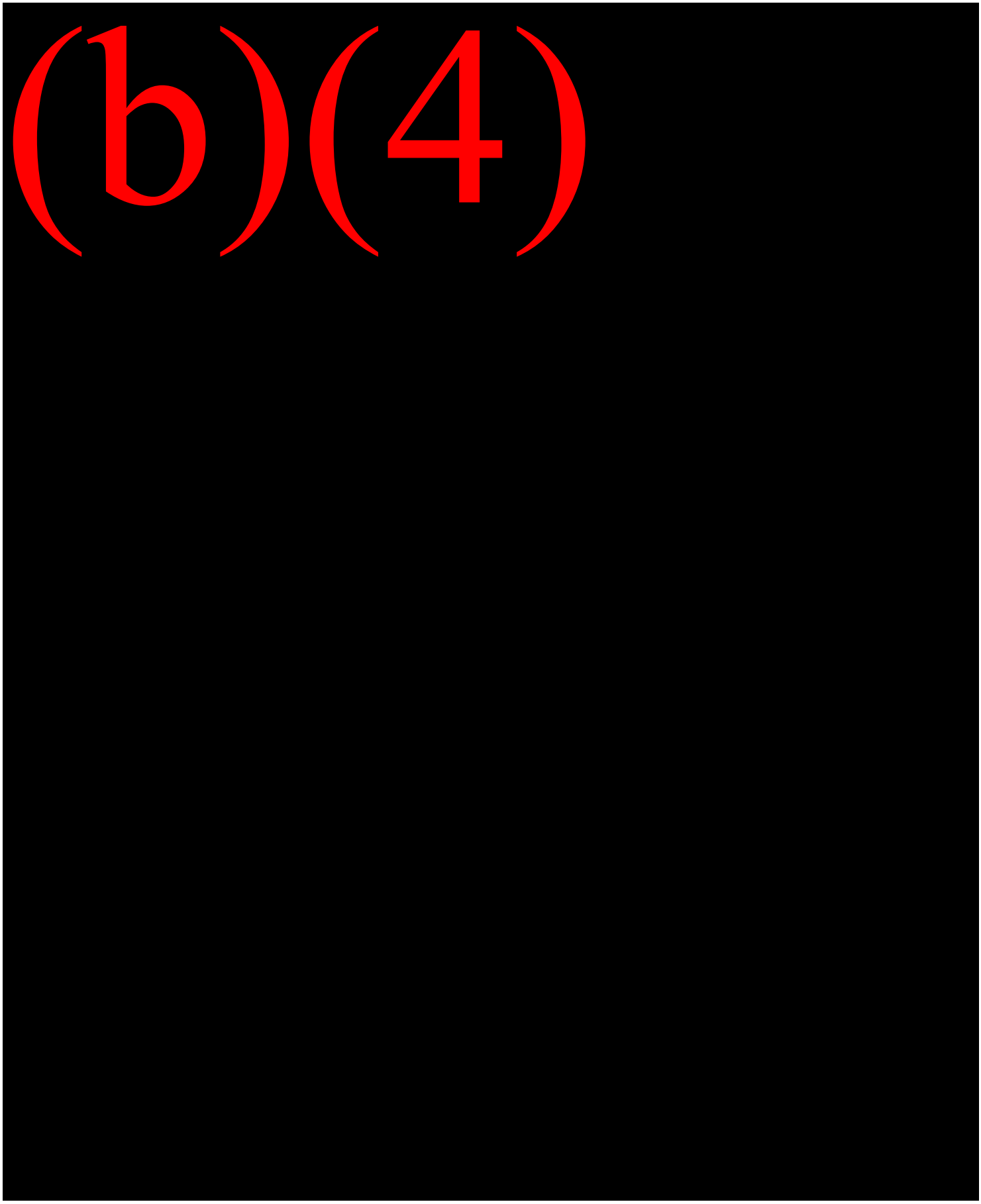
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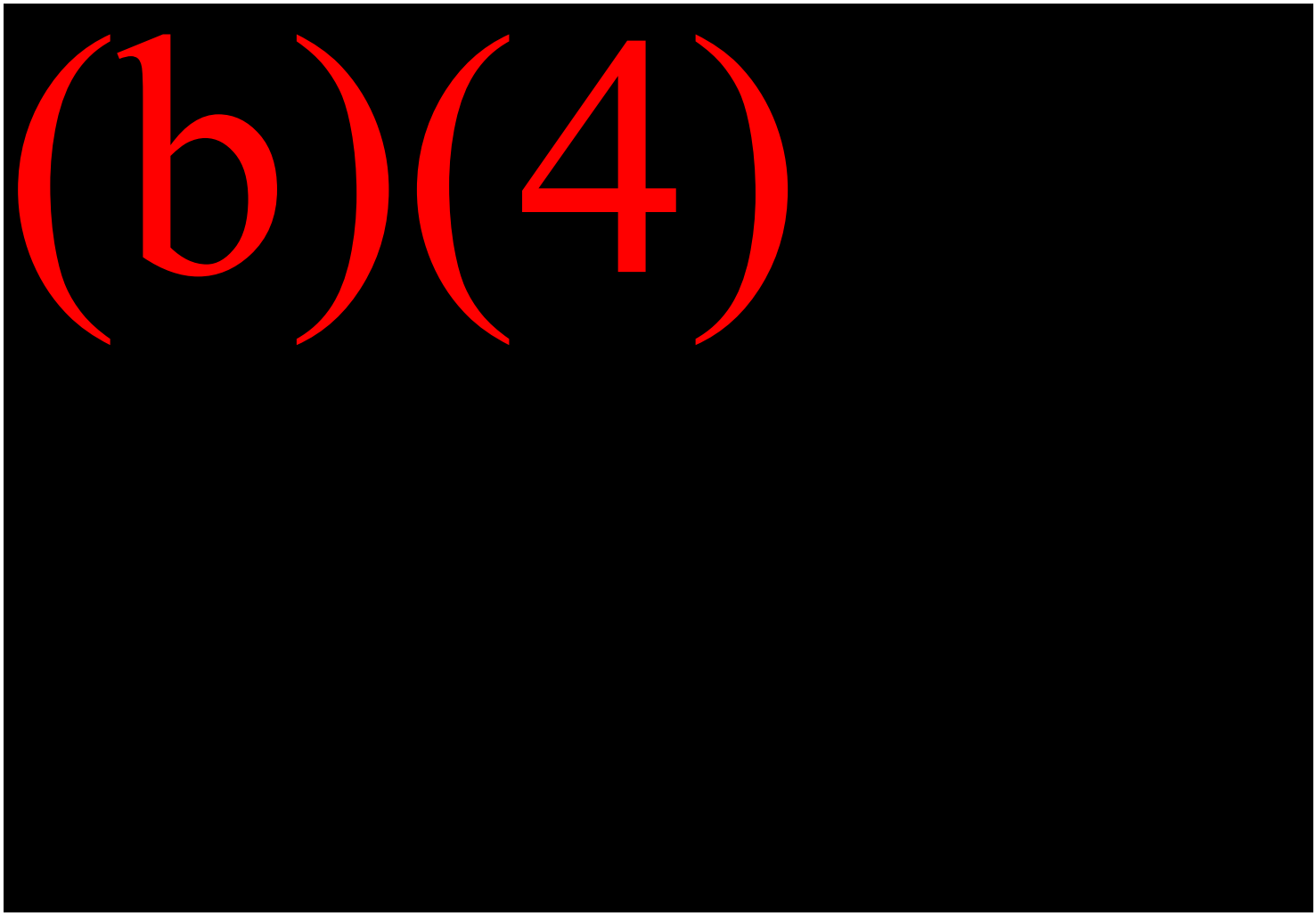
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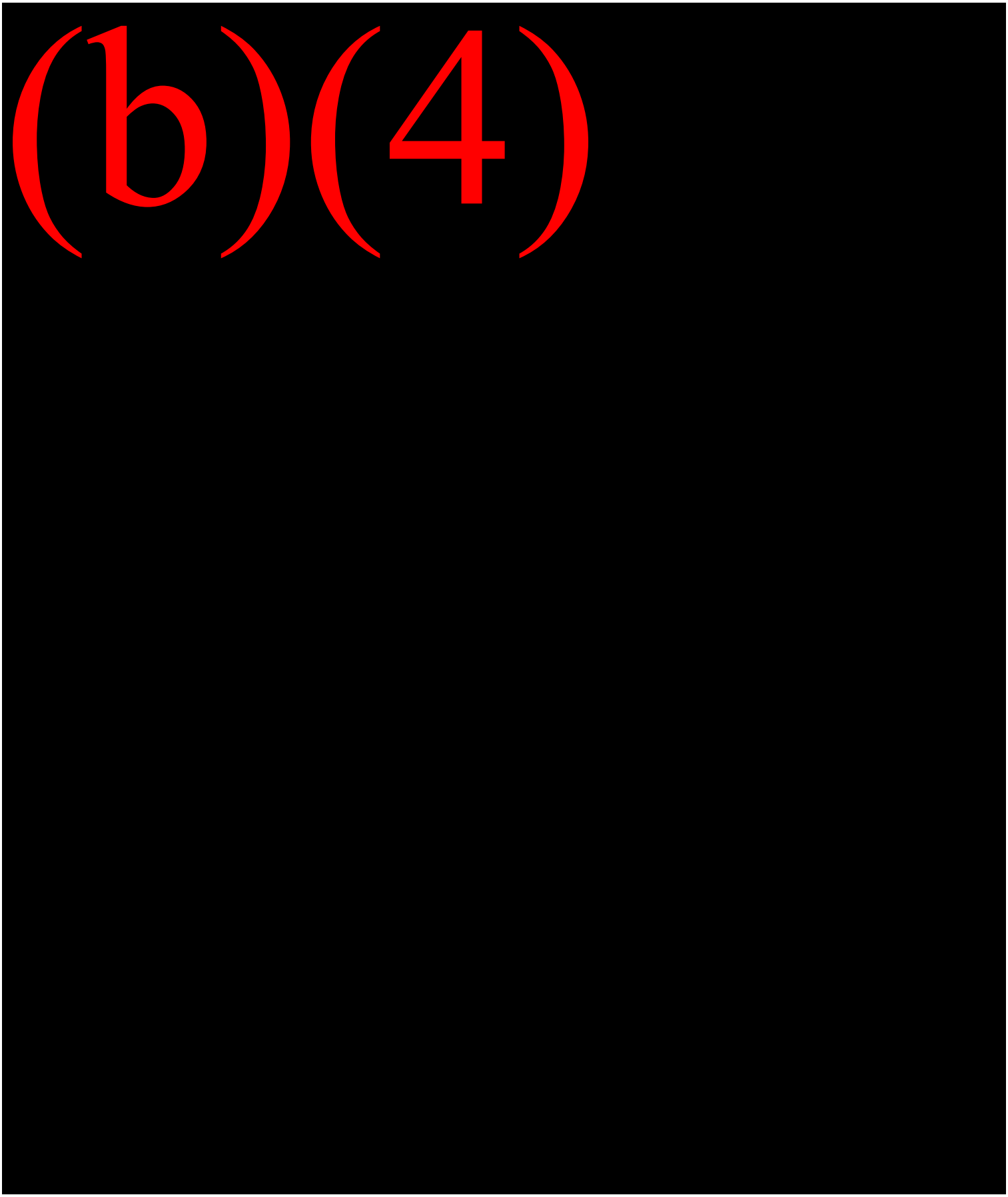
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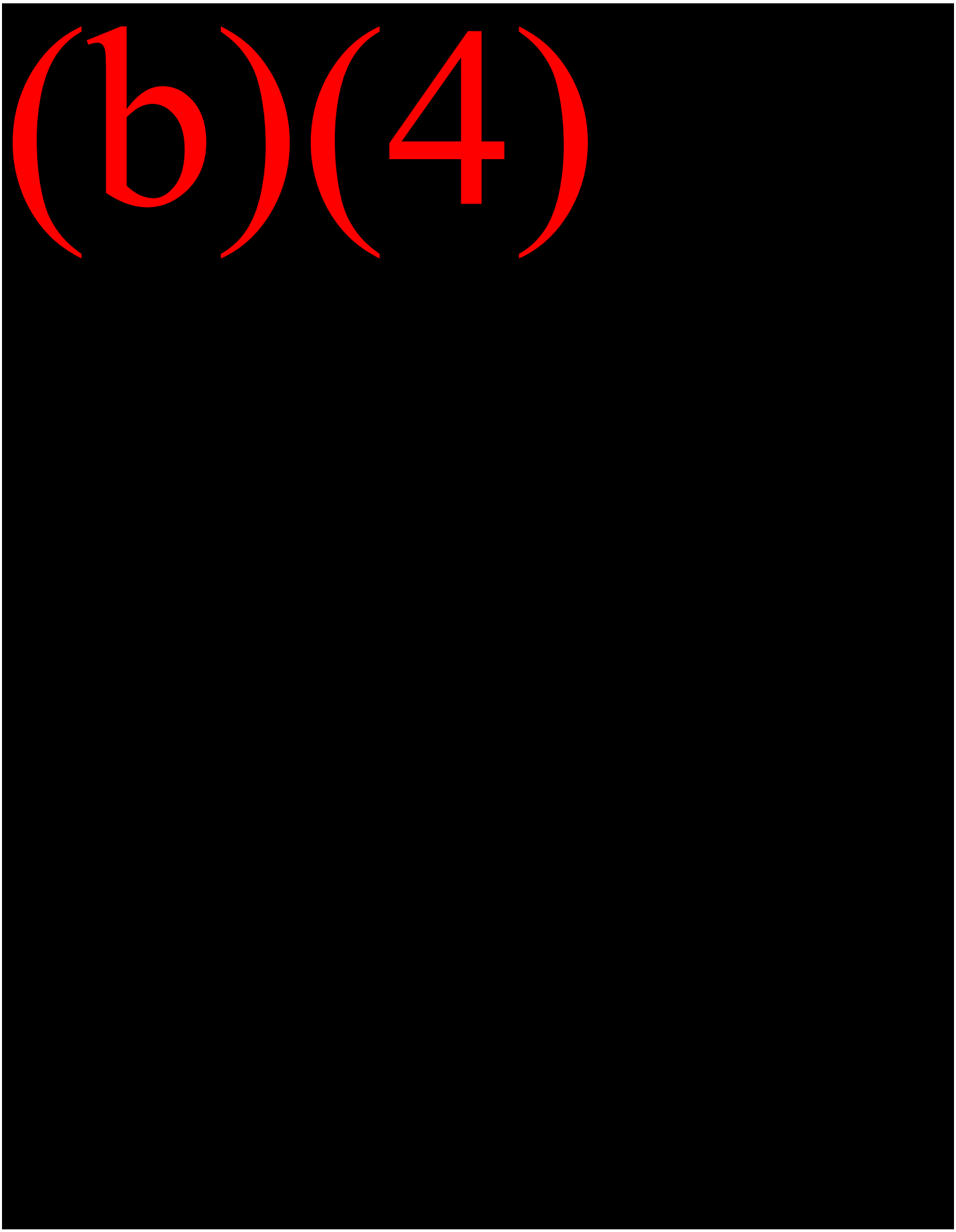


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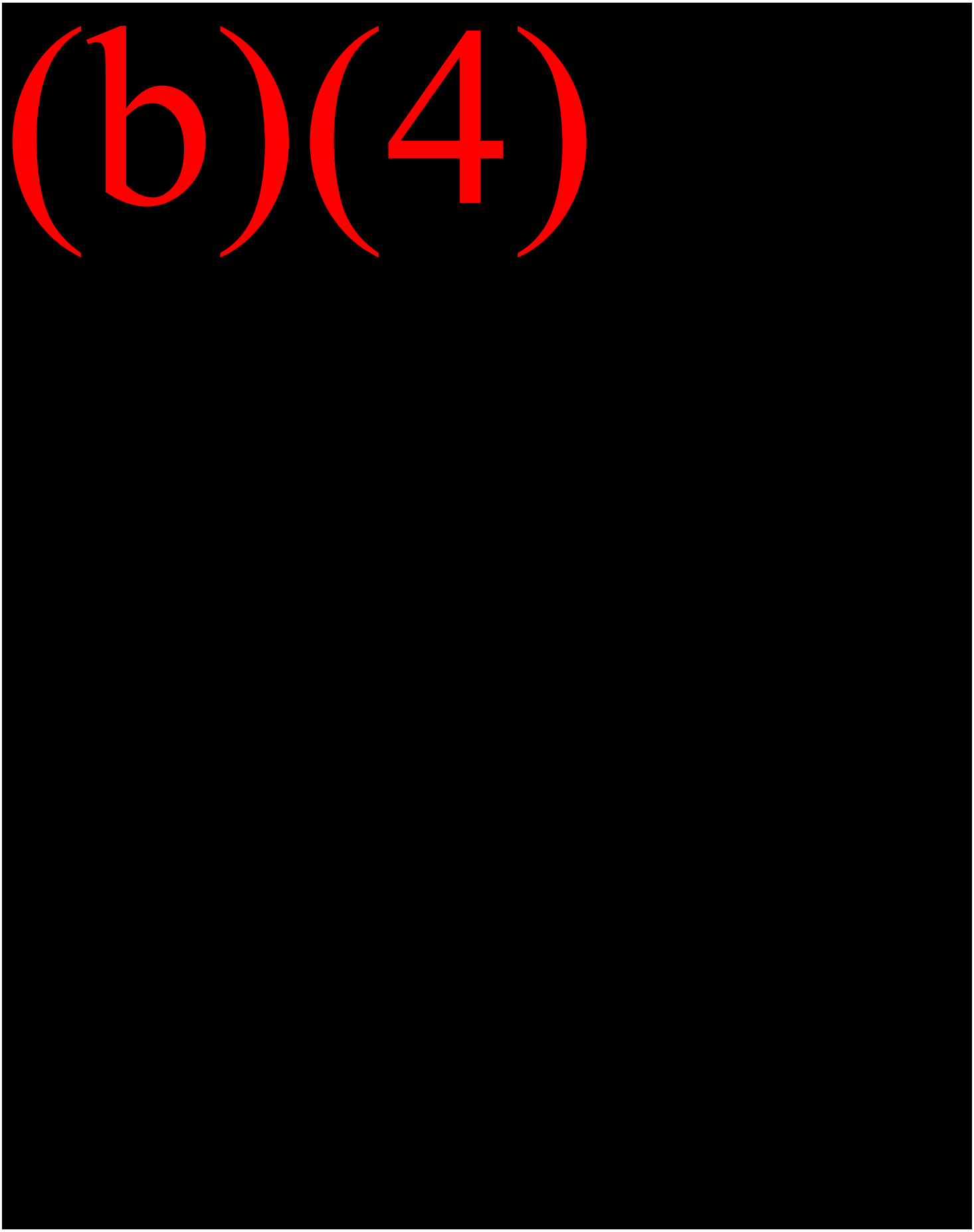
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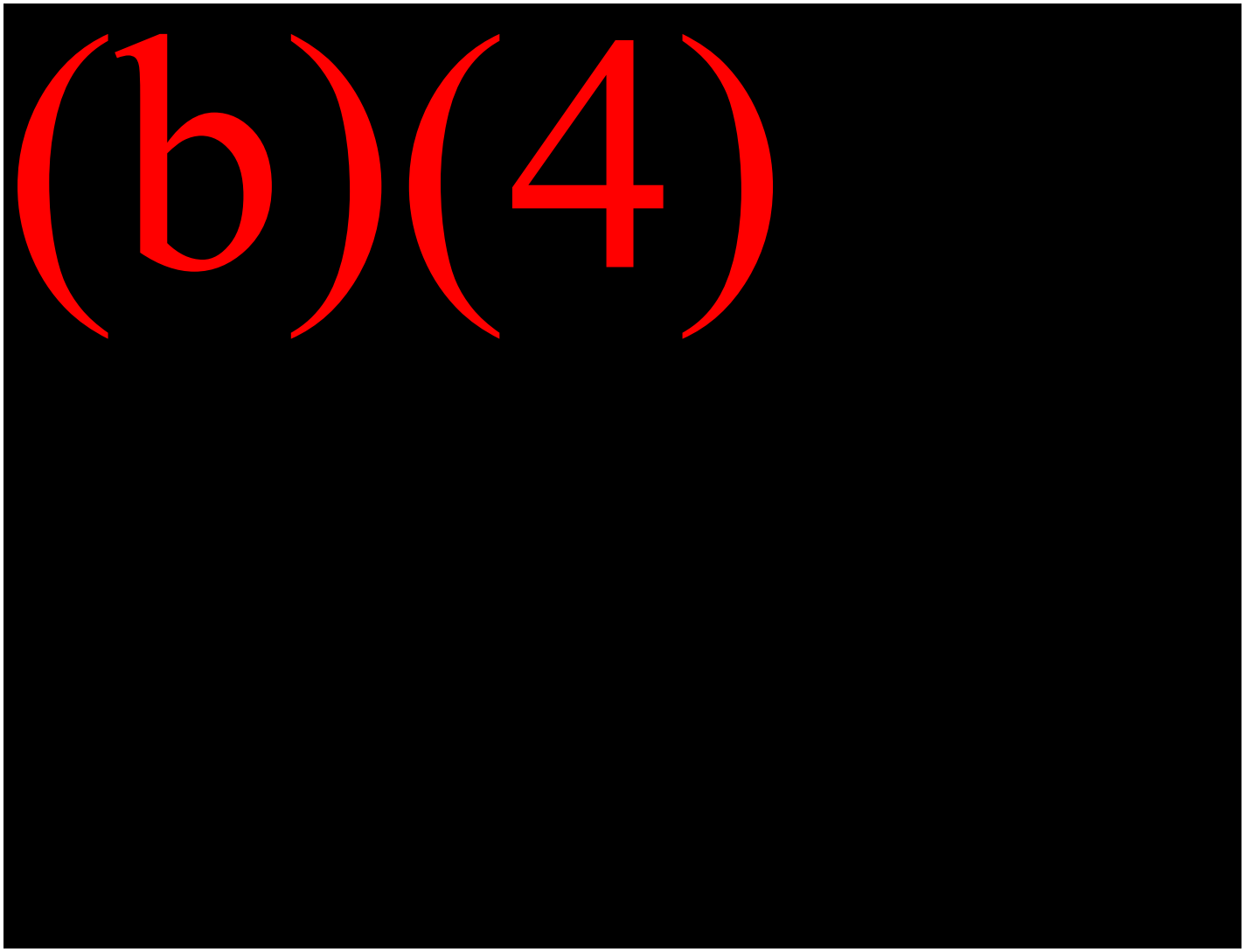
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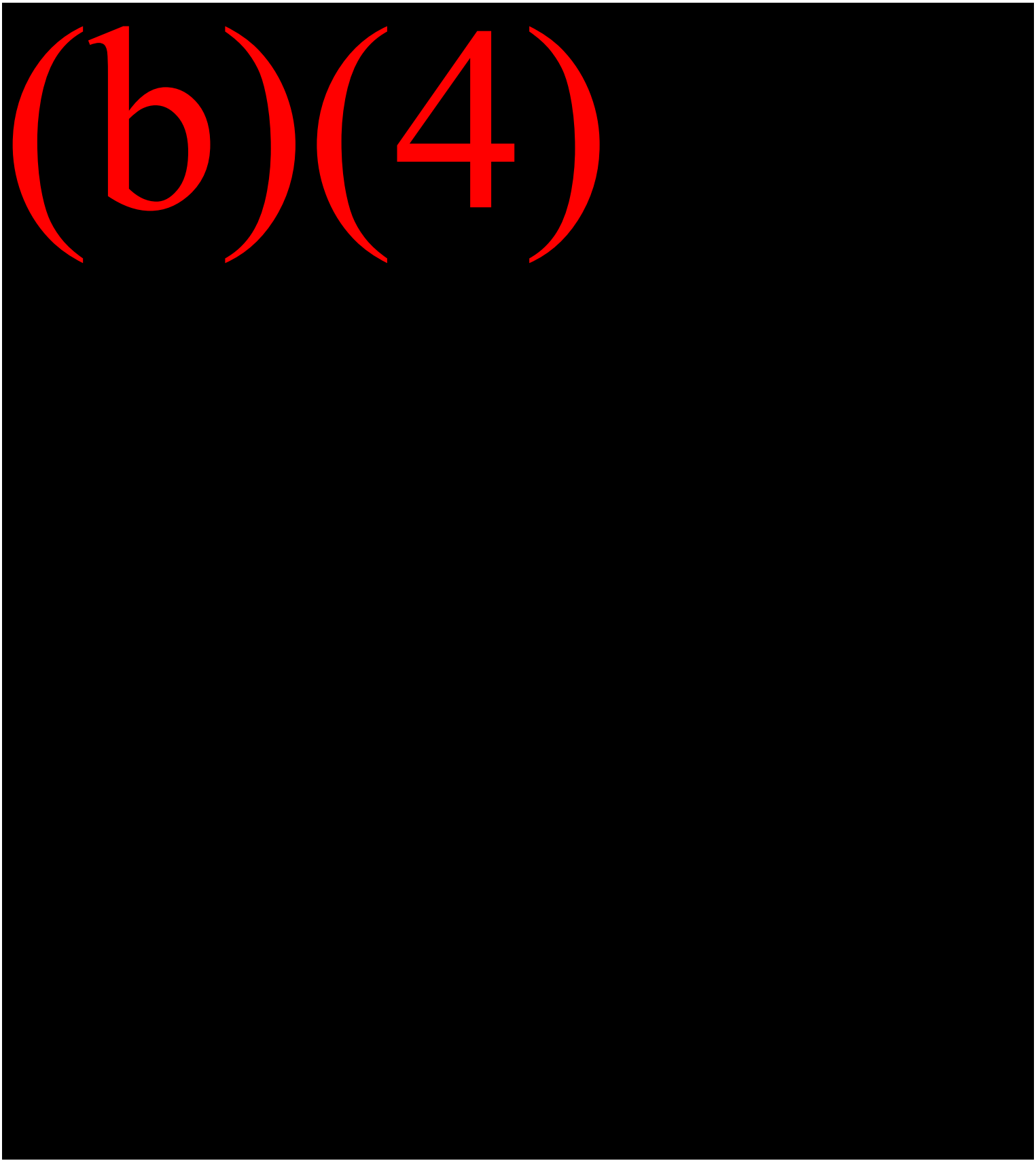
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Citrated Reagent Precision Protocol



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Citrated Reagent Precision Protocol Rev (b)(4) Test Report

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Heparin Neutralization Test Protocol

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Functional Fibrinogen (CFF) Reagent Linearity Protocol

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Functional Fibrinogen (CFF) Reagent Linearity Test Report

Linearity Test Protocol Data



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CORA

CORA® System

SMS (Service Maintenance and Setup)

USER GUIDE

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Welcome

The purpose of this document is to provide instructions for the System Service Maintenance and Setup (SMS) software – a component of the CORA (Coagulation Resonance Analyzer) System. This manual provides instructions only for using the SMS software. For instructions on operating the CORA System analyzer, please refer to the *CORA System User Manual*.

Section I: About the CORA system and SMS software

In this section you will find information on the CORA system's operating principles, intended use, indications for use, and a brief description of the SMS software.

Section II: Getting Started

This section provides an overview of the software and describes installation and hardware requirements.

Sections III: Logging into SMS

This section provides instructions for launching and logging into the SMS software.

Sections IV - XII: Using the SMS software

These sections include complete instructions for using the SMS software.





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Important Precautions

1. Read and understand the entire contents of this manual before operating the SMS software – especially precautionary information and specifications.
2. The SMS software is to be operated by qualified personnel only.
3. If this software is used in a manner inconsistent with this manual, protections provided by the software may be impaired.

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Section I: About the CORA System

Background on the CORA system

Hemostasis is the physiological control of bleeding and is a complex process incorporating vasculature, platelets, coagulation factors (FI-FXIII), fibrinolytic proteins, and coagulation inhibitors. Normal hemostasis is a delicate balance between hemorrhage and thrombosis. The CORA System is an In Vitro Diagnostics (IVD) device that can be used to quantify the hemostatic function of a blood sample.

Intended Use

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The CORA System records the kinetic changes in a sample of citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

Indications for Use

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Software Overview

The CORA system consists of an instrument, disposable cartridges, and remote software that controls the CORA instrument's Service, Maintenance and Settings (SMS) functions. The SMS software allows an administrator or technician to access the CORA instrument via an Ethernet connection, and perform a number of functions, including querying existing data, managing user accounts, updating instrument settings, and backing up data.

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Section II: Getting Started

Overview

The SMS software is a program that controls the CORA instrument's Service, Maintenance and Settings (SMS) functions. The SMS software is intended to run on a separate computer connected to the instrument via the Ethernet network interface connection.

The SMS software allows only a single remote user, with Administrative privileges or above, to log into the analyzer and do the following:

- Lock the analyzer for exclusive administrative access – and unlock.
- Manage users accounts (add and delete accounts, assign user roles and temporary passwords)
- Retrieve the following information:
    - Cartridge tables
    - Patient and Wet QC tests
    - System settings
- Update the following information:
    - Cartridge tables
    - System and user settings
    - Custom normal ranges for patient tests
    - Analyzer firmware
- Back up and restore analyzer data.

SMS software installation

The SMS software is a Windows application that connects to the analyzer over the Local Area Network (LAN). No files need to be installed on the computer. Instead, a set of application files must reside locally on the computer. These files are set up by the service technician who installs CORA analyzer at your site.

Hardware requirements

The SMS software runs in hardware with the following minimum system requirements:

- Windows 7
- 1GB RAM
- 500 MB Storage
- Ethernet connection to a local network where the analyzer(s) are present.

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Section III: Logging into SMS

Note: *Only users assigned the roles of Administrator, Field Technician, or Distributor can log into the SMS software.*

You can use one of the following two methods to launch the SMS software:

- Run the Discovery program and select the desired analyzer to connect to within the LAN subnet.
- Manually launch the SMS software using a known IP address.

Run Discovery to launch SMS

The Discovery program allows you to discover all analyzers that are connected within a LAN subnet (these are the analyzers that are connected to the same router your computer is connected to). You can then select one of the listed analyzers to connect to and launch the SMS software.

Note: *You can connect to an analyzer only if it shows "Disabled" in the Current State column and has no local user logged into it (no user ID appears in the Local User column).*

To run Discovery:

1. On the computer, navigate to **CORADiscovery.exe** and double click the file to launch the program.
2. In the *CORADiscovery* screen, click **Find Instruments**.

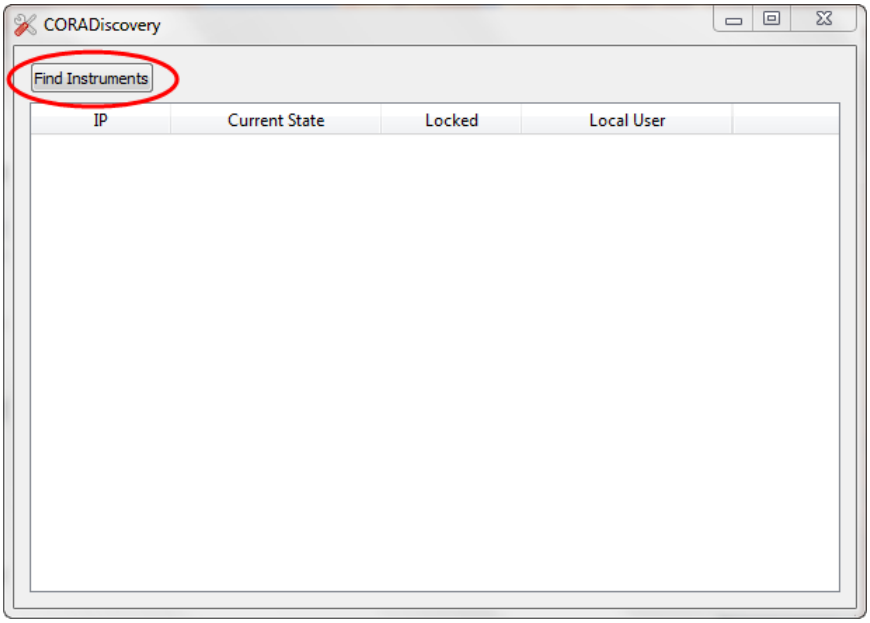


Figure 1: CORADiscovery screen

Each analyzer within the subnet appears in the list on the *CORADiscovery* screen and displays its IP address, current state, whether it is locked by an SMS user, and whether a local user is logged in.

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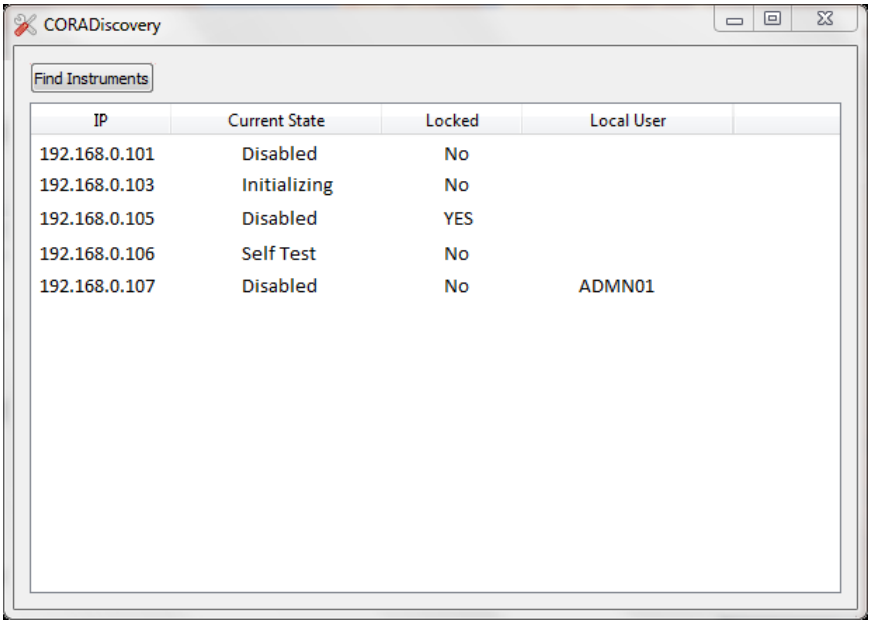


Figure 1.2: List of discovered analyzers

3. Double-click the IP address of the desired analyzer to open the SMS software.

Manually launch SMS

If you know the IP address of the analyzer, you can manually launch the SMS software by doing the following:

1. On the computer, navigate to **CORASMSMain.exe** and double click the file to launch the program.
2. In the *Select IP* screen, enter the IP address for the analyzer, and then click **OK**.

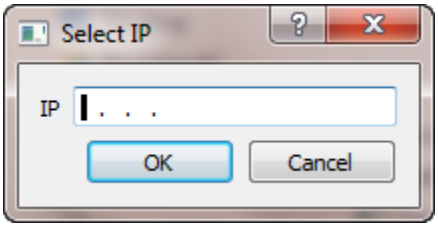


Figure 2: Select IP

Connect to the analyzer

Once the SMS software is open, you can connect to the analyzer if no user is logged on locally. This locks the analyzer for your exclusive use.

1. On the SMS-T *Main* screen, click the **Connect** button at the top left.

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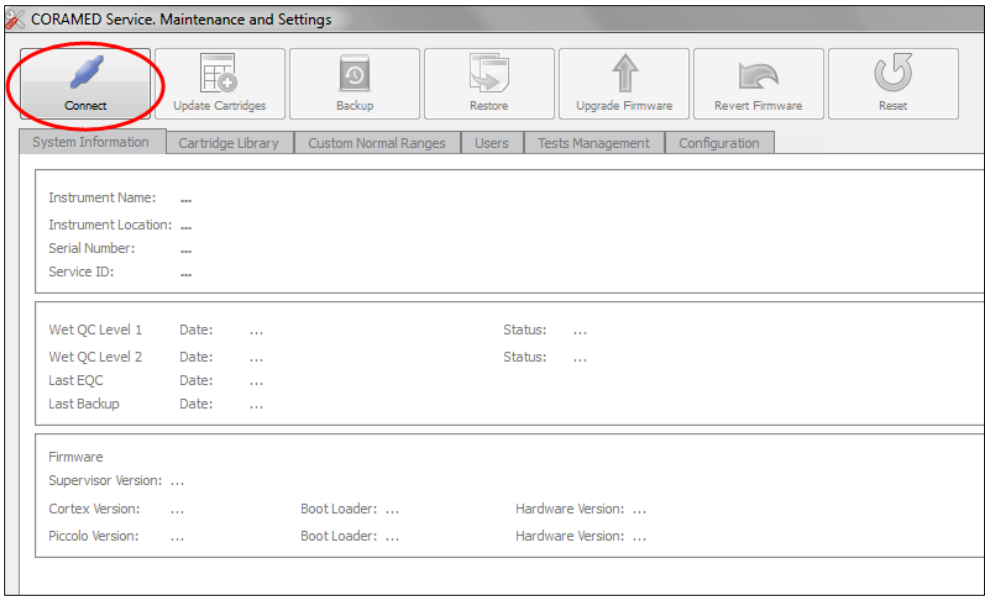


Figure 3: SMS Main screen before connecting

2. In the *User Login* screen, enter the user name and password appropriate to the specific CORA analyzer that you are connected to, and then click **Login**.

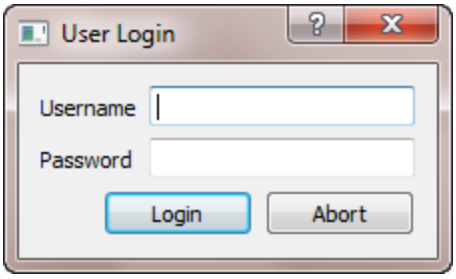


Figure 4: User Login

Login error messages

If SMS displays the following error message, it means that a user is still logged into the analyzer. If this is the case, log out of the analyzer and log into SMS again.

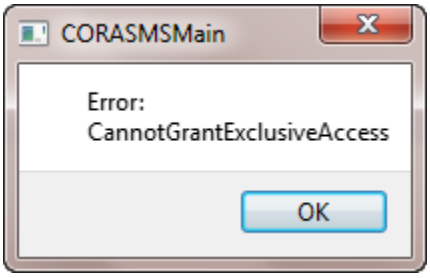


Figure 5: Error – user logged into analyzer

If SMS displays the following timeout error message, it means that the computer cannot communicate with the analyzer.

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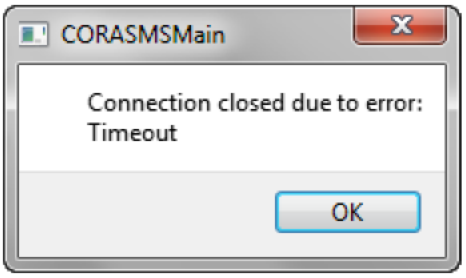


Figure 5.2: Error – timeout

Refer to the following table for possible sources of the error and suggested methods to resolve the issue.

Possible source of error	Suggested resolution
You used an incorrect IP address when logging into SMS.	Check the analyzer's IP address.
The Ethernet cables are not hooked up properly.	Make sure the computer/analyzer Ethernet cables are plugged into "LAN" ports, not the Internet port.
The router is not powered on.	Make sure the router is plugged in.
Either the computer or the analyzer has not successfully obtained an IP address from the router.	Check the computer IP address: 1. From the computer's **Start** menu, type "cmd" in the *Search* box, and then press **Enter**. 2. In the command prompt screen, type "ipconfig" and press **Enter**. 3. View the IP address next to "IPv4 Address." Check the analyzer IP address: 1. Verify that the LAN settings are set to DHCP. 2. Verify that the IP address appears on the About screen.

Note: *It is recommended that you power cycle the analyzer (turn the analyzer off and then back on again) after making any adjustments to the cables or router.*

Successful login

Upon successful login, the SMS *Main* screen is enabled and the analyzer displays the *Remote Control* screen.

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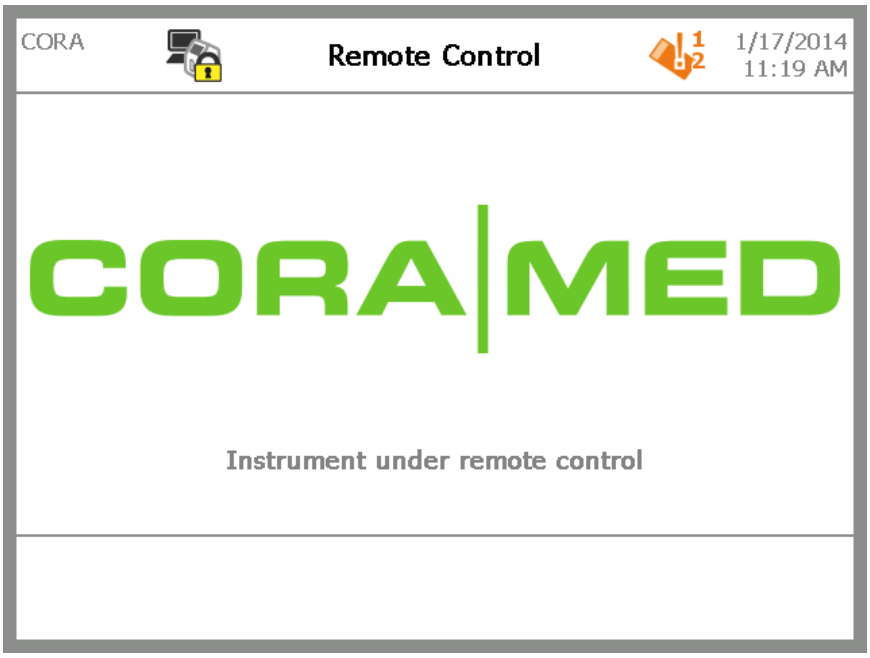
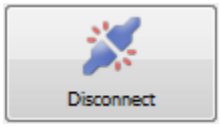


Figure 16: Remote Control screen

Log out of SMS

1. On the SMS *Main* screen click the **Disconnect** button.



You are logged out of the SMS software. The analyzer is no longer under remote control and can be logged into by local users.

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Section IV: Viewing System Information

Information about the analyzer can be viewed on the **System Information** tab. The information is organized into three sections. The top section displaying instrument details such as name, location, serial number and service ID. The middle section displays status information including the most recent Wet QC and backup dates. The bottom section displays the firmware versions installed on the analyzer.

To view system information:

1. From the SMS *Main* screen, click the **System Information** tab.

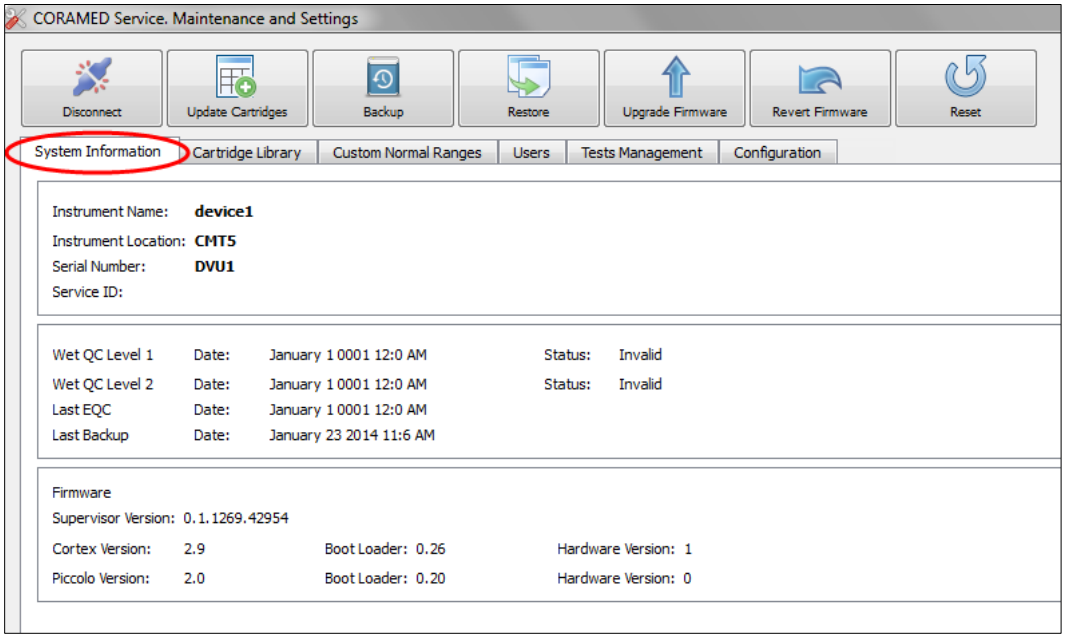


Figure 6: System Information tab

2. View the system information.

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Section V: Managing the Cartridge Library and Scripts

In addition to the barcode on the cartridge, the analyzer system also uses a cartridge library to determine the type of test the cartridge is intended to perform. The cartridge library holds information about each test such as microfluidic scripts, names of channels, reference ranges, etc.

You can view cartridge library information on the Cartridge Library tab. You can also upload the latest library version to the analyzer.

View the cartridge library information

The current cartridge library information is available for viewing on the **Cartridge Library** tab. The following information is displayed:

- Current cartridge library version
- Cartridge Name
- Sample type
- Test Type (Patient or Wet QC)
- Revision
- ID
- Channel Tests (CH1,CH2,CH3,CH4)

To view cartridge library information:

1. On the SMS *Main* screen, click the **Cartridge Library** tab.

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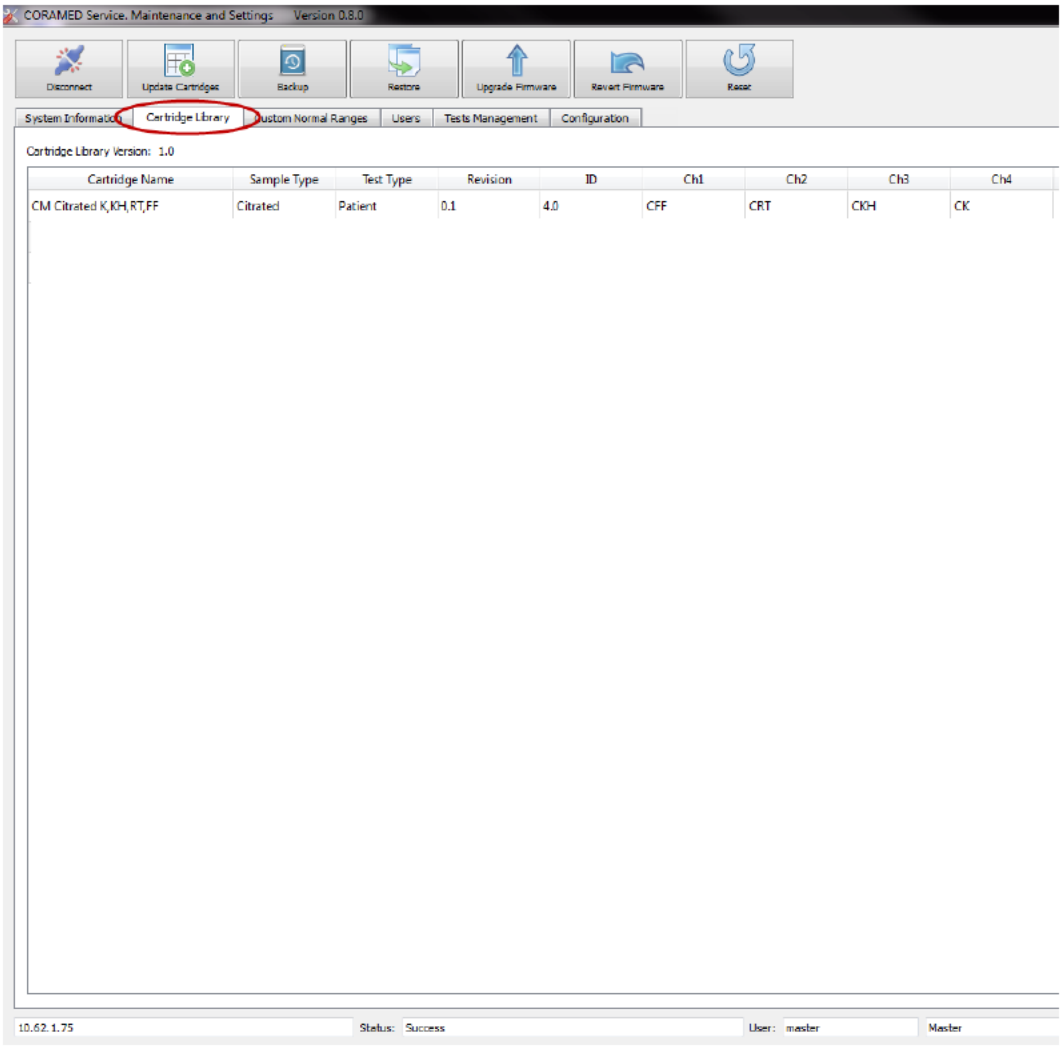


Figure 7: Cartridge Library tab

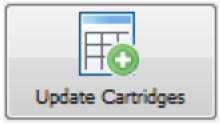
2. View the cartridge library information.

Update the cartridge library

Periodically, the cartridge library is updated by Coramed Technologies. When this occurs, you can upload the latest version to the analyzer. The cartridge library file is made up of two zipped files: the cartridge library file and the microfluidic scripts file.

To update the cartridge library:

1. On the SMS *Main* toolbar, click **Update Cartridges**.



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2. In the *Open cartridge release* window, navigate to the location of the latest cartridge zip file, and then click **Open**.

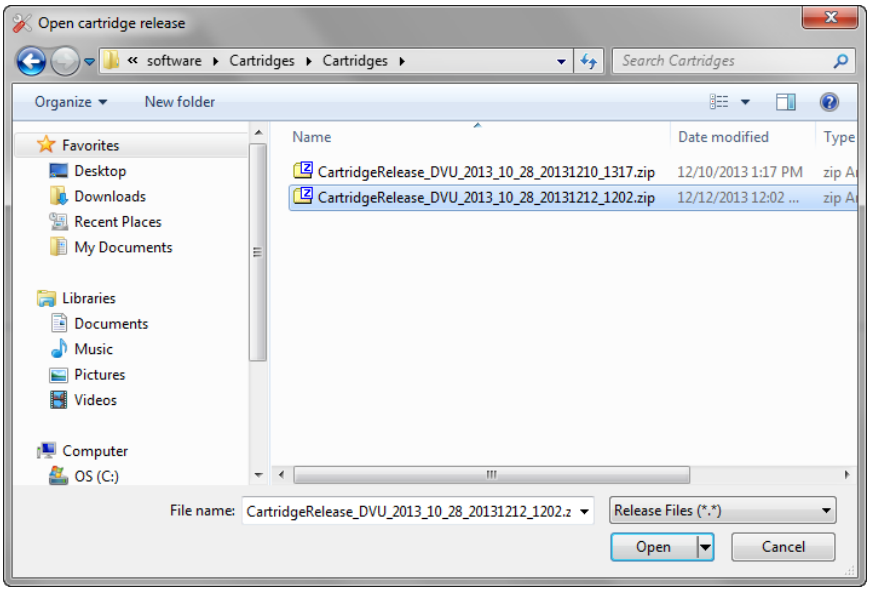


Figure 8: Open cartridge release window

A progress message appears as the cartridge and script files are uploaded.

3. In the power cycle message that appears, click **Yes**.

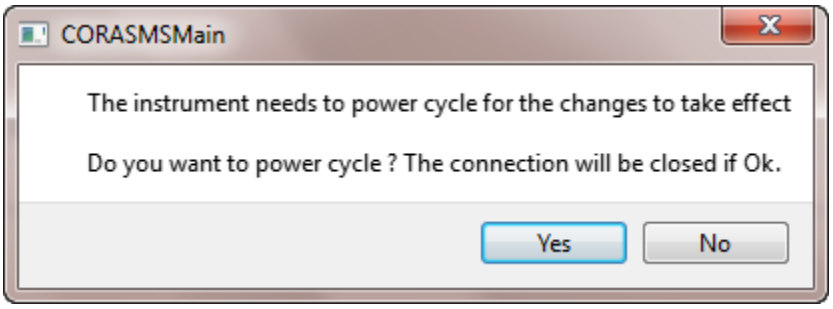


Figure 9: Power cycle message

The SMS software resets the analyzer automatically.

When you log back into SMS, the new version number appears at the top of the table on the **Cartridge Library** tab.

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Section VI: Managing Custom Normal Ranges

The manufacturer's normal ranges that are defined for each test are contained in the cartridge library. However, if a site chooses to establish their own reference ranges, these values can be defined on the **Custom Normal Ranges** tab.

Add custom normal ranges

To add a new user-defined normal range for a test type:

1. On the SMS *Main* screen, click the **Custom Normal Ranges** tab.

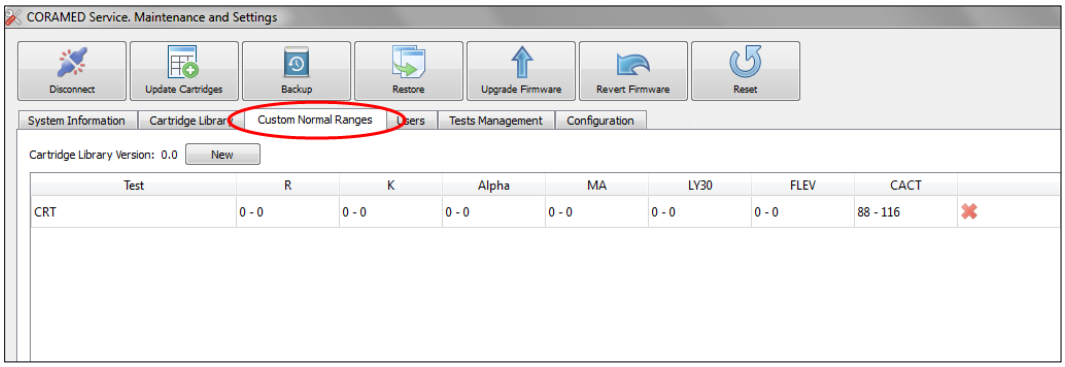


Figure 10: Custom Normal Ranges tab

2. Click **New**.

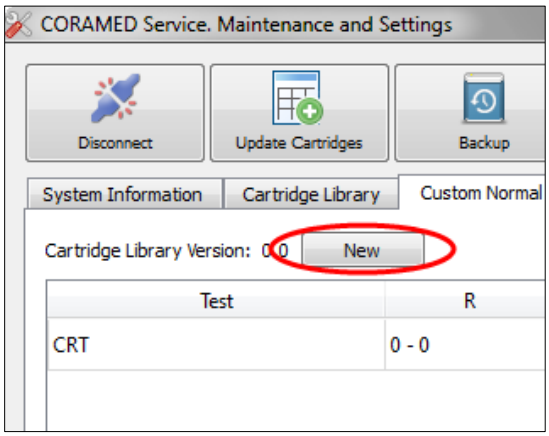


Figure 11: New button

3. In the *New Normal Ranges* screen, do the following:
    a. In the *Name* field, enter the name for the test.

    Note: *Make sure the name is entered exactly as it appears on the analyzer results screen. This field is case sensitive.*

    b. Next to each parameter for which you want to specify custom ranges, type or use the arrows to enter the low (left box) and high (right box) ranges. If a parameter is

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not required for the test, leave the value at 0-0. Figure 12 shows an example of custom ranges entered for citrated kaolin tests.

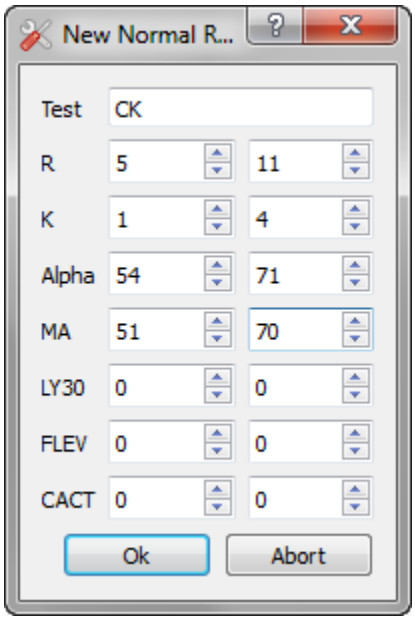


Figure 12: New Normal Ranges

4. Click **Ok**.
5. In the power cycle message that appears, click **Yes**.

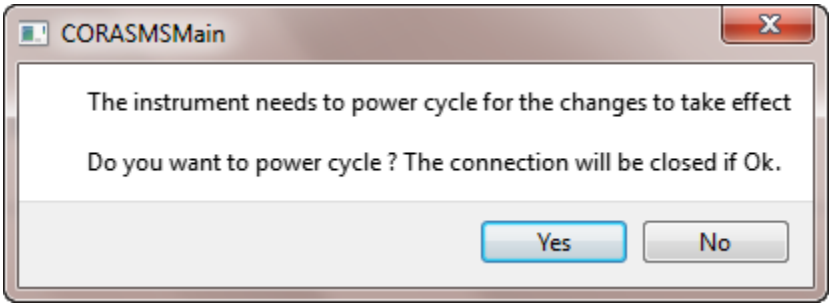


Figure 13: Power cycle message

The SMS software resets the analyzer. When you log back into SMS, the new custom normal ranges appear in the list.

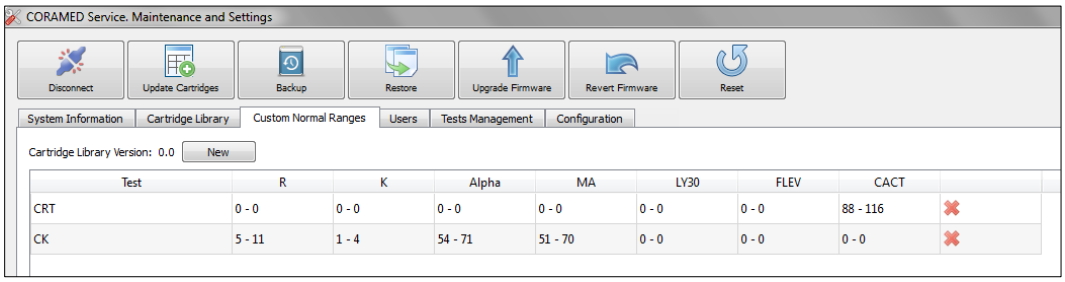


Figure 14: New custom ranges on the Custom Normal Ranges tab

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Delete custom normal ranges

To delete user-defined normal ranges for a test type:

1. On the **Custom Normal Ranges** tab, next to the desired test type, click the delete button.

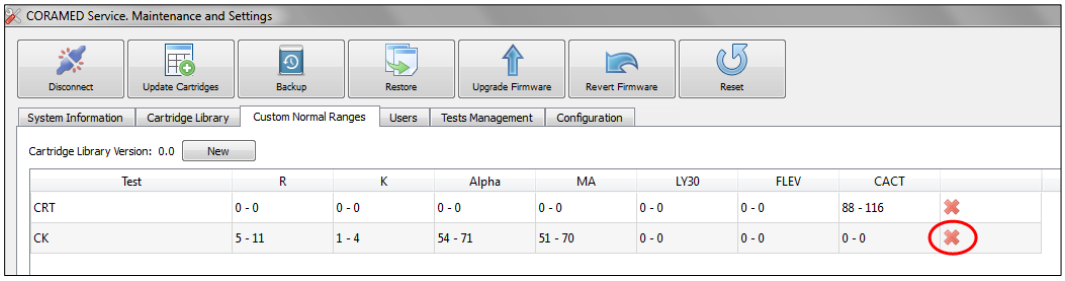


Figure 15: Delete button

2. In the *Delete Normal Range* confirmation message, click **OK**.

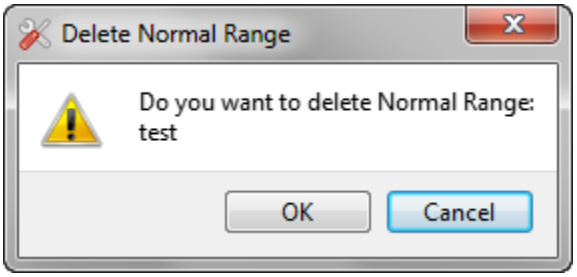


Figure 16: Delete Normal Range confirmation message

3. In the power cycle message that appears, click **Yes**.

   The SMS software resets the analyzer automatically.

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Section VII: Managing Users

Add a new user account

With the appropriate privileges, you can add a new user to the system and assign the user a role. The role that you assign to the new user must be lower in hierarchy than your own user role. From the top down, the hierarchy levels are as follows: Distributor, Field Technician, Administrator, and Operator.

To add a new user account:

1. From the SMS *Main* screen, click the **Users** tab.

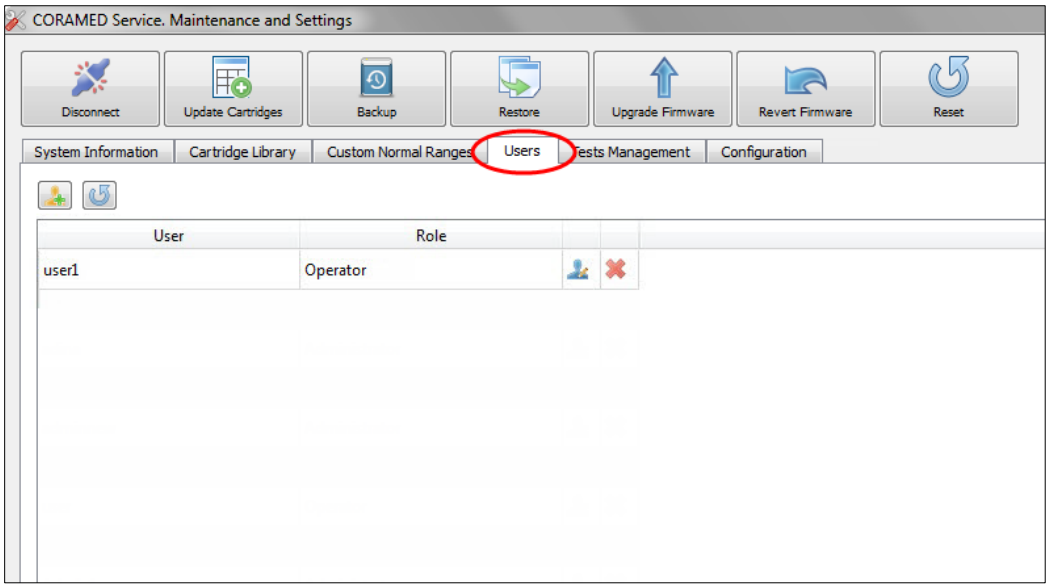


Figure 17: Users tab

2. Click the **Add User** button.

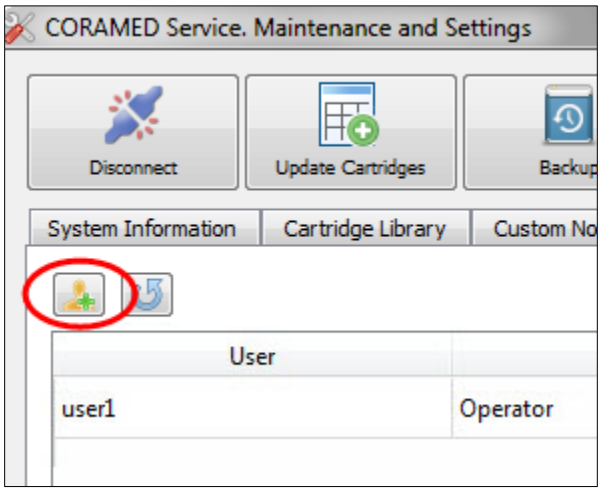


Figure 18: Add user button

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3. In the *Create user* screen, do the following:

   a. In the *User field*, enter a name for the new user. Note that user names are case sensitive.

   b. In the *Password* and *Password re-type* fields, enter a password based on the following criteria:

   - The password cannot contain the user's user name.
   - The minimum length of the password is 8 characters.
   - The maximum length of the password is 12 characters.
   - The password must contain at least one numeric character or symbol (the special characters "&" and "#" are not accepted).
   - The password cannot be a duplicate of any of the user's previous eight passwords.

   Note: *This is a temporary password only. Upon first login to the analyzer, the user is requested to change this password.*

   c. In the *Role* drop-down list, select the appropriate role for the user.

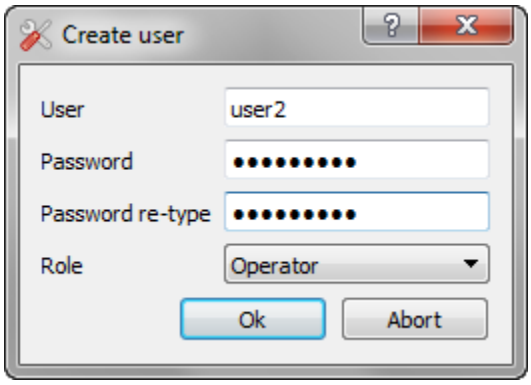


Figure 19: Create user

4. Click **OK**.

   The new user account appears on the **Users** tab.

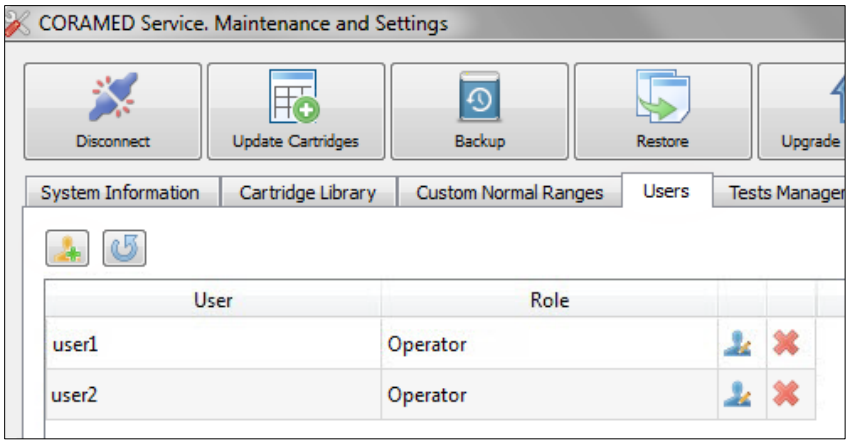


Figure 20: New user on Users tab

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Modify a user account

To modify a user account password or role:

1. On the **User** tab, click the **Modify** button next to the desired user account.

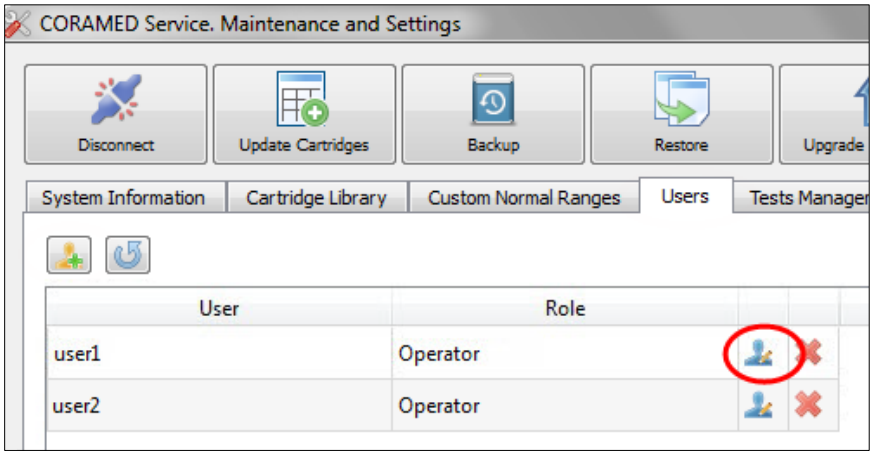


Figure 21: Modify user button

2. On the *Modify user* screen, change the password and/or role information for the user account.

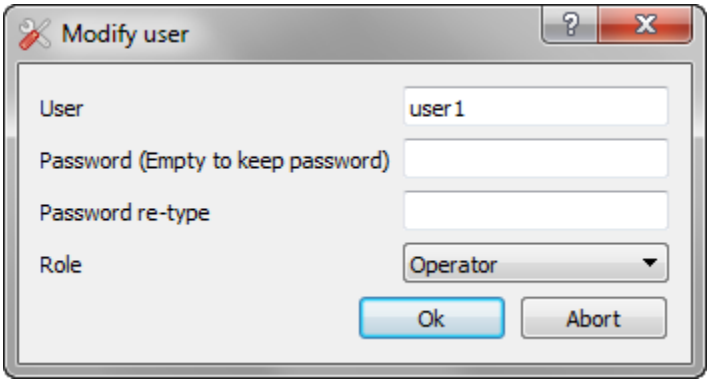


Figure 22: Modify user

3. Click **Ok**.

Delete a user account

To delete a user account from the system:

1. On the **User** tab, click the **Delete** button next to the desired user account.

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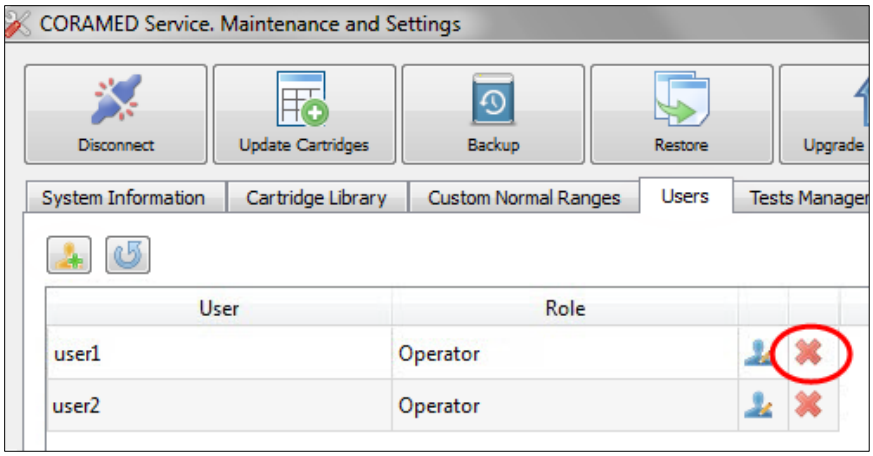


Figure 23: Delete button for the user account

2. In the confirmation message, click **OK**.

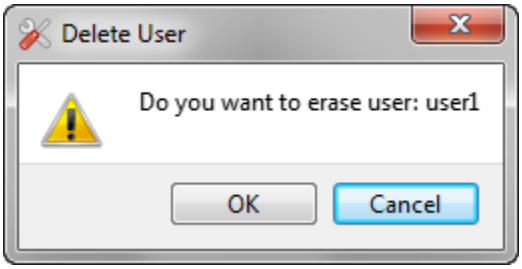


Figure 24: Delete User confirmation message

3. Click **Ok**. The user account no longer appears in the list on the **Users** tab.

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Section VIII: Viewing Test information

All Wet QC and patient test results stored in the analyzer are available for viewing on the **Tests Management** tab. The following information is displayed for each test:

- Patient ID
- Cartridge name
- Date and Time of test
- Status of results

To view test information:

1. On the SMS *Main* screen, click the **Tests Management** tab.

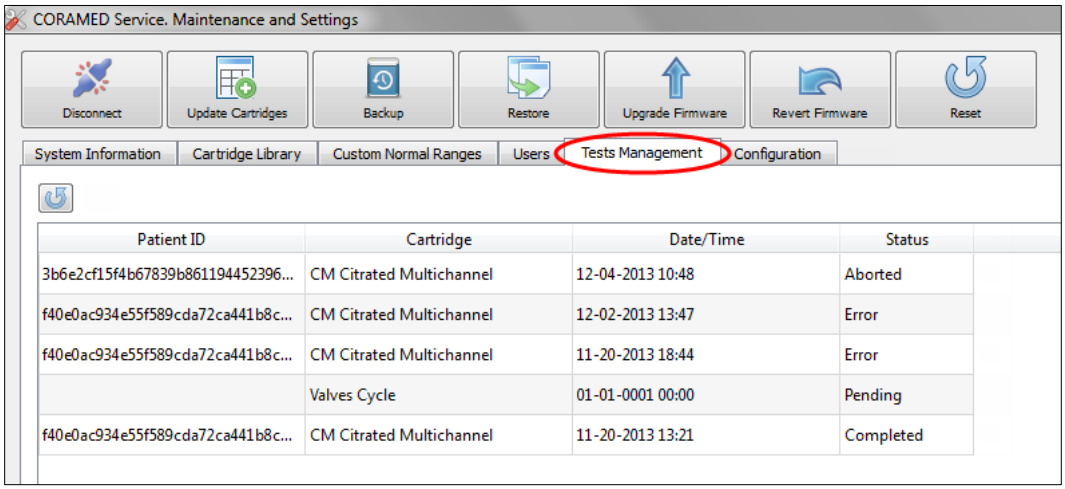


Figure 25: Tests Management tab

2. View the test information.

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Section IX: Configuring the Analyzer

Configuration settings that you apply in SMS apply only to the analyzer to which you are connected. These settings are maintained for all users that log into the analyzer.

To view or change configuration settings for the analyzer:

1. On the SMS *Main* screen, click the **Configuration** tab.

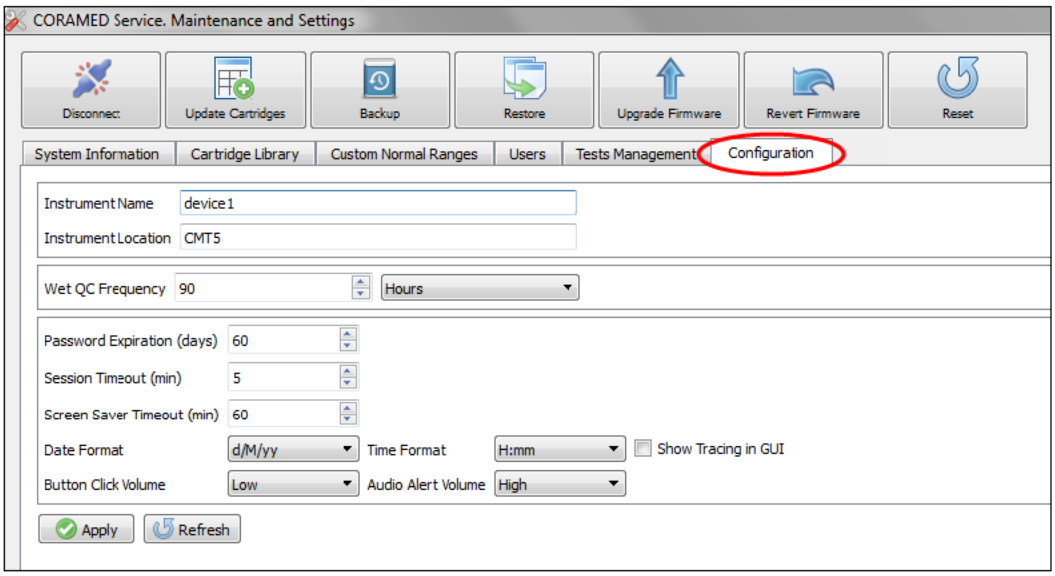


Figure 26: Configuration tab

2. View or change the values for the following fields:

Field	Action
Instrument Name	Enter a name for the analyzer up to a maximum of 20 characters.
Instrument Location	Enter a location for the analyzer up to a maximum of 20 characters.
Wet QC Frequency	Enter a value up to a maximum of 90.
Hours/Days	Select Hours or Days for the desired unit of time for Wet QC frequency.
Password Expiration (days)	Enter a value up to a maximum of 90.
Session Timeout (min)	Enter a value up to a maximum of 60.
Screen Saver Timeout (min)	Enter a value up to a maximum of 60.
Date Format	Select from 10 available date formats.
Time Format	Select from 5 available time formats.
Button Click Volume	Select from 5 available volume levels.
Audio Alert Volume	Select from 5 available settings

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3. Click **Apply**.
4. In the power cycle message that appears, click **Yes**.

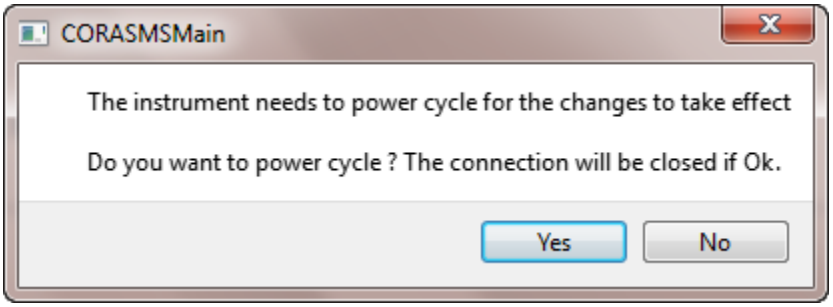


Figure 27: Power cycle message

The SMS software resets the analyzer automatically.

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Section X: Upgrading the Firmware

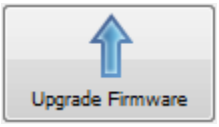
Upgrading the CORA analyzer firmware is performed using the SMS software in a two-step process: uploading the firmware files and committing the firmware. In the first step, a binary file is uploaded to the analyzer. The analyzer checks the CRC (Cyclic Redundancy Check) Values file and returns a CRC response message. In the second step, the firmware is committed, which resets the instrument and conducts the actual upgrade upon initialization.

The SMS software also provides a mechanism to revert to a previous firmware version.

Upgrade to a newer firmware version

To upgrade the firmware version:

1. On the SMS *Main* screen toolbar, click **Upgrade Firmware**.



2. In the *Upgrade Firmware* screen, next to *File*, click **Browse**.

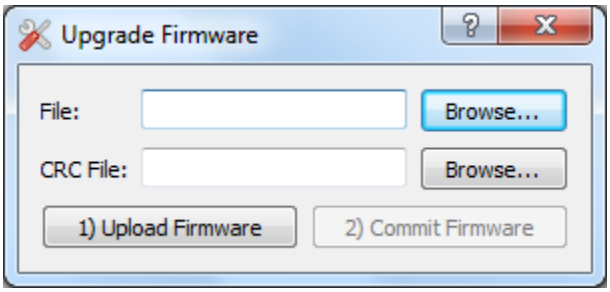


Figure 28: Upgrade Firmware screen

3. In the *Open firmware release* screen, navigate to the location of the latest firmware zip file, and then click **Open**.

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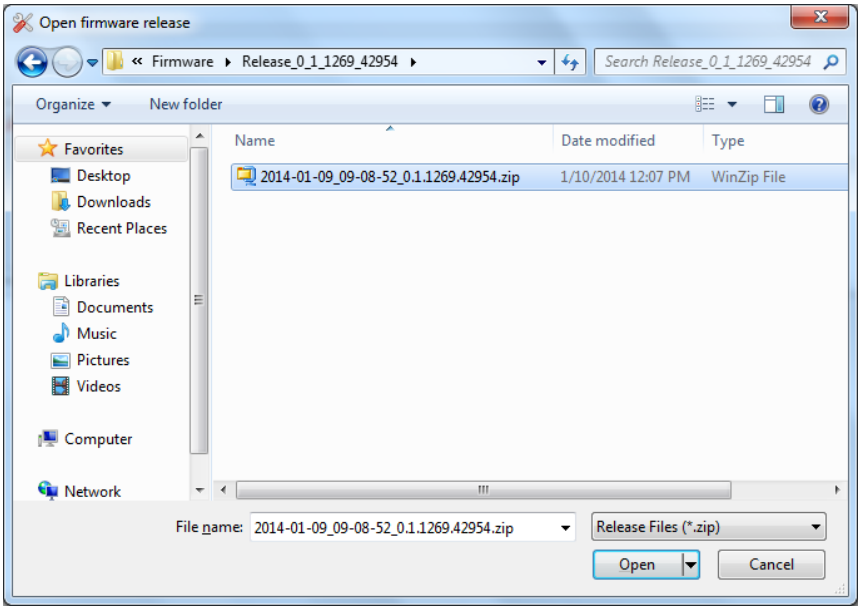


Figure 29: Browse to the location of the current firmware zip file

4. In the Windows *Open* screen, select the current firmware file, and then click **Open**.
5. In the *Upgrade Firmware* screen, next to *CRC File*, click **Browse** and navigate to the location of the latest CRC file.

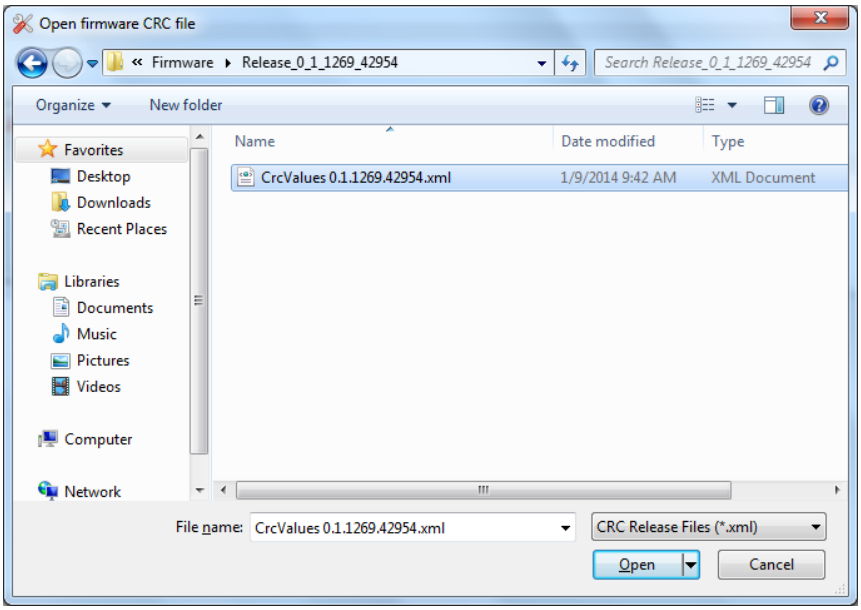


Figure 30: Browse to the location of the current CRC file

6. In the *Upgrade Firmware* screen, click **Upload Firmware**.

   When the analyzer finishes checking the binary and CRC Values files, the **Commit Firmware** button is enabled.

7. Click **Commit Firmware**.

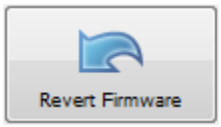
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The SMS software closes and the analyzer resets. The upgrade of the firmware is completed during re-initialization of the analyzer.

Revert to a previous firmware version

1. On the SMS *Main* screen toolbar, click **Revert Firmware**.



The SMS software closes and the analyzer resets. The previous firmware version is loaded during re-initialization of the analyzer.

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Section XI: Managing Backups

The CORA analyzer stores a maximum of 300 patient tests and 300 WQC tests (L1 and L2 combined). When the number of patient or WQC tests reaches 270, the analyzer prompts you to back up the data. The SMS includes functionality to perform backups and to restore a previously generated backup.

Each backup includes the following data:

- User accounts
- Configuration settings
- Cartridge tables
- Normal ranges
- Patient test results
- WQC test results
- Instrument unique ID
- Audit trail logs

Note: *Patient ID data is hashed during the backup process.*

If a backup is restored to a machine that already includes data, all data is restored with the exception of test results and configuration settings.

Perform a backup

To perform a backup of the analyzer:

1. On the SMS *Main* toolbar, click **Backup**.



2. In the *Save As* window, do the following:
    a. Accept the default location for the backup file (Backups folder in the application directory) or navigate to a location of your choice.

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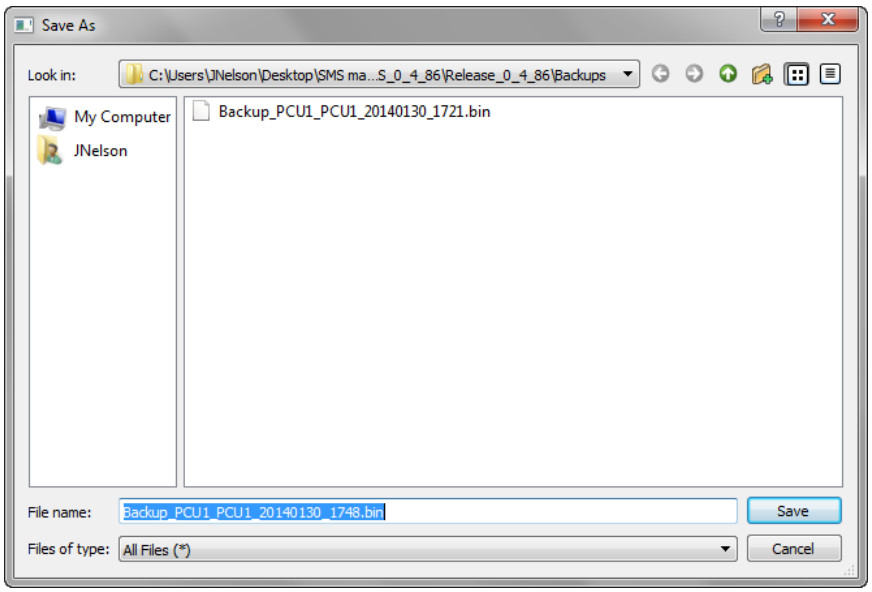


Figure 31: Select a location for the backup file

b. Accept the default name for the backup file (Backup_<serial number>_<instrument name>_ <yyyyMMdd>_<hhmm>.bin), or rename the file.

c. Click **Save**.

   A process message appears during the backup process, which can take up to ten minutes to complete. When the process is complete, the new file appears in the specified location.

Restore a previous backup

When you restore a backup to an analyzer, the data that is restored depends on whether or not the analyzer contains test results.

If there are *no* test results on the analyzer, the SMS software restores the following information from a backup:

- User accounts
- Configuration settings
- Cartridge tables
- Normal ranges
- Patient test results
- WQC test results (only if the backup is from the same analyzer)
- Audit trail logs

If there are test results already on the analyzer, the SMS software prevents the overwriting of test results and logs. Therefore, only the following information is restored from a backup:

- User accounts

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- Configuration settings
- Cartridge tables
- Normal ranges

To restore a previously generated backup file:

1. On the SMS *Main* toolbar, click **Restore**.



2. In the *Open* window, navigate to the Backup folder.

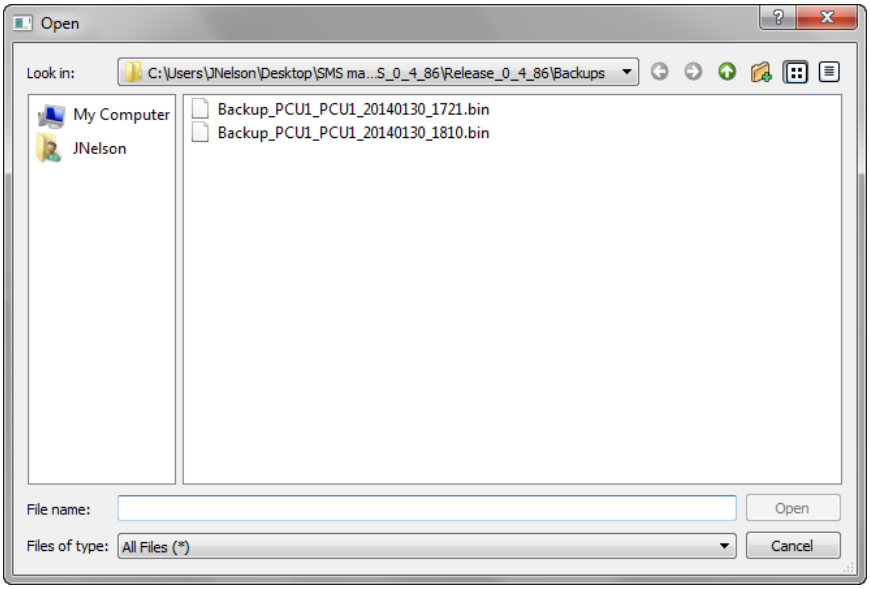


Figure 32: Navigate to the Backup folder

3. Select the desired backup file and click **Open**.

   A process message appears during the restore process.

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Section XII: Manually Resetting the Analyzer

The SMS software provides the ability to reset the instrument manually. To reset the analyzer, click the **Reset** button on the SMS toolbar.



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(b)(4) Test Protocol

(b)(4)

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Proprietary Name and Established Name

Proprietary Name: CORA® (Coagulation Resonance Analysis) System and the following citrated assays and reagents

CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent

Established Name: Whole Blood Hemostasis System

Intended Use

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The Citrated Multichannel Cartridge, to be used with the CORA System analyzer, contains four independent assays (CK, CRT, CKH and CFF), described below.

The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).

The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CKH assay monitors the effects of heparin in 3.2% citrated whole blood specimens on the CORA System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests.

The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Summary and Explanation of the Test

The CORA System and the Citrated Multichannel Cartridge are used to test the hemostasis properties of citrated blood samples using four different assays/reagents simultaneously, one in each of the four cartridge channels. For the CK assay, Kaolin-activated test methods are used to reduce variability and to reduce the running time of a native whole blood sample. The CRT assay maximally accelerates the clotting process by simultaneously activating the intrinsic and extrinsic coagulation pathways, allowing

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for the maximum clot strength to be reached more quickly. CKH is similar to CK but with the addition of heparinase, to neutralize the effects of heparin in the blood. If there is heparin present, the R time for CK will be significantly longer than the R time for CKH. The CFF assay fully inhibits all the platelets, thereby excluding their contribution to clot strength, and therefore measures only the functional fibrinogen contribution to clot strength.

Principles of the Procedure

CK Principle

Kaolin is a standardized reagent consisting of dry Kaolin and 0.85% Saline solution. Kaolin-activated test methods are used to reduce variability and to reduce the running time of a native whole blood sample. Use of these particles of hydrated aluminum silicate shortens coagulation time because Kaolin acts as a contact surface activator (intrinsic pathway), which activates Factor XII and platelets and stimulates the reserve clotting ability of a blood sample. Kaolin is combined with $CaCl_2$ to neutralize any sodium citrate in the blood.

CRT Principle

RapidTEG maximally accelerates the clotting process by simultaneously activating the intrinsic and extrinsic coagulation pathways using a high concentration of Kaolin and Tissue Factor (TF). This closely reflects the physiological clotting process and yields results significantly faster than a native, Kaolin, and/or TF activated test. $CaCl_2$ is included to neutralize any sodium citrate in the blood.

CKH Principle

Heparin is commonly used as an anticoagulant in surgical procedures. Even very low concentrations of Heparin, fractions of IU/mL of blood, can noticeably increase the R time and can even completely anticoagulate the blood, making it difficult if not impossible to monitor developing coagulopathies that are masked by high levels of therapeutic Heparin. The Kaolin with Heparinase assay will rapidly and specifically neutralize the anticoagulant property of Heparin. $CaCl_2$ is included to neutralize any sodium citrate in the blood

CFF Principle

The Functional Fibrinogen reagent activates the extrinsic pathway using tissue factor and inhibits platelet aggregation using a platelet inhibitor that binds to GPIIb/IIIa receptors. The Functional Fibrinogen reagent fully inhibits all the platelets, thereby excluding their contribution to clot strength (MA), and therefore measures only the functional fibrinogen contribution (MA_{PI}) to clot strength. Functional Fibrinogen is combined with $CaCl_2$ to neutralize any sodium citrate in the blood. Determining the independent contribution of platelets and fibrinogen further improves the use of the CORA System in helping to detect and diagnose hemostasis defects.

Reagents

CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
Dried Kaolin and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 35.45% Kaolin (concentration 0.011896% w/w), 21.97% water, and 42.58% Calcium Chloride 2 M solution.

CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
Dried Kaolin, Tissue Factor and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 11.73% Kaolin (concentration 14.098 % w/w), 46.92% Tissue Factor (concentration 3.88 µg/mL), and 41.35% Calcium Chloride 2M solution.

CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
Dried Kaolin and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 57.42% Kaolin (concentration 0.012854% w/w) and 42.58% Calcium Chloride 2 M solution; dried Heparinase,

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900 nL spot in blood well of channel, consisting of 23.66% Heparinase (concentration 0.38 IU) and 76.34% water.

CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent
Dried Tissue Factor and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 58.65% Tissue Factor (concentration 0.00055 µg/mL) and 41.35% Calcium Chloride 2 M solution; dried ReoPro®, 900 nL spot in blood well of channel, consisting of 100% ReoPro®.

Warnings or Precautions:

For In-Vitro Diagnostic Use

Sources of Reagent Error

Cartridges should be refrigerated (2° C to 8° C) when not in use.

Sources of Procedural Error

Use only citrated tubes. Do not collect blood samples into heparin tubes or any other tubes not specifically recommended.

Instructions for reconstitution, mixing, dilution, etc.

None required.

Handling Instructions:

While operating the CORA system, wear powder-free examining gloves and wash hands immediately after removing the gloves. Also, operators should switch gloves between patients and after completion of testing, and wear fluid-resistant clothing.

Storage instructions

CORA Citrated Multichannel cartridges are for single use only and should be stored refrigerated at 2°C to 8°C prior to removal from storage for use. Cartridges should be discarded after use.

Analyzer

Refer to CORA System User's Manual

Specimen Collection and Preparation for Analysis

Use only citrated tubes for blood draws. No additives or preservatives are necessary to maintain the integrity of the sample, but samples must be used within 2 hours of draw to maintain in-use stability.

Known Interfering Factors

CK assay was tested for interference factors according to CLSI EP7-A2. Potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Only Hemolysis, and Hemodilution levels above 20%, were found to be interferents.

CRT assay was tested for interference factors according to CLSI EP7-A2. Potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). All except EACA and Absence of a Discard Tube were found to be interferents, with Hemodilution being an interferent above 20% concentration.

CKH assay was tested for interference factors according to CLSI EP7-A2. The potential interferent tested was Protamine. Results show that Protamine is an interferent at concentrations above 0.062 mg/mL.

CFF assay was tested for interference factors according to CLSI EP7-A2. Potential interferents tested were Heparin and Hemodilution. Heparin was found to be an interferent for Functional Fibrinogen above Heparin concentrations of 1 IU/mL, and Hemodilution was found to be an interferent above hemodilution levels of 30%.

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Procedure

Materials Provided

One (1) Citrated Multichannel cartridge sealed with desiccant pack in foil pouch. Cartridge contains the following dried reagents: Kaolin, RapidTEG, Kaolin with Heparinase and Functional Fibrinogen, all with Calcium Chloride.

Materials Required (but not supplied)

CORA® Analyzer (Coramed Technologies) – see User's Manual for instructions for use.
Transfer pipette(s) (Samco Scientific #212 or equivalent)
Blood drawing supplies (any medical supplier)

Test Procedure

1. Remove the cartridge from refrigerated storage.
2. Tear open the pouch, remove the cartridge and discard the pouch and desiccant pack.
3. From the main menu on the CORA analyzer, select "new test".
4. Select the patient ID you wish to use. If the patient is not listed, you may add a new patient by selecting the "+" option and entering a patient ID on the screen. Then press "next".
5. Insert the cartridge into the slot as indicated on the screen with the bar code on the left side.
6. After the cartridge pretest is completed and you have verified that the assay is what you intended to run, press "next". If the cartridge is not the desired assay, press "stop" and start over.
7. Add blood to the cartridge sample port to above the level indicated on the cartridge.
8. After loading the sample press "next".
9. The test will run and results will be displayed as they become available.
10. When the test is completed, the analyzer will prompt to remove the cartridge and will return to the table of results.
11. Remove the used cartridge from the slot as demonstrated on the LCD display, and discard the cartridge.
12. Press "done" from the results screen to return to the home page.

Calibration

The CORA analyzer does not require routine calibration.

Quality Control Procedures

The CORA analyzer performs internal QC checks during a pretest when the cartridge is inserted. This verifies that all electromechanical and pneumatic functions of the analyzer-cartridge combination are operating satisfactorily. Laboratories should perform additional QC testing as required by their laboratory's procedures. Coramed provides Abnormal WQC materials to be used for this purpose.

Whereas the internal QC of the analyzer effectively tests analyzer functions, a QC methodology is required to verify that reagents in cartridges are still viable at time of use. This ensures that cartridges have not been mishandled between production and arrival at the lab, or have not been subject to adverse environmental conditions or otherwise mishandled while in lab storage. This can supplement the laboratory's development of its own Individualized Quality Control Plan (IQCP) based on the lab's risk analysis, in accordance with CLSI EP23. This risk analysis would take into account the lab's specific situations that could affect reagent quality, such as environmental storage controls.

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Coramed recommends that normal and abnormal donor control checks be performed for each new shipment of citrated multichannel assay cartridges. Additional QC checks may be performed on a monthly, weekly, daily or shift basis based on the laboratory's quality control policies. The end user should follow the recommendations of local and state regulatory agencies as well as facility policies.

Coramed recommends that the lab perform two levels of QC testing whenever indicated by the IQCP using the following procedure.

i. Establish a known normal quality control using blood drawn from healthy adults.
ii. The normal donor control should not have taken any medication known to affect coagulation levels and should have prior citrated multichannel cartridge tests that have fallen within the established normal reference ranges.
iii. Prepare an abnormal quality control using Abnormal WQC material, representing an abnormal sample, following instructions in the Abnormal QC Material Product Insert, #01-182.
iv. The "normal" donor should have test results that fall within established reference ranges. For the Abnormal WQC sample, reagent performance is verified if parameters fall within the following Reference Ranges

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (degrees)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563 - 873

Results

No calculations are necessary to obtain test results; these are displayed on the CORA analyzer display, and may be printed if a printer is attached.

CK Test Results

The R, K, Angle and MA parameters are measured and displayed at the conclusion of the test, along with the corresponding reference ranges established for these parameters.

CRT Test Results

The MA parameter is measured and displayed at the conclusion of the test, along with the corresponding reference ranges established for these parameters.

CKH Test Results

The R parameter is the only one of importance for this test. It is measured and displayed at the conclusion of the test, along with the corresponding reference range established for the R parameter for Kaolin with Heparinase.

CFF Test Results

The MA parameter and the estimated Functional Fibrinogen Level (FLEV) are measured and displayed at the conclusion of the test.

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Limitation of the Procedure

Use of Results

CORA results should always be considered within the clinical context of the individual patient's case. In the event of inconsistencies with the patient's clinical status, samples should be repeated or supplemented with additional clinical information and/or data.

Expected Values

Expected values for test results are within the Reference Ranges for a reference population that were established according to CLSI C28-A3c. The following tables contain the reference range data for each reagent and parameter. It is recommended that customers validate reference ranges based on their local population.

CK Reference Ranges

Citrated Blood Parameter	N	Range
R (min)	157	4.6 – 9.1
K (min)	157	0.8 – 2.1
Angle (deg)	155	63 - 78
MA (mm)	151	52 - 69

CRT Reference Ranges

Citrated Blood Parameter	N	Range
MA	152	52 - 70

CKH Reference Ranges

Citrated Blood Parameter	N	Range
R	155	4.3 – 8.3

CFF Reference Ranges

Citrated Blood Parameter	N	Range
MA	151	15 - 32
FLEV	152	278 - 581

Specific Performance Characteristics

CK Precision

The precision of the CORA Kaolin test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the Kaolin Assay was CV less than 15% for the R parameter, less than 10% for the MA parameter, less than 10% for the Angle parameter and less than 25% for the K parameter.

CK Sensitivity and Specificity

The Kaolin reagent is often used in conjunction with tests performed on blood samples from patients administered with heparin, with the goal of either determining heparin effect (titration of dose) or determining full reversal (post-protamine) of heparin administered. It is, therefore, important that the Clinical Sensitivity and Specificity for the presence of heparin be determined. Five different heparin spiked samples were examined, with concentrations spread across the heparin therapeutic ranges (0.2 to

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6.0 IU/mL). 0.2 IU/mL is the lowest therapeutic dose typically used and 6.0 IU/mL represents a typical dose of heparin used when patients are fully heparinized during cardio-pulmonary by-pass. In addition, five (5) non-heparin spiked samples were analyzed. Kaolin's sensitivity to Heparin was 100%, with the R parameter elongated and out of range for all concentrations. Specificity was also 100%, with all un-spiked samples having an R parameter within normal range.

CRT Precision

The precision of the CORA RapidTEG test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the RapidTEG Assay was less than 10% for the MA parameter.

CKH Precision

The precision of the CORA Kaolin with Heparinase test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the Kaolin with Heparinase Assay was CV less than 15% for the R parameter.

CKH Neutralization

The Kaolin with Heparinase assay was tested to verify that 6 IU of Heparinase per 1 mL of blood will effectively neutralize the effects of both Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) on Kaolin-activated citrated whole blood samples. This is the amount of Heparinase used in the Kaolin with Heparinase assay. Tests were performed using UHF and LMWH spiked samples and un-spiked samples. All tests reported R parameter values within the normal range, confirming the neutralization effectiveness of the assay.

CFF Precision

The precision of the CORA Functional Fibrinogen test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the Functional Fibrinogen Assay was CV less than 10% for the MA and FLEV parameters.

CFF Linearity

The Function Fibrinogen assay was tested for linearity according to CLSI EP6-A. Linearity with respect to Fibrinogen concentration levels is shown below.

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Clinical Performance - Method Comparison and Reader Studies

Method Comparison studies were conducted at three clinical sites on patient samples following CLSI EP09-A3 Guideline. The subjects enrolled were patients undergoing cardiovascular surgery or cardiology procedures, with blood samples drawn pre- and post-surgery and in the ICU. In order to broaden the range of comparison, up to 10% contrived samples were added. Summary statistics are presented below.

Method Comparison Statistics Summary – All Clinical Sites					
Parameter	**R**	**Intercept**	**95% CI**	**Slope**	**95% CI**
CK – R (min)	0.868	-0.325	-0.425	1.069	1.034
			-0.225		1.103
CK – K (min)	0.740	-0.097	-0.292	0.906	0.769
			0.098		1.042
CK – Alpha (deg)	0.680	7.305	-13.160	0.940	0.640
			27.769		1.240
CK – MA (mm)	0.924	2.351	0.166	0.948	0.912
			4.536		0.983
CKH – R (min)	0.812	-0.329	-0.393	1.057	1.026
			-0.265		1.089
CRT|CK – MA (mm)	0.929	-0.126	-1.909	0.978	0.948
			1.656		1.007
CFF – MA (mm)	0.938	-0.774	-1.836	1.126	1.072
			0.289		1.180
CFF – FLEV (mg/dl)	0.928	-12.495	-36.810	1.127	1.059
			11.819		1.194

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In addition, a Reader Study was conducted to assess the comparison of CORA System and TEG 5000 results based on reading printed test outcomes. The study was performed at three sites, using three experienced TEG 5000 doctors as readers at each site, for a total of nine readers. 30 test outcomes were compared for each of the reagent test categories, for a total of 270 reading comparisons per reader. Excellent agreement between the two devices was demonstrated.

In both the Method Comparison Study and Reader Study, the CORA RapidTEG (CRT) MA parameter was compared to the TEG 5000 Kaolin (CK) MA parameter, to demonstrate that the CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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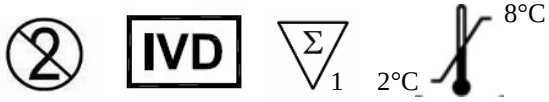
Name and Place of Business of Manufacturer:

Coramed Technologies
6225 W Howard St
Niles, IL 60714 USA

Date of Issuance of Last Labeling Revision: June 3, 2015

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REF CRT-CC-0L2

Rx Only

CONTROL

Proprietary Name and Established Name

Proprietary Name: Abnormal WQC Material to be used with the CORA® (Coagulation Resonance Analysis) System

Established Name: Whole Blood Hemostasis System

Intended Use

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The CORA System records the kinetic changes in a sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The Abnormal WQC (Wet Quality Control) Material is to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Summary and Explanation of the Test

The CORA System is used to test the hemostasis properties of blood samples. The CORA analyzer performs internal QC checks during a pretest when the cartridge is inserted. This verifies that all electromechanical and pneumatic functions of the analyzer-cartridge combination are operating satisfactorily. Laboratories should perform QC testing as required in accordance with their laboratory policies and procedures.

Principles of the Procedure

The CORA Hemostasis System whole blood coagulation Abnormal Wet Quality Control contains a preparation of animal citrated plasma. It has been formulated specifically as a quality control for the CORA System, representing an "abnormally low" level of coagulation. This control contains no human material. It is for in vitro diagnostic use and professional use only.

Reagents

Abnormal Wet Quality Control Material

The Abnormal WQC Material consists of one 1 mL vial of lyophilized bovine citrated plasma and one 1 mL vial of diluent water for reconstituting the lyophilized material.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Warnings and Precautions:

For In-Vitro Diagnostic Use

Hazards

The Abnormal WQC Material is potentially hazardous in case of ingestion, inhalation, skin contact and eye contact. It contains animal source material; therefore, it should be treated as potentially infectious. Use universal precautions for handling potentially bio-hazardous material. It may cause adverse effects for the environment if discarded improperly.

Sources of Reagent Error

- Do not freeze the controls.

Sources of Procedural Error

- Carefully follow the instructions for the preparation of the Abnormal WQC Material. For correct reconstitution, the full vial of diluent water must be poured into the vial of lyophilized control. Failure to do so may result in inaccurate results.
- Timing - Do not use controls if they have been reconstituted for more than 2 hours

Instructions for reconstitution, mixing, dilution, etc.

The entire contents of the diluent water vial must be placed into the Abnormal WQC vial for proper concentration, and thoroughly mixed.

Storage instructions

Abnormal WQC Materials are for single use only and should be stored refrigerated at 2°C to 8°C prior to removal from storage for use.

Analyzer

Refer to CORA System User's Manual

Specimen Collection and Preparation for Analysis

No specimen collection is required for running this quality control test. No additives or preservatives are necessary to maintain the integrity of the material, but reconstituted Abnormal WQC Material must be used within 2 hours of reconstitution.

Procedure

Materials Provided

One (1) Abnormal WQC vial and one (1) Water vial.

Materials Required (but not supplied)

CORA® Analyzer (Coramed Technologies)
Transfer pipette(s) (Samco Scientific #212 or equivalent)

Test Procedure (used in conjunction with Citrated Multichannel cartridges)

1. Remove the cartridge from refrigerated storage.
2. Tear open the pouch, remove the cartridge and discard the pouch and desiccant pack.
3. From the main menu on the CORA analyzer, select "new qc".
4. Insert the cartridge into the slot as indicated on the screen with the bar code on the left side.
5. After the cartridge pretest is completed and you have verified that the assay is what you intended to run, press "next". If the cartridge is not the desired assay, press "stop" and start over.
6. Prepare the Abnormal WQC sample according to the following instructions:
   a) Allow the control and the diluent water vial(s) to sit for approximately 10 minutes to equilibrate to room temperature.
   b) Make sure the control is on the bottom of the vial. You may need to tap the vial a few times.

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c) Remove the seal and stopper of the lyophilized control, taking care to avoid sharp metal edges.
d) Into each vial of lyophilized control, slowly pour 1 vial of 1 mL of diluent water, provided. Make sure no water drips out.
e) Re-insert the stopper into the control vial.
f) Hold the stopper in place, vigorously shake the vial until fully reconstituted, and then let it stand for 5 minutes at room temperature.
g) Shake the vial vigorously again and let stand 5 more minutes.

7. Using the transfer pipette, deliver the Abnormal WQC material to the cartridge sample port to above the level indicated on the cartridge.
8. After loading the sample press "next".
9. The test will run and results will be displayed as they become available.
10. When the test is completed, the analyzer will prompt to remove the cartridge and will return to the table of results.
11. Remove the used cartridge from the slot as demonstrated on the LCD display, and discard the cartridge.
12. Press "done" from the results screen to return to the home page.

Results

No calculations are necessary to obtain test results; these are displayed on the CORA analyzer display, and may be printed if a printer is attached.

Limitations of the Procedure

Use of Results

- Results outside of the normal ranges listed below may be caused by improperly prepared control material or product deterioration. It is recommended that any failed Abnormal WQC test should be repeated. Repeated failures should be reported to the supervisor.
- Do not report any patient results until the control parameters are within their appropriate ranges.

Expected Values

Expected values for test results are within the Reference Ranges that were established based on testing by Coramed, following Clinical and Laboratory Standards Institute (CLSI) publication C28-A3c, Defining, Establishing and Verifying Reference Intervals. Each laboratory may establish its own level of performance to monitor quality assurance. Follow your institution's policy to establish mean target values and ranges for the quality controls.

Reference Ranges for Abnormal WQC and Citrated Multichannel Reagents

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (degrees)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563 - 873

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

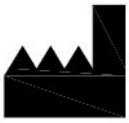
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Specific Performance Characteristics

Precision

The precision of the CORA Abnormal WQC Material was evaluated according to CLSI EP5-A2. Testing was performed in Coramed' laboratory for within-device (20-day tests using Abnormal WQC with citrated reagents), and multi-site reproducibility tests were performed across three sites, three lots, three operators and three analyzers. Results included Coefficient of Variance (CV) values for all tests completed. For these precision tests, the precision for the Abnormal WQC Material was CV less than 10% for all parameters.

Name and Place of Business of Manufacturer:

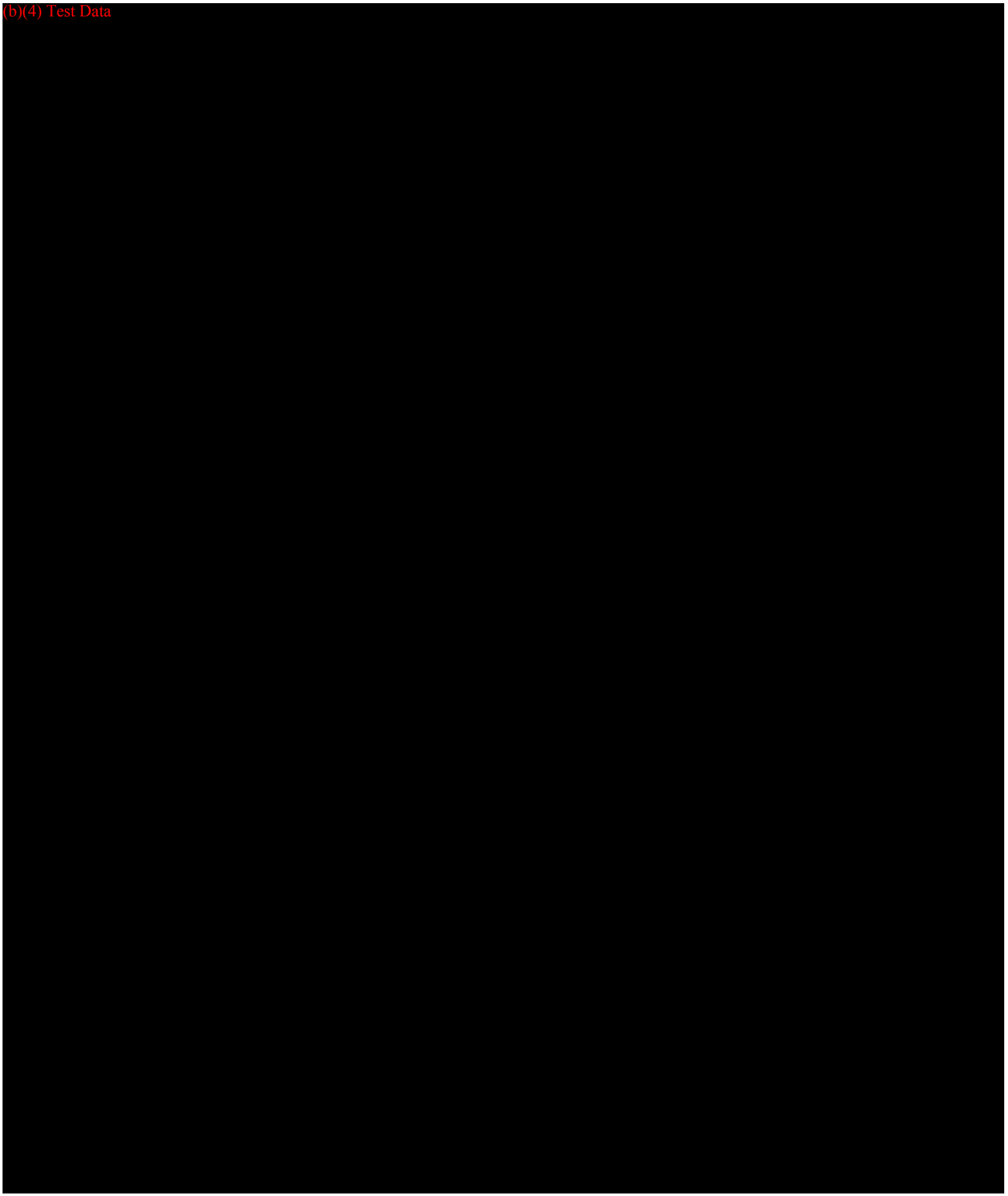


Coramed Technologies
6225 W Howard St
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Date of Issuance of Last Labeling Revision: June 4, 2015

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

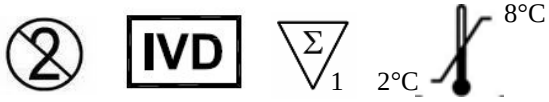


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REF CRT-CC-0L2

Rx Only

CONTROL

Proprietary Name and Established Name

Proprietary Name: Abnormal WQC Material to be used with the CORA® (Coagulation Resonance Analysis) System

Established Name: Whole Blood Hemostasis System

Intended Use

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The CORA System records the kinetic changes in a sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The Abnormal WQC (Wet Quality Control) Material is to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Summary and Explanation of the Test

The CORA System is used to test the hemostasis properties of blood samples. The CORA analyzer performs internal QC checks during a pretest when the cartridge is inserted. This verifies that all electromechanical and pneumatic functions of the analyzer-cartridge combination are operating satisfactorily. Laboratories should perform QC testing as required in accordance with their laboratory policies and procedures.

Principles of the Procedure

The CORA Hemostasis System whole blood coagulation Abnormal Wet Quality Control contains a preparation of animal citrated plasma. It has been formulated specifically as a quality control for the CORA System, representing an "abnormally low" level of coagulation. This control contains no human material. It is for in vitro diagnostic use and professional use only.

Reagents

Abnormal Wet Quality Control Material

The Abnormal WQC Material consists of one 1 mL vial of lyophilized bovine citrated plasma and one 1 mL vial of diluent water for reconstituting the lyophilized material.

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Warnings and Precautions:

For In-Vitro Diagnostic Use

Hazards

The Abnormal WQC Material is potentially hazardous in case of ingestion, inhalation, skin contact and eye contact. It contains animal source material; therefore, it should be treated as potentially infectious. Use universal precautions for handling potentially bio-hazardous material. It may cause adverse effects for the environment if discarded improperly.

Sources of Reagent Error

- Do not freeze the controls.

Sources of Procedural Error

- Carefully follow the instructions for the preparation of the Abnormal WQC Material. For correct reconstitution, the full vial of diluent water must be poured into the vial of lyophilized control. Failure to do so may result in inaccurate results.
- Timing - Do not use controls if they have been reconstituted for more than 2 hours

Instructions for reconstitution, mixing, dilution, etc.

The entire contents of the diluent water vial must be placed into the Abnormal WQC vial for proper concentration, and thoroughly mixed.

Storage instructions

Abnormal WQC Materials are for single use only and should be stored refrigerated at 2°C to 8°C prior to removal from storage for use.

Analyzer

Refer to CORA System User's Manual

Specimen Collection and Preparation for Analysis

No specimen collection is required for running this quality control test. No additives or preservatives are necessary to maintain the integrity of the material, but reconstituted Abnormal WQC Material must be used within 2 hours of reconstitution.

Procedure

Materials Provided

One (1) Abnormal WQC vial and one (1) Water vial.

Materials Required (but not supplied)

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Test Procedure (used in conjunction with Citrated Multichannel cartridges)

1. Remove the cartridge from refrigerated storage.
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6. Prepare the Abnormal WQC sample according to the following instructions:
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e) Re-insert the stopper into the control vial.
f) Hold the stopper in place, vigorously shake the vial until fully reconstituted, and then let it stand for 5 minutes at room temperature.
g) Shake the vial vigorously again and let stand 5 more minutes.

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8. After loading the sample press "next".
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10. When the test is completed, the analyzer will prompt to remove the cartridge and will return to the table of results.
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Results

No calculations are necessary to obtain test results; these are displayed on the CORA analyzer display, and may be printed if a printer is attached.

Limitations of the Procedure

Use of Results

- Results outside of the normal ranges listed below may be caused by improperly prepared control material or product deterioration. It is recommended that any failed Abnormal WQC test should be repeated. Repeated failures should be reported to the supervisor.
- Do not report any patient results until the control parameters are within their appropriate ranges.

Expected Values

Expected values for test results are within the Reference Ranges that were established based on testing by Coramed, following Clinical and Laboratory Standards Institute (CLSI) publication C28-A3c, Defining, Establishing and Verifying Reference Intervals. Each laboratory may establish its own level of performance to monitor quality assurance. Follow your institution's policy to establish mean target values and ranges for the quality controls.

Reference Ranges for Abnormal WQC and Citrated Multichannel Reagents

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (degrees)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563 - 873

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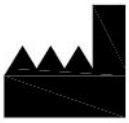
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Specific Performance Characteristics

Precision

The precision of the CORA Abnormal WQC Material was evaluated according to CLSI EP5-A2. Testing was performed in Coramed' laboratory for within-device (20-day tests using Abnormal WQC with citrated reagents), and multi-site reproducibility tests were performed across three sites, three lots, three operators and three analyzers. Results included Coefficient of Variance (CV) values for all tests completed. For these precision tests, the precision for the Abnormal WQC Material was CV less than 10% for all parameters.

Name and Place of Business of Manufacturer:



Coramed Technologies
6225 W Howard St
Niles, IL 60714 USA

Date of Issuance of Last Labeling Revision: June 4, 2015

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2016-2049; Released by CDRH on 01/25/2017



Proprietary Name and Established Name

Proprietary Name: CORA® (Coagulation Resonance Analysis) System and the following citrated assays and reagents

CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent

Established Name: Whole Blood Hemostasis System

Intended Use

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The Citrated Multichannel Cartridge, to be used with the CORA System analyzer, contains four independent assays (CK, CRT, CKH and CFF), described below.

The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).

The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CKH assay monitors the effects of heparin in 3.2% citrated whole blood specimens on the CORA System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests.

The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Summary and Explanation of the Test

The CORA System and the Citrated Multichannel Cartridge are used to test the hemostasis properties of citrated blood samples using four different assays/reagents simultaneously, one in each of the four cartridge channels. For the CK assay, Kaolin-activated test methods are used to reduce variability and to reduce the running time of a native whole blood sample. The CRT assay maximally accelerates the clotting process by simultaneously activating the intrinsic and extrinsic coagulation pathways, allowing

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for the maximum clot strength to be reached more quickly. CKH is similar to CK but with the addition of heparinase, to neutralize the effects of heparin in the blood. If there is heparin present, the R time for CK will be significantly longer than the R time for CKH. The CFF assay fully inhibits all the platelets, thereby excluding their contribution to clot strength, and therefore measures only the functional fibrinogen contribution to clot strength.

Principles of the Procedure

CK Principle

Kaolin is a standardized reagent consisting of dry Kaolin and 0.85% Saline solution. Kaolin-activated test methods are used to reduce variability and to reduce the running time of a native whole blood sample. Use of these particles of hydrated aluminum silicate shortens coagulation time because Kaolin acts as a contact surface activator (intrinsic pathway), which activates Factor XII and platelets and stimulates the reserve clotting ability of a blood sample. Kaolin is combined with $CaCl_2$ to neutralize any sodium citrate in the blood.

CRT Principle

RapidTEG maximally accelerates the clotting process by simultaneously activating the intrinsic and extrinsic coagulation pathways using a high concentration of Kaolin and Tissue Factor (TF). This closely reflects the physiological clotting process and yields results significantly faster than a native, Kaolin, and/or TF activated test. $CaCl_2$ is included to neutralize any sodium citrate in the blood.

CKH Principle

Heparin is commonly used as an anticoagulant in surgical procedures. Even very low concentrations of Heparin, fractions of IU/mL of blood, can noticeably increase the R time and can even completely anticoagulate the blood, making it difficult if not impossible to monitor developing coagulopathies that are masked by high levels of therapeutic Heparin. The Kaolin with Heparinase assay will rapidly and specifically neutralize the anticoagulant property of Heparin. $CaCl_2$ is included to neutralize any sodium citrate in the blood

CFF Principle

The Functional Fibrinogen reagent activates the extrinsic pathway using tissue factor and inhibits platelet aggregation using a platelet inhibitor that binds to GPIIb/IIIa receptors. The Functional Fibrinogen reagent fully inhibits all the platelets, thereby excluding their contribution to clot strength (MA), and therefore measures only the functional fibrinogen contribution (MA_{PI}) to clot strength. Functional Fibrinogen is combined with $CaCl_2$ to neutralize any sodium citrate in the blood. Determining the independent contribution of platelets and fibrinogen further improves the use of the CORA System in helping to detect and diagnose hemostasis defects.

Reagents

CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
Dried Kaolin and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 35.45% Kaolin (concentration 0.011896% w/w), 21.97% water, and 42.58% Calcium Chloride 2 M solution.

CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
Dried Kaolin, Tissue Factor and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 11.73% Kaolin (concentration 14.098 % w/w), 46.92% Tissue Factor (concentration 3.88 µg/mL), and 41.35% Calcium Chloride 2M solution.

CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
Dried Kaolin and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 57.42% Kaolin (concentration 0.012854% w/w) and 42.58% Calcium Chloride 2 M solution; dried Heparinase,

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900 nL spot in blood well of channel, consisting of 23.66% Heparinase (concentration 0.38 IU) and 76.34% water.

CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent
Dried Tissue Factor and Calcium Chloride, 900 nL spot in reagent chamber of channel, consisting of 58.65% Tissue Factor (concentration 0.00055 µg/mL) and 41.35% Calcium Chloride 2 M solution; dried ReoPro®, 900 nL spot in blood well of channel, consisting of 100% ReoPro®.

Warnings or Precautions:

For In-Vitro Diagnostic Use

Sources of Reagent Error

Cartridges should be refrigerated (2° C to 8° C) when not in use.

Sources of Procedural Error

Use only citrated tubes. Do not collect blood samples into heparin tubes or any other tubes not specifically recommended.

Instructions for reconstitution, mixing, dilution, etc.

None required.

Handling Instructions:

While operating the CORA system, wear powder-free examining gloves and wash hands immediately after removing the gloves. Also, operators should switch gloves between patients and after completion of testing, and wear fluid-resistant clothing.

Storage instructions

CORA Citrated Multichannel cartridges are for single use only and should be stored refrigerated at 2°C to 8°C prior to removal from storage for use. Cartridges should be discarded after use.

Analyzer

Refer to CORA System User's Manual

Specimen Collection and Preparation for Analysis

Use only citrated tubes for blood draws. No additives or preservatives are necessary to maintain the integrity of the sample, but samples must be used within 2 hours of draw to maintain in-use stability.

Known Interfering Factors

CK assay was tested for interference factors according to CLSI EP7-A2. Potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Only Hemolysis, and Hemodilution levels above 20%, were found to be interferents.

CRT assay was tested for interference factors according to CLSI EP7-A2. Potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). All except EACA and Absence of a Discard Tube were found to be interferents, with Hemodilution being an interferent above 20% concentration.

CKH assay was tested for interference factors according to CLSI EP7-A2. The potential interferent tested was Protamine. Results show that Protamine is an interferent at concentrations above 0.062 mg/mL.

CFF assay was tested for interference factors according to CLSI EP7-A2. Potential interferents tested were Heparin and Hemodilution. Heparin was found to be an interferent for Functional Fibrinogen above Heparin concentrations of 1 IU/mL, and Hemodilution was found to be an interferent above hemodilution levels of 30%.

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Procedure

Materials Provided

One (1) Citrated Multichannel cartridge sealed with desiccant pack in foil pouch. Cartridge contains the following dried reagents: Kaolin, RapidTEG, Kaolin with Heparinase and Functional Fibrinogen, all with Calcium Chloride.

Materials Required (but not supplied)

CORA® Analyzer (Coramed Technologies) – see User's Manual for instructions for use.
Transfer pipette(s) (Samco Scientific #212 or equivalent)
Blood drawing supplies (any medical supplier)

Test Procedure

1. Remove the cartridge from refrigerated storage.
2. Tear open the pouch, remove the cartridge and discard the pouch and desiccant pack.
3. From the main menu on the CORA analyzer, select "new test".
4. Select the patient ID you wish to use. If the patient is not listed, you may add a new patient by selecting the "+" option and entering a patient ID on the screen. Then press "next".
5. Insert the cartridge into the slot as indicated on the screen with the bar code on the left side.
6. After the cartridge pretest is completed and you have verified that the assay is what you intended to run, press "next". If the cartridge is not the desired assay, press "stop" and start over.
7. Add blood to the cartridge sample port to above the level indicated on the cartridge.
8. After loading the sample press "next".
9. The test will run and results will be displayed as they become available.
10. When the test is completed, the analyzer will prompt to remove the cartridge and will return to the table of results.
11. Remove the used cartridge from the slot as demonstrated on the LCD display, and discard the cartridge.
12. Press "done" from the results screen to return to the home page.

Calibration

The CORA analyzer does not require routine calibration.

Quality Control Procedures

The CORA analyzer performs internal QC checks during a pretest when the cartridge is inserted. This verifies that all electromechanical and pneumatic functions of the analyzer-cartridge combination are operating satisfactorily. Laboratories should perform additional QC testing as required by their laboratory's procedures. Coramed provides Abnormal WQC materials to be used for this purpose.

Whereas the internal QC of the analyzer effectively tests analyzer functions, a QC methodology is required to verify that reagents in cartridges are still viable at time of use. This ensures that cartridges have not been mishandled between production and arrival at the lab, or have not been subject to adverse environmental conditions or otherwise mishandled while in lab storage. This can supplement the laboratory's development of its own Individualized Quality Control Plan (IQCP) based on the lab's risk analysis, in accordance with CLSI EP23. This risk analysis would take into account the lab's specific situations that could affect reagent quality, such as environmental storage controls.

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Coramed recommends that normal and abnormal donor control checks be performed for each new shipment of citrated multichannel assay cartridges. Additional QC checks may be performed on a monthly, weekly, daily or shift basis based on the laboratory's quality control policies. The end user should follow the recommendations of local and state regulatory agencies as well as facility policies.

Coramed recommends that the lab perform two levels of QC testing whenever indicated by the IQCP using the following procedure.

i. Establish a known normal quality control using blood drawn from healthy adults.
ii. The normal donor control should not have taken any medication known to affect coagulation levels and should have prior citrated multichannel cartridge tests that have fallen within the established normal reference ranges.
iii. Prepare an abnormal quality control using Abnormal WQC material, representing an abnormal sample, following instructions in the Abnormal QC Material Product Insert, #01-182.
iv. The "normal" donor should have test results that fall within established reference ranges. For the Abnormal WQC sample, reagent performance is verified if parameters fall within the following Reference Ranges

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (degrees)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563 - 873

Results

No calculations are necessary to obtain test results; these are displayed on the CORA analyzer display, and may be printed if a printer is attached.

CK Test Results

The R, K, Angle and MA parameters are measured and displayed at the conclusion of the test, along with the corresponding reference ranges established for these parameters.

CRT Test Results

The MA parameter is measured and displayed at the conclusion of the test, along with the corresponding reference ranges established for these parameters.

CKH Test Results

The R parameter is the only one of importance for this test. It is measured and displayed at the conclusion of the test, along with the corresponding reference range established for the R parameter for Kaolin with Heparinase.

CFF Test Results

The MA parameter and the estimated Functional Fibrinogen Level (FLEV) are measured and displayed at the conclusion of the test.

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Limitation of the Procedure

Use of Results

CORA results should always be considered within the clinical context of the individual patient's case. In the event of inconsistencies with the patient's clinical status, samples should be repeated or supplemented with additional clinical information and/or data.

Expected Values

Expected values for test results are within the Reference Ranges for a reference population that were established according to CLSI C28-A3c. The following tables contain the reference range data for each reagent and parameter. It is recommended that customers validate reference ranges based on their local population.

CK Reference Ranges

Citrated Blood Parameter	N	Range
R (min)	157	4.6 – 9.1
K (min)	157	0.8 – 2.1
Angle (deg)	155	63 - 78
MA (mm)	151	52 - 69

CRT Reference Ranges

Citrated Blood Parameter	N	Range
MA	152	52 - 70

CKH Reference Ranges

Citrated Blood Parameter	N	Range
R	155	4.3 – 8.3

CFF Reference Ranges

Citrated Blood Parameter	N	Range
MA	151	15 - 32
FLEV	152	278 - 581

Specific Performance Characteristics

CK Precision

The precision of the CORA Kaolin test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the Kaolin Assay was CV less than 15% for the R parameter, less than 10% for the MA parameter, less than 10% for the Angle parameter and less than 25% for the K parameter.

CK Sensitivity and Specificity

The Kaolin reagent is often used in conjunction with tests performed on blood samples from patients administered with heparin, with the goal of either determining heparin effect (titration of dose) or determining full reversal (post-protamine) of heparin administered. It is, therefore, important that the Clinical Sensitivity and Specificity for the presence of heparin be determined. Five different heparin spiked samples were examined, with concentrations spread across the heparin therapeutic ranges (0.2 to

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6.0 IU/mL). 0.2 IU/mL is the lowest therapeutic dose typically used and 6.0 IU/mL represents a typical dose of heparin used when patients are fully heparinized during cardio-pulmonary by-pass. In addition, five (5) non-heparin spiked samples were analyzed. Kaolin's sensitivity to Heparin was 100%, with the R parameter elongated and out of range for all concentrations. Specificity was also 100%, with all un-spiked samples having an R parameter within normal range.

CRT Precision

The precision of the CORA RapidTEG test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the RapidTEG Assay was less than 10% for the MA parameter.

CKH Precision

The precision of the CORA Kaolin with Heparinase test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the Kaolin with Heparinase Assay was CV less than 15% for the R parameter.

CKH Neutralization

The Kaolin with Heparinase assay was tested to verify that 6 IU of Heparinase per 1 mL of blood will effectively neutralize the effects of both Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) on Kaolin-activated citrated whole blood samples. This is the amount of Heparinase used in the Kaolin with Heparinase assay. Tests were performed using UHF and LMWH spiked samples and un-spiked samples. All tests reported R parameter values within the normal range, confirming the neutralization effectiveness of the assay.

CFF Precision

The precision of the CORA Functional Fibrinogen test was evaluated according to CLSI EP5-A2. Precision testing was performed over five non-consecutive days using combinations of three donors, three different cartridge lots, two operators and multiple analyzers. Also, supplementary precision testing was performed using spiked samples from normal donors to achieve hypo and hyper parameter test results near the extremes of Analytical Measurement Ranges, and testing was performed on samples from patients taking anticoagulant medications. Results included Coefficient of Variance (CV) values for all tests completed. The precision for the Functional Fibrinogen Assay was CV less than 10% for the MA and FLEV parameters.

CFF Linearity

The Function Fibrinogen assay was tested for linearity according to CLSI EP6-A. Linearity with respect to Fibrinogen concentration levels is shown below.

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Clinical Performance - Method Comparison and Reader Studies

Method Comparison studies were conducted at three clinical sites on patient samples following CLSI EP09-A3 Guideline. The subjects enrolled were patients undergoing cardiovascular surgery or cardiology procedures, with blood samples drawn pre- and post-surgery and in the ICU. In order to broaden the range of comparison, up to 10% contrived samples were added. Summary statistics are presented below.

Method Comparison Statistics Summary – All Clinical Sites					
Parameter	**R**	**Intercept**	**95% CI**	**Slope**	**95% CI**
CK – R (min)	0.868	-0.325	-0.425	1.069	1.034
			-0.225		1.103
CK – K (min)	0.740	-0.097	-0.292	0.906	0.769
			0.098		1.042
CK – Alpha (deg)	0.680	7.305	-13.160	0.940	0.640
			27.769		1.240
CK – MA (mm)	0.924	2.351	0.166	0.948	0.912
			4.536		0.983
CKH – R (min)	0.812	-0.329	-0.393	1.057	1.026
			-0.265		1.089
CRT|CK – MA (mm)	0.929	-0.126	-1.909	0.978	0.948
			1.656		1.007
CFF – MA (mm)	0.938	-0.774	-1.836	1.126	1.072
			0.289		1.180
CFF – FLEV (mg/dl)	0.928	-12.495	-36.810	1.127	1.059
			11.819		1.194

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In addition, a Reader Study was conducted to assess the comparison of CORA System and TEG 5000 results based on reading printed test outcomes. The study was performed at three sites, using three experienced TEG 5000 doctors as readers at each site, for a total of nine readers. 30 test outcomes were compared for each of the reagent test categories, for a total of 270 reading comparisons per reader. Excellent agreement between the two devices was demonstrated.

In both the Method Comparison Study and Reader Study, the CORA RapidTEG (CRT) MA parameter was compared to the TEG 5000 Kaolin (CK) MA parameter, to demonstrate that the CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

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Date of Issuance of Last Labeling Revision: June 3, 2015

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

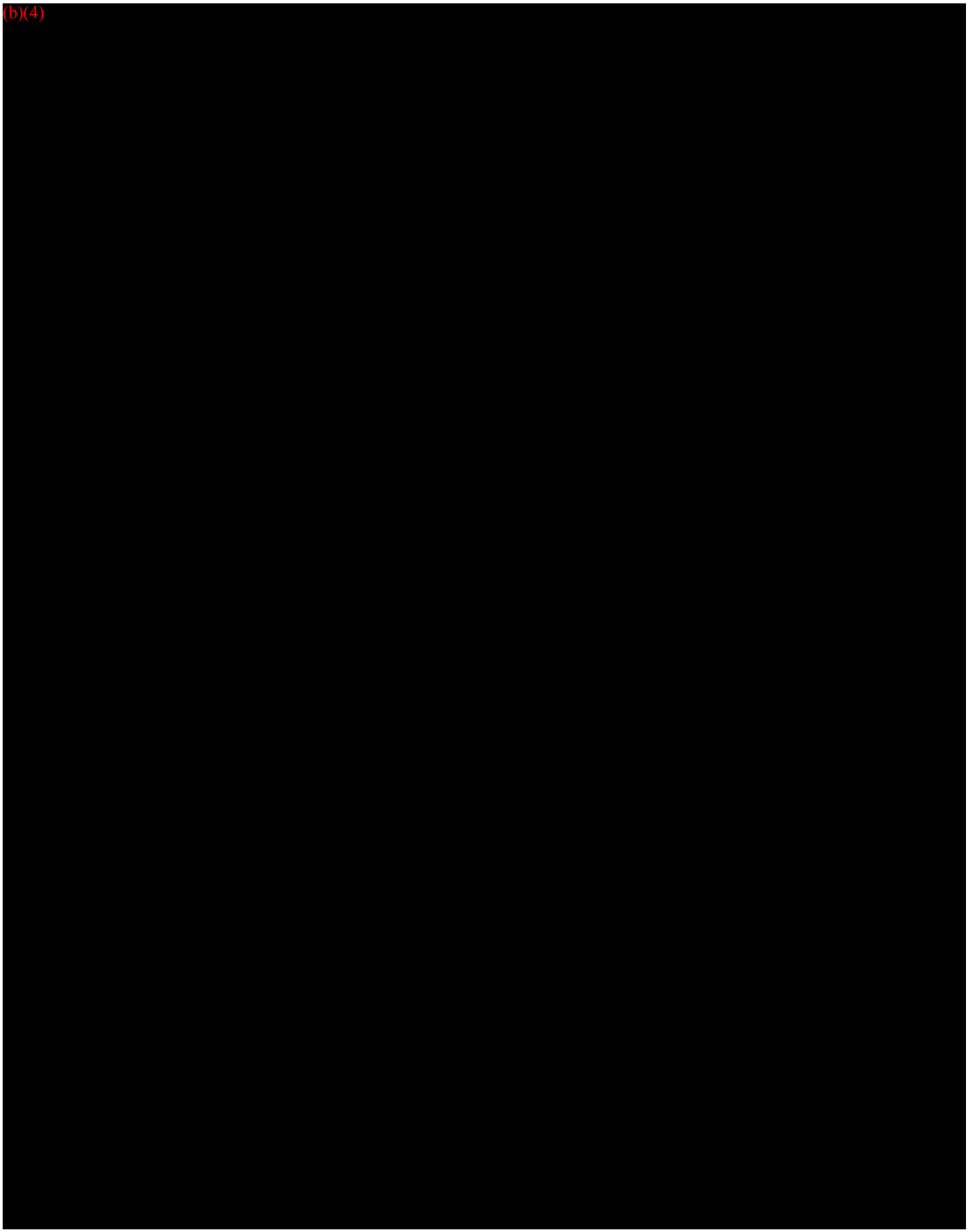
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(b)(4) **Test Report**

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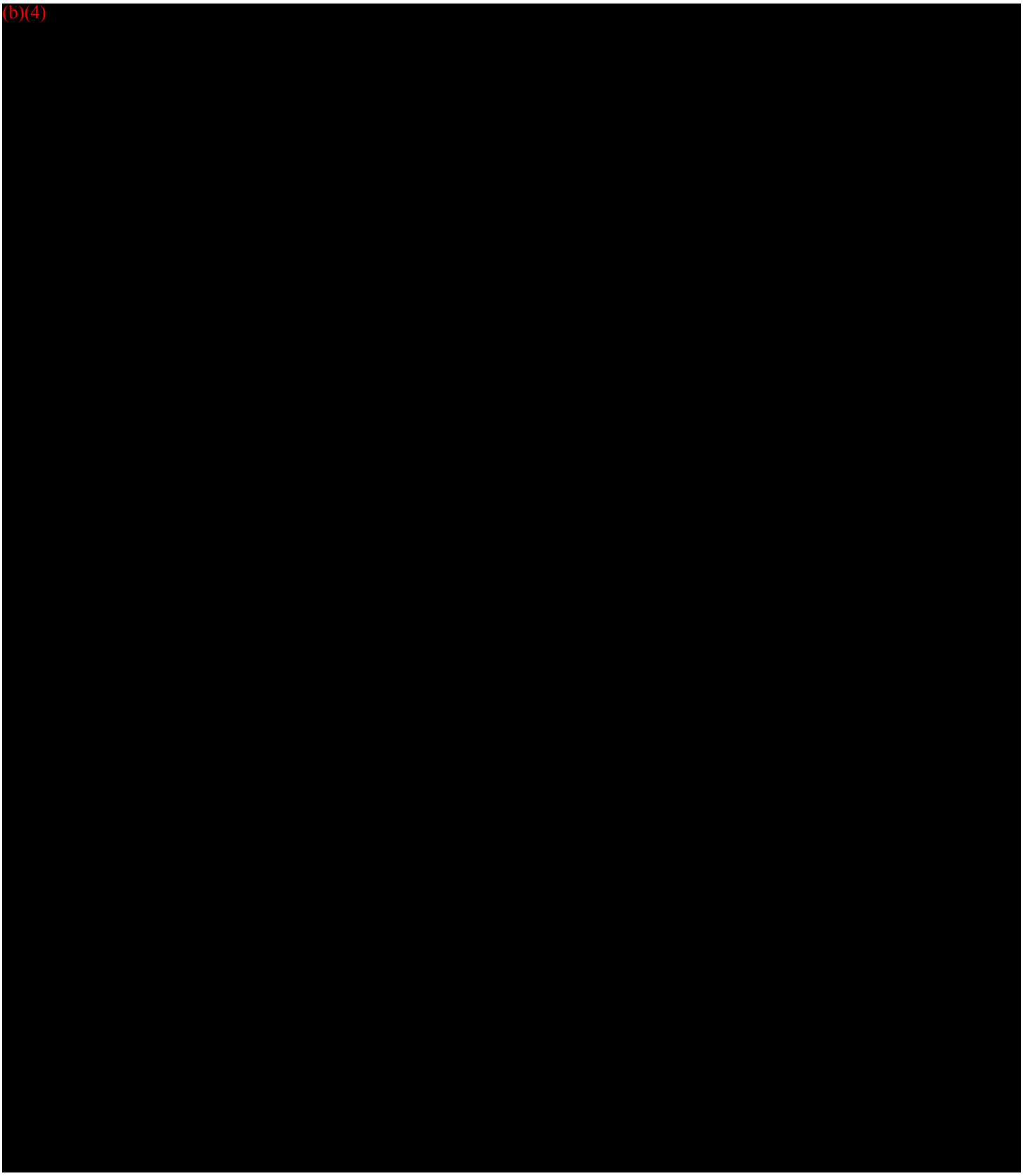
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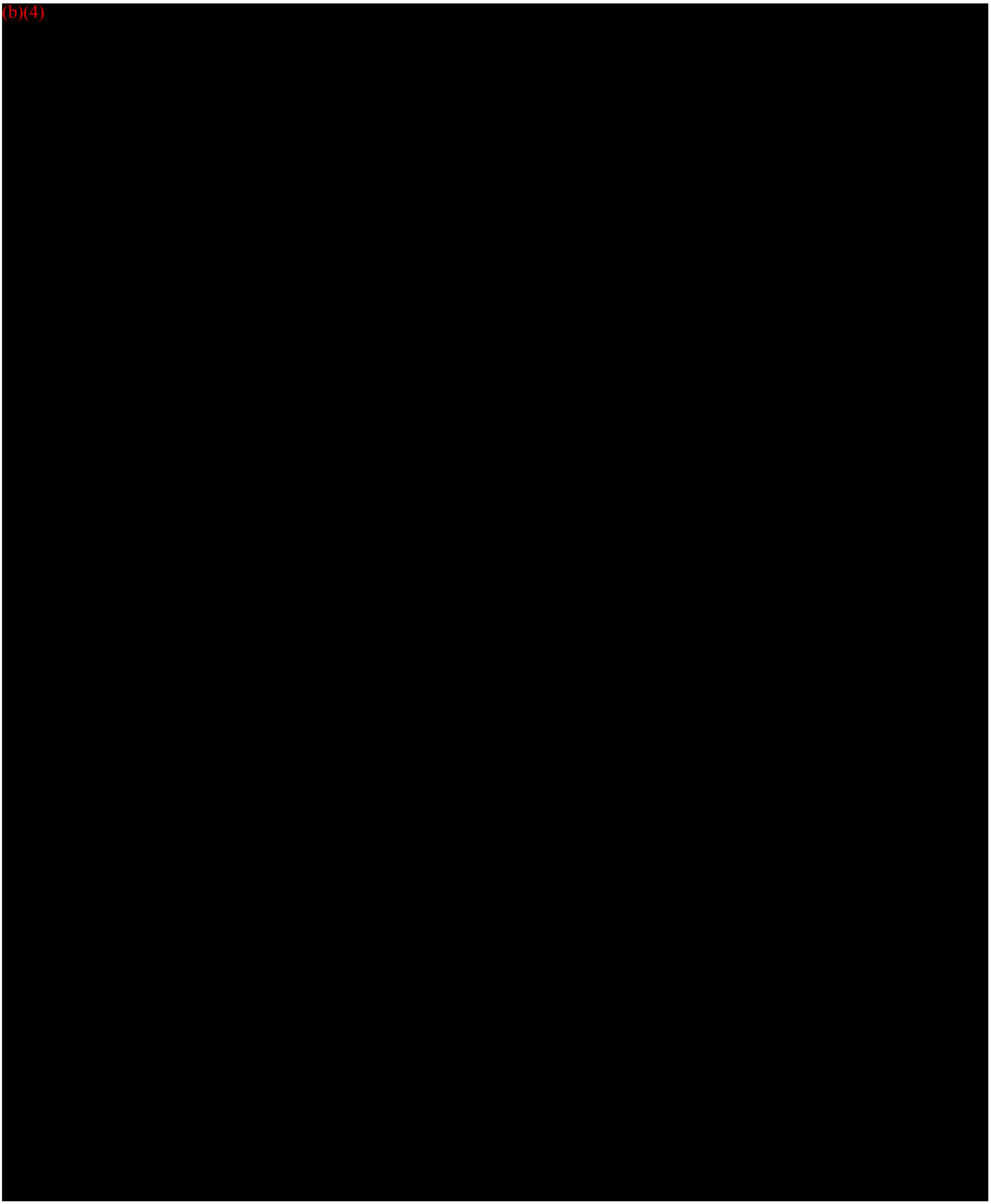
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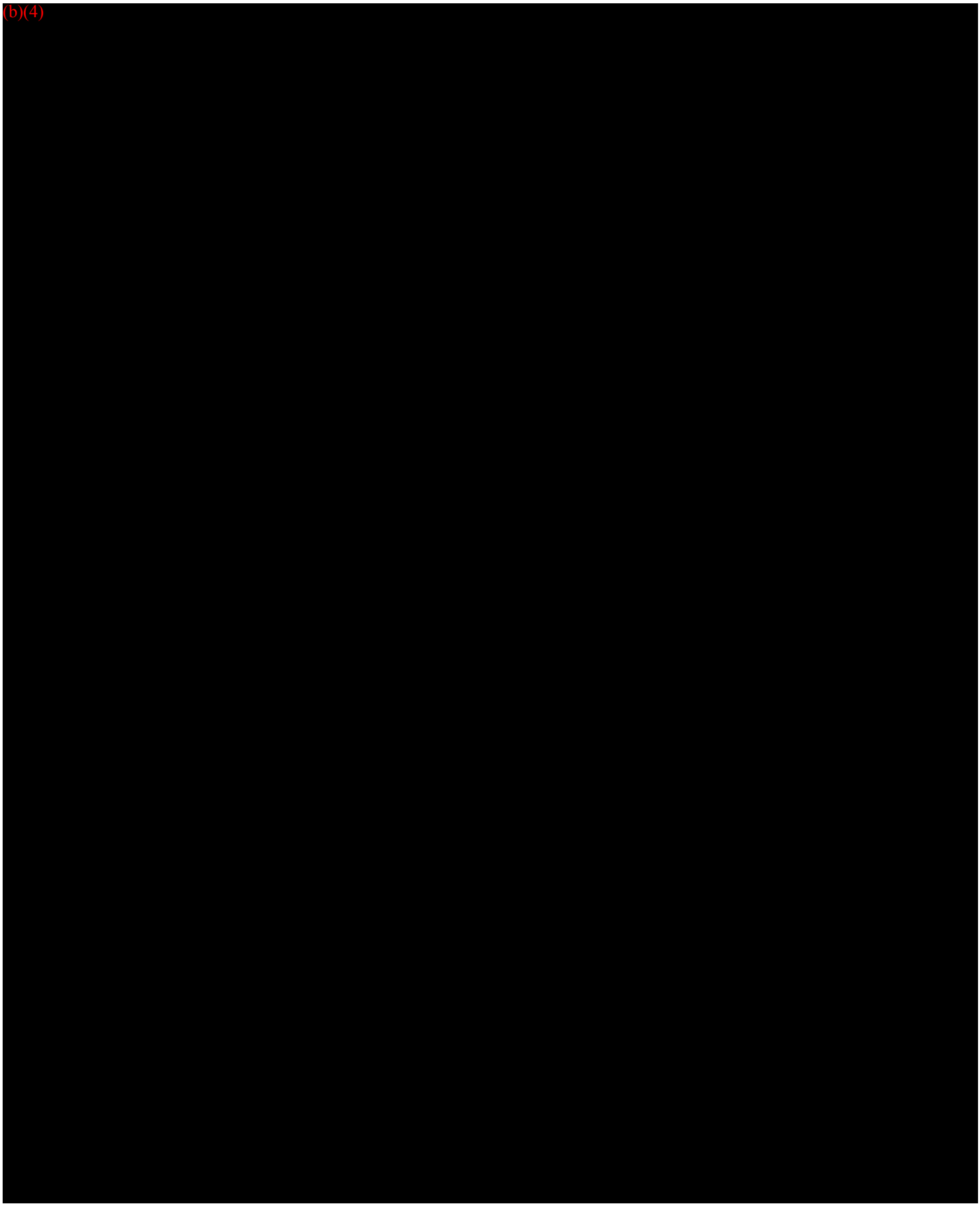
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*
K150041

Device Name
CORA Hemostasis System - Abnormal Wet Quality Control (WQC) Material

Indications for Use *(Describe)*

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample.

The Abnormal Wet Quality Control Material is to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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CORA|MED

CORA® System 510(k) Summary

APPLICANT INFORMATION

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Email for contact person: nbrunner@coramedtech.com

Date that Summary was prepared: June 23, 2015

DEVICE INFORMATION

Trade name (proprietary name): CORA® (Coagulation Resonance Analysis) System and the following assays and reagents

- Citrated Assays and Reagents
  - CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
  - CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
  - CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
  - CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent

Common name (usual name): Whole Blood Hemostasis System

Classification Name: 21CFR 864.5425 Multipurpose System for *in vitro* Coagulation Studies

PREDICATE DEVICE

- Thrombelastograph® Coagulation Analyzer (TEG®) – 5000 Series, K002177, Product Code JPA (System, Multipurpose, for In Vitro Coagulation Studies), Haemoscope Corporation

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DESCRIPTION OF THE DEVICE

System Description

The CORA System consists of a four-channel diagnostic analyzer with integrated computer module, system reagents (CK, CRT, CKH, and CFF), and Abnormal Quality Control material and microfluidic test cartridges. See below for a description of system reagents. Reagents are dried-in-place within the cartridges during manufacturing. Abnormal Quality Control material is lyophilized and can be reconstituted with water as needed for WQC testing with reagent cartridges.

To perform a test, a disposable CORA Cartridge is inserted into the analyzer. Blood or WQC material is added to an entry port on the cartridge and drawn into the cartridge under analyzer control. The amount of the sample drawn into the cartridge is automatically determined by the volume of the blood chambers in the cartridge. Once in the disposable, the sample is metered into as many as four separate analysis channels, depending upon the assays being performed. Reconstitution of reagents dried within the cartridge is accomplished by moving the sample back and forth through reagent chambers, under the control of microfluidic valves and bellows (pumps) within the cartridge. After each sample has been mixed with reagent, it is delivered to a test cell where it is monitored for visco-elastic changes due to coagulation. Excess sample material is moved under microfluidic control into an enclosed waste chamber within the cartridge.

The CORA Measurement Technique

The CORA technology is based on a disposable containing up to four independent measurement cells. Each cell consists of a short vertically-oriented injection molded tube (ring) with a diameter of 2.5mm and a length of 4.5mm. Detection of clotting in the CORA System is performed optically. Under control of the analyzer, approximately 20µl of prepared sample is delivered to the tube, where a meniscus naturally forms at each end of the tube. The tube is positioned so that the lower meniscus partially blocks light traveling from a collimated source toward a photodiode.

During testing, a piezoelectric actuator drives the measurement cell(s) through a motion profile composed of summed sinusoids at different frequencies. The profile has a maximum amplitude of under 10µm and contains frequencies from 10-500Hz. Some, but not all, of the measurement cell motion will induce motion in the sample meniscus, which will be detected by the photodiode. The resulting motion of the meniscus is monitored optically and recorded by the analyzer to calculate the resonant frequency and modulus of elasticity (stiffness) of the sample. By performing a Fast Fourier Transform (FFT) on meniscus motion data, it is possible to determine the frequencies of input motion that caused the greatest deflection of the sample (these are called the resonant frequencies).

Resonance is the tendency of a material or structure to oscillate with greater amplitude at some frequencies than others. The exact frequencies at which resonance occurs will depend on the stiffness and mass of the sample. Stiffness, in turn, is a function of a material's modulus of elasticity and the boundary conditions to which the material is exposed, such as the geometry and materials of a test cell. By holding these boundary conditions and sample mass constant from run to run, the CORA System allows direct comparison of elasticity between samples.

In a typical test, blood that has been delivered to the measurement cell will not clot for several minutes. During this time the sample has no inherent stiffness except that provided by surface tension, and since this remains constant the measured resonant frequencies will not change. Once clotting begins, however, the elastic modulus and thus the resonant frequencies increase rapidly. During fibrinolysis, the process is reversed, with elastic modulus and resonant frequencies decreasing. In tests where clotting does not occur, the resonant frequency of the sample will not change. During coagulation, however, a clot will bind to the test tube (ring) and the resonant frequency will rise with increasing firmness of the clot. The

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CORA Analyzer collects meniscus motion data, tracks changing resonant frequencies and analyzes the frequency data to provide semi-quantitative parameters describing the clot. Results are presented in a format similar to the TEG 5000.

Both the TEG 5000 and CORA System monitor the elastic modulus of clots. Method Comparison testing has been performed, yielding data from approximately 300 patients from three sites (Mayo Clinic, University of Pittsburgh Medical Center, and Sinai Hospital, Baltimore). These data include all applicable parameters from the four citrated tests (CK, CKH, CRT and CFF). The TEG 5000 measures the changes of the linkage forces of the clot between the cup and pin over time, while the CORA System measures the changes of the resonant frequency of the clot over time. Despite the difference in the way the two analyzers measure the changes in the modulus of elasticity of the clot over time, they measure the same physical phenomenon and produce the same result when converted from their specific units of measurement (forces for the TEG5000 and frequency for the CORA System) to millimeters. The fact that these results are similar across all reagents used in both technologies is demonstration that the two technologies measure the same phenomenon, the changes in elastic modulus.

The following definitions apply to calculated parameters in the CORA System:

CORA Parameter	Definition	Parameter Relation to Hemostasis
R	R is the time from the start of the test until initial fibrin formation. This represents the enzymatic portion of coagulation.	Normal / reduced / increased speed of coagulation initiation
K	K is the time after R needed to reach a certain level of clot strength. This represents clot kinetics.	Normal / reduced / increased speed of coagulation amplification and propagation
Alpha α (angle)	Alpha is the angle representing the rate increase in the clot strength and the rapidity of fibrin build-up and cross-linking.	Normal / reduced / increased speed of coagulation amplification and propagation
MA	MA, or Maximum Amplitude, represents the maximum firmness of the clot during the test.	Normal / reduced / increased clot elasticity/strength
FLEV	FLEV is an estimate of the fibrinogen level in the blood sample.	Estimated Functional Fibrinogen Level

Citrated Assays

The CK assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle), and Maximum Clot Strength (MA). K and Alpha are complementary parameters and should be used in conjunction with Clotting Time (R) and Maximum Clot Strength (MA).

The CRT assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via both the intrinsic and extrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CFF assay is a semi-quantitative *in vitro* diagnostic assay for monitoring hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. CFF is used in conjunction with CK and clotting characteristics are described by the functional parameter Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

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The CKH assay is a semi-quantitative *in vitro* diagnostic assay used in conjunction with the CORA System to monitor the effects of heparin in the blood stream of a patient. CKH is used in conjunction with CK and heparin influence is determined by comparing Clotting Times (R) between the two tests.

Wet Quality Control (WQC)

Abnormal Wet Quality Control (WQC) material consists of bovine plasma with buffers and stabilizers, and is used instead of hypocoagulable blood, in conjunction with the Citrated Multichannel system cartridge. When used with the Citrated Multichannel cartridge, this material provides consistent and repeatable values for CORA parameters to confirm reagent quality and viability.

Abnormal WQC Intended Use

The Abnormal WQC (Wet Quality Control) Material is intended to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

INTENDED USE AND INDICATIONS FOR USE

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The CORA System records the kinetic changes in a sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARING THE CORA SYSTEM TO THE TEG 5000 PREDICATE DEVICE

Table of Similarities

Item	TEG® 5000 Predicate	CORA® System
Analyzer		
Technological Purpose	Monitoring the response of a clot to low levels of applied strain	Monitoring the response of a clot to low levels of applied strain
What is measured	Changes in clot elasticity over time	Changes in clot elasticity over time
Initial Warm Up Time	5 min	5 min
Time to Complete a Test	Varies with assay	Same as TEG 5000
Assays and Reagents		
Intrinsic Contact Activation Reagent (CK)	Kaolin and $CaCl_2$	Kaolin and $CaCl_2$, same materials as TEG 5000

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Item	TEG® 5000 Predicate	CORA® System
Intrinsic Contact Activation Reagent with Heparinase for heparin reversal (CKH)	Kaolin and $CaCl_2$ with Heparinase	Kaolin, Heparinase and $CaCl_2$, same materials as TEG 5000
Citrated RapidTEG (CRT) (Tissue Factor and Kaolin Activation)	Tissue Factor (TF), Kaolin and $CaCl_2$	Tissue Factor (TF), Kaolin and $CaCl_2$, same materials as TEG5000
Citrated Functional Fibrinogen (CFF) / Platelet-Blocked (Tissue Factor Activation)	ReoPro®, Tissue Factor and $CaCl_2$, same materials as CORA	ReoPro®, Tissue Factor and $CaCl_2$, same materials as TEG 5000
Calcium Chloride Reagent (CC) (for re-calcification)	$CaCl_2$ reagent	$CaCl_2$ same materials as TEG 5000
Quality Control Material (WQC Abnormal Control)	TEG coagulation control – Level II	TEG coagulation control – Abnormal, same materials as TEG 5000

Table of Differences

Item	TEG® 5000 Predicate	CORA® System
Analyzer	Thrombelastography analyzer, separate computer and software	Fully integrated Thrombelastography analyzer
Measuring Technique	Direct-contact measurement of shear elasticity of a coagulating sample	Non-contact measurement of shear elasticity of a coagulating sample
Measuring Channels	Two, each independent and interchangeable (can be used with any approved reagent)	Four, each independent and interchangeable (can be used with any approved reagent)
Signal Transducer	Electromechanical detection (rotary variable inductive transformer) of rotary motion of a pin suspended in the sample	Optical detection (silicon photodiode) of the motion of a free surface of the sample
Temperature Control	20° to 40°C	20° to 50°C
Sample Volume (per channel)	360-380 µl	63 µl
Total Reaction Volume (single channel)	360-380 µl	20 µl
Mains Supply Voltage	120V, 60Hz and 220V, 50Hz model available	100-240V, 50-60Hz (international power supply)
Analyzer Input Voltage	24 volts AC, 30 watts max	12 volts DC, 60 watts max
Environment	Level and vibration free position, no solar radiation Operating temperature: 10° to 35 °C Storage Temperature: -30° to +50 °C (analyzer only) Relative humidity 20-80% (non-condensing)	Stable and level surface. Operating Temperature 10° to 32°C Storage Temperature: -20° to 50°C (analyzer only) Relative humidity 20 to 80% (non-condensing)

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Item	TEG® 5000 Predicate	CORA® System
Sample Preparation	Performed by the operator using pipettes to reconstitute reagents and mix reagents with the sample	Performed under analyzer control within the disposable cartridge
Pipetting	Manual accurate pipettes (10, 20, 50, 100, 340, 360, 500, 1000µl)	Unmetered transfer pipette or syringe; blood sample is added until it fills to a level above the line marked on the blood intake well of the cartridge
Consumables	Cups & Pins (acrylic plastic)	Carrier (acrylic plastic) with microfluidics laminate and test rings (acrylic plastic)

SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Analytical Precision

Testing was performed in Coramed's laboratory for precision, using CLSI EP5-A2 as guidance. Acceptance criteria for all reagents are: CV ≤ 15% for the R parameter, CV ≤ 25% for the K parameter, and CV ≤ 10% for the Alpha and MA parameters. Three types of donor citrated whole blood (CWB) were used in this precision testing:

- Hypo (donors with natural coagulation levels of R parameter near the upper limit of the reference range and MA parameter near the lower limit of the reference range);
- Normal (donors with natural coagulation levels of R and MA parameters near the center of the reference ranges):
- Hyper (donors with natural coagulation levels of R parameter near the lower limit of the reference range and MA parameter near the upper limit of the reference range

Testing was performed with blood draws from three donors (one Hypo, one Normal, and one Hyper) on each of five days (non-consecutive). Testing was performed by two operators using three reagent lots and twelve analyzers, two replicates. The structure of this precision test is shown below.

Sample Type (Hypo, Normal or Hyper)												
	Day 1 (Total of 5 days)											
Operator	Operator 1						Operator 2					
Reagent lot	1		2		3		1		2		3	
Analyzer	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2

Structure of Precision Testing

Precision test estimates by test, parameter and donor sample test level are shown in the table on the following page. All acceptance criteria were met.

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Test	Parameter	Level	n	Mean	Reagent Lot		Operator*		Analyzer (within Operator, Reagent Lot)		Day (within Analyzer, Operator, Reagent Lot)		Repeatability		Total		Total without Day (Within Day)	
					SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
CFF	FLEV	Hypo	120	269.8	2.36	0.9%	0	0.0%	0	0.0%	5.32	2.0%	5.87	2.2%	8.27	3.1%	6.33	2.3%
CFF	FLEV	Normal	120	376.8	0	0.0%	2.25	0.6%	0	0.0%	5.49	1.5%	3.98	1.1%	7.15	1.9%	4.57	1.2%
CFF	FLEV	Hyper	120	597.4	0	0.0%	0	0.0%	0	0.0%	49.38	8.3%	9.62	1.6%	50.31	8.4%	9.62	1.6%
CFF	MA	Hypo	120	14.8	0.11	0.8%	0	0.0%	0	0.0%	0.29	2.0%	0.33	2.2%	0.45	3.0%	0.35	2.3%
CFF	MA	Normal	120	20.6	0	0.0%	0.13	0.6%	0	0.0%	0.3	1.5%	0.22	1.1%	0.39	1.9%	0.25	1.2%
CFF	MA	Hyper	120	32.7	0	0.0%	0	0.0%	0	0.0%	2.71	8.3%	0.53	1.6%	2.76	8.4%	0.53	1.6%
CKH	R	Hypo	120	8.2	0	0.0%	0	0.0%	0.18	2.2%	0.36	4.3%	0.76	9.2%	0.86	10.0%	0.78	9.5%
CKH	R	Normal	120	6.0	0	0.0%	0.05	0.9%	0.09	1.6%	0.14	2.3%	0.42	7.1%	0.46	7.7%	0.44	7.3%
CKH	R	Hyper	120	4.9	0	0.0%	0.05	1.1%	0	0.0%	0.28	5.7%	0.5	10.0%	0.58	12.0%	0.5	10.0%
CK	Angle	Hypo	120	68.7	0	0.0%	1.09	1.6%	0	0.0%	1.61	2.3%	3.01	4.4%	3.59	5.2%	3.2	4.7%
CK	Angle	Normal	120	72.1	0	0.0%	0	0.0%	0	0.0%	1.14	1.6%	1.73	2.4%	2.07	2.9%	1.73	2.4%
CK	Angle	Hyper	120	76.7	0	0.0%	0	0.0%	0	0.0%	1.84	2.4%	1.77	2.3%	2.56	3.3%	1.77	2.3%
CK	K	Hypo	120	1.8	0.03	1.9%	0.06	3.6%	0	0.0%	0.13	7.2%	0.18	10.0%	0.23	13.0%	0.19	11.0%
CK	K	Normal	120	1.4	0	0.0%	0	0.0%	0	0.0%	0.09	6.7%	0.16	12.0%	0.19	13.0%	0.16	12.0%
CK	K	Hyper	120	0.9	0	0.0%	0	0.0%	0	0.0%	0.12	12.0%	0.18	20.0%	0.22	23.0%	0.18	20.0%
CK	MA	Hypo	120	52.4	0.33	0.6%	0.55	1.0%	0.26	0.5%	0.83	1.6%	0.77	1.5%	1.33	2.5%	1.03	2.0%
CK	MA	Normal	120	59.4	0	0.0%	0.5	0.8%	0.48	0.8%	0.57	1.0%	0.86	1.4%	1.24	2.1%	1.1	1.9%
CK	MA	Hyper	120	68.0	0	0.0%	0.2	0.3%	0	0.0%	0.9	1.3%	0.52	0.8%	1.06	1.6%	0.56	0.8%
CK	R	Hypo	120	8.9	0	0.0%	0.29	3.3%	0	0.0%	0.64	7.1%	0.85	9.5%	1.1	12.0%	0.9	10.0%
CK	R	Normal	120	6.5	0	0.0%	0	0.0%	0	0.0%	0.28	4.3%	0.49	7.6%	0.56	8.7%	0.49	7.6%
CK	R	Hyper	120	5.2	0.13	2.5%	0	0.0%	0	0.0%	0.31	5.8%	0.66	13.0%	0.74	14.0%	0.67	13.0%
CRT	MA	Hypo	120	52.4	0.39	0.7%	0.22	0.4%	0	0.0%	0.92	1.8%	0.59	1.1%	1.18	2.3%	0.74	1.4%
CRT	MA	Normal	120	62.7	0	0.0%	0.15	0.2%	0.14	0.2%	0.37	0.6%	0.31	0.5%	0.52	0.8%	0.37	0.6%
CRT	MA	Hyper	120	69.4	0	0.0%	0	0.0%	0	0.0%	0.91	1.3%	0.2	0.3%	0.93	1.3%	0.2	0.3%

*Operator = Operator + operator-by-reagent lot interaction

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In addition, Coramed's Citrated Reagent Precision Protocol Rev. 02 was written to supplement precision data originally provided to FDA in 510(k) K150041. This protocol specifies testing to be performed outside of reference range values but within the Analytical Measurement Range (AMR) limits. This report presents data and statistics resulting from the execution of this protocol.

The following pages contain tables of precision statistics. Table 1 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from normal donors but spiked to achieve hypocoagulable (hypo) and hypercoagulable (hyper) results. Three donors for each reagent-parameter and spiking type were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each donor-reagent-parameter-hypo/hyper type, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B
Sample	Hypercoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

The focus of this study was on achieving values for the primary coagulation parameters R, MA and FLEV outside the reference ranges but within AMR limits, and taking the resulting K and Alpha (angle) values as is. Total Precision %CV values were all within pre-established limits, except for one CFF MA hypo outcome (11.6% for a limit of 10%) and 2 outcomes for Angle. The K and Angle parameters indicate the kinetics of the clotting process, and are not clinically significant as the main parameters representing coagulation, platelet and fibrinogen activities and abnormalities. The CFF MA CV% is higher because the MA value is small (mean of 6.5 mm) and although the Standard Deviation is very small (0.8mm) the resulting CV% is just over the limit. When the SD is so small there is no clinical significance for the differences making this CV% acceptable.

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Table 2 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from patients taking anticoagulants Dabigatran and Warfarin. Four Dabigatran patients and two Warfarin patients for each reagent-parameter were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each patient-reagent-parameter, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1		2		3		4		5		6	
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

Results for this testing were generally within limits, except for a few minor exceptions. As the data shows, all the MAs, for CK, CRT, and CFF, are within the specified expected CV% across the board while for the R parameter, there are no significant differences between lots, operators and devices and the only CVs (for CK and CKH – R parameter) somewhat exceeding 15% come from repeatability (16.9% for MH-DB003 for CK and 15.9% for MH-DB004 for CKH). Even though the, K and Angle are not parameters that are considered clinically significant the raw data indicates that the single angle CV% that is above the limit was due to an outlier while the K parameter has high CVs due to the fact that elongated coagulation results in higher CVs for that parameter.

Test	Param	Spiking	Patient ID	N	Mean	Lot		Operator		Instrument		Repetition		Total	
						StDev	CV	StDev	CV	StDev	CV	StDev	CV	StDev	CV

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CK	R	hyper	D101	12	2.1	0	0	0	0	0.1	4.5	0.1	3.1	0.1	5.5
CK	R	hyper	D108	12	2.7	0	0	0	1	0.1	3.5	0.1	2.4	0.1	4.3
CK	R	hyper	D169	12	2.2	0.1	2.8	0	0	0.1	3.1	0.1	2.5	0.1	4.6
CK	R	hypo	D141	12	16.1	0	0	1.1	6.9	1.3	8	0.7	4.3	1.7	10.8
CK	R	hypo	D169	12	15.3	0.8	5.3	0	0	1.6	10.2	1.1	7.1	2	13.2
CK	R	hypo	D108	12	12.1	0.1	1	0.1	0.9	0.9	7.2	0.7	5.6	1.1	9.3
CK	K	hyper	D101	12	0.5	0	0	0	0	0	3.9	0	4.1	0	5.7
CK	K	hyper	D108	12	0.4	0	3.8	0	3.8	0	7.2	0	6.5	0	10.7
CK	K	hyper	D169	12	0.5	0	0	0	0	0	8.2	0	8.2	0.1	11.6
CK	K	hypo	D141	12	3	0.2	5.2	0.2	6	0.3	9.9	0.2	8.2	0.4	14.6
CK	K	hypo	D169	12	3.1	0.5	16.4	0	0	0.5	14.8	0.3	10	0.7	22.7
CK	K	hypo	D108	12	2.2	0	0	0.1	6.4	0.3	12	0.1	6.2	0.3	14.6
CK	Angle	hyper	D101	12	80	0.8	1.1	1.5	1.8	7.2	9	6.9	8.7	10.1	12.6
CK	Angle	hyper	D108	12	85.1	0.1	0.2	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hyper	D169	12	84.3	0.1	0.1	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hypo	D141	12	54.7	0	0	0	0	8.4	15.4	5.4	9.9	10	18.3
CK	Angle	hypo	D169	12	42.7	1	2.4	1.9	4.5	1.8	4.3	1.6	3.7	3.1	7.2
CK	Angle	hypo	D108	12	66.7	3	4.4	0	0	4.8	7.2	3.3	5	6.3	9.5
CK	MA	hyper	D108	12	71.6	0	0	0.5	0.7	0.3	0.4	0.3	0.4	0.5	0.8
CK	MA	hyper	D169	12	70	0	0	0.1	0.1	0.2	0.2	0.1	0.2	0.2	0.3
CK	MA	hyper	D121	12	71.1	0	0	0	0	0.9	1.3	0.6	0.8	1.1	1.5
CK	MA	hypo	D141	12	42	0.2	0.6	0	0	1.5	3.5	0.9	2.1	1.7	4.1
CK	MA	hypo	D169	12	46.6	0	0	0	0	0.8	1.8	0.5	1.1	1	2.1
CK	MA	hypo	D108	12	45.4	0	0	0.8	1.8	1.2	2.7	0.9	2	1.7	3.7
CKH	R	hyper	D101	12	2	0.1	4.8	0	0	0	2.4	0.1	2.8	0.1	5.5
CKH	R	hyper	D108	12	2.6	0	0	0	0	0.1	2.6	0	1.6	0.1	3.1
CKH	R	hyper	D169	12	2.2	0	0	0	0	0	1.5	0	1	0	1.8
CKH	R	hypo	D141	12	15.7	0	0	1	6.4	0.7	4.5	0.6	4.1	1.3	8.2
CKH	R	hypo	D169	12	14.5	0	0	0.8	5.2	0.8	5.7	0.5	3.2	1.1	7.9
CKH	R	hypo	D108	12	12.3	0.6	5	0	0	0.8	6.3	0.5	4.4	1.1	8.8
CRT	MA	hyper	D108	12	70.8	0.2	0.3	0	0	0.1	0.2	0.1	0.2	0.2	0.3
CRT	MA	hyper	D121	12	72.5	0.2	0.3	0	0	0.4	0.5	0.4	0.5	0.5	0.8
CRT	MA	hyper	D145	12	73	0.2	0.2	0	0	0.2	0.3	0.2	0.2	0.3	0.4
CRT	MA	hypo	D141	12	41.3	0	0	0	0	0.7	1.8	0.5	1.2	0.9	2.2
CRT	MA	hypo	D169	12	44.4	0	0	0.3	0.7	0.6	1.3	0.4	0.9	0.8	1.7
CRT	MA	hypo	D108	12	45.5	0	0	0.4	0.9	1	2.1	0.5	1.1	1.1	2.5
CFF	MA	hyper	D101	12	49.9	0.1	0.1	0	0	0.5	0.9	0.3	0.5	0.5	1.1
CFF	MA	hyper	D141	12	44.3	0	0	0	0	0.5	1.2	0.3	0.6	0.6	1.3
CFF	MA	hyper	D145	12	47	0	0	0	0	0.7	1.4	0.5	1	0.8	1.7
CFF	MA	hypo	D101	12	10.2	0.2	1.5	0	0	0.3	3	0.2	1.7	0.4	3.6
CFF	MA	hypo	D125	12	9.5	0	0	0.2	1.8	0.4	4	0.3	2.7	0.5	5
CFF	MA	hypo	D169	12	6.5	0	0	0.7	10.1	0.3	4.9	0.4	6	0.8	11.6
CFF	FLEV	hyper	D101	12	910.7	1.2	0.1	0	0	8.6	0.9	5	0.5	10	1.1
CFF	FLEV	hyper	D141	12	809	0	0	0	0	9.6	1.2	5.2	0.6	10.9	1.3
CFF	FLEV	hyper	D145	12	858.1	0	0	0	0	11.9	1.4	8.5	1	14.7	1.7
CFF	FLEV	hypo	D101	12	186.4	2.9	1.5	0	0	5.5	3	3.1	1.7	6.8	3.6
CFF	FLEV	hypo	D125	12	173.4	0	0	3.1	1.8	7	4	4.6	2.6	8.7	5
CFF	FLEV	hypo	D169	12	157.5	1.8	1.2	1.1	0.7	2	1.3	1.7	1.1	3.2	2.1

Spiked Precision – Table 1

Test	Param	PatientID	N	Mean	Lot		Operator		Instrument		Repetition		Total	
					StDev	CV	StDev	CV	StDev	CV	StDev	CV	StDev	CV
CK	R	MH-DB001	12	13	0	0	0	0	0.4	3.2	1.2	8.9	1.2	9.4
CK	R	MH-DB002	12	21.3	0	0	0	0	1	4.7	2.1	10.1	2.3	11

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CK	R	MH-DB003	12	14.4	0	0	0	0	0	0	2.4	16.9	2.4	16.9
CK	R	MH-DB004	12	11.8	0.5	4	0.5	4.3	0	0	1.6	13.9	1.7	14.8
CK	R	MH-WR001	12	9.9	0.7	7	0.3	2.7	0.3	2.6	0.5	4.9	0.8	8.5
CK	R	MH-WR002	12	10.1	1	10.2	0	0	0.3	3.2	1	10	1.4	13.6
CK	K	MH-DB001	12	1.3	0	0	0	0	0	0	0.2	18.2	0.2	18.2
CK	K	MH-DB002	12	2.4	0	0	0	0	0.4	15.4	1	42	1	44.5
CK	K	MH-DB003	12	1.3	0	0	0	0	0	0	0.3	19.8	0.3	19.8
CK	K	MH-DB004	12	0.9	0.1	11.4	0	0	0	0	0.3	33	0.3	34.4
CK	K	MH-WR001	12	2.2	0	0	0	0	0	0	0.2	8.2	0.2	8.2
CK	K	MH-WR002	12	2	0	0	0	0	0	0	0.4	19.1	0.4	19.1
CK	Angle	MH-DB001	12	72.5	0	0	0	0	0	0	3.6	5	3.6	5
CK	Angle	MH-DB002	12	55.5	0	0	0	0	10.3	18.6	11.6	20.8	15.2	27.4
CK	Angle	MH-DB003	12	72.7	0	0	0	0	0	0	3.2	4.3	3.2	4.3
CK	Angle	MH-DB004	12	79.5	0	0	0	0	0	0	3.4	4.3	3.4	4.3
CK	Angle	MH-WR001	12	65	0	0	0	0	0	0	1.1	1.7	1.1	1.7
CK	Angle	MH-WR002	12	67.1	0	0	1.1	1.6	0	0	3	4.4	3.1	4.6
CK	MA	MH-DB001	12	60.2	0	0	0	0	0	0	0.9	1.5	0.9	1.5
CK	MA	MH-DB002	12	64.5	0	0	0.2	0.4	0	0	0.6	1	0.7	1
CK	MA	MH-DB003	12	64.1	0	0	0.4	0.7	0	0	0.5	0.8	0.7	1
CK	MA	MH-DB004	12	71.9	0.1	0.1	0.5	0.6	0	0	0.5	0.7	0.7	0.9
CK	MA	MH-WR001	12	60.6	0	0	0	0	0	0	0.9	1.4	0.9	1.4
CK	MA	MH-WR002	12	59.7	0	0	0	0	1	1.6	0.8	1.3	1.2	2
CKH	R	MH-DB001	12	12.2	0.8	6.8	0	0	0	0	0.7	5.8	1	8.2
CKH	R	MH-DB002	12	19.3	0	0	1.6	8.4	0	0	2.2	11.4	2.6	13.5
CKH	R	MH-DB003	12	13.5	0	0	0.5	4	0	0	1.4	10.6	1.5	11.1
CKH	R	MH-DB004	12	11.3	0	0	0	0	0	0	1.8	15.9	1.8	15.9
CKH	R	MH-WR001	12	8.4	0	0	0.1	0.8	0	0	0.8	9.7	0.8	9.8
CKH	R	MH-WR002	12	9.1	0.5	5.1	0	0	0	0	0.7	7.4	0.8	8.6
CRT	MA	MH-DB001	12	64.9	0.1	0.1	0	0	0.1	0.1	0.1	0.2	0.1	0.2
CRT	MA	MH-DB002	12	67.7	0.1	0.1	0	0	0	0	0.2	0.2	0.2	0.2
CRT	MA	MH-DB003	12	66	0	0	0	0	0	0	0.1	0.2	0.1	0.2
CRT	MA	MH-DB004	12	73.8	0.1	0.1	0	0	0.1	0.1	0.2	0.2	0.2	0.3
CRT	MA	MH-WR001	12	64	0.1	0.1	0	0	0	0	0.2	0.3	0.2	0.3
CRT	MA	MH-WR002	12	64.7	0	0	0	0	0	0	0.3	0.4	0.3	0.4
CFF	MA	MH-DB001	12	20.7	0.1	0.4	0	0	0.3	1.3	0.1	0.6	0.3	1.4
CFF	MA	MH-DB002	12	23.7	0.3	1.3	0.3	1.4	0	0	0.2	0.7	0.4	1.6
CFF	MA	MH-DB003	12	23.4	0.2	1	0	0	0	0	0.3	1.5	0.4	1.7
CFF	MA	MH-DB004	12	51.9	1.1	2.2	0	0	0	0	0.4	0.8	1.1	2
CFF	MA	MH-WR001	12	20.7	0	0	0	0	0	0	0.4	1.7	0.4	1.7
CFF	MA	MH-WR002	12	24.7	0.1	0.4	0.3	1.2	0	0	0.3	1.3	0.4	1.7
CFF	FLEV	MH-DB001	12	377.3	1.4	0.4	0	0	4.8	1.3	2.4	0.6	5.3	1.4
CFF	FLEV	MH-DB002	12	432.2	5.8	1.3	6.2	1.4	0	0	3	0.7	6.8	1.6
CFF	FLEV	MH-DB003	12	426.5	4.5	1	0	0	0	0	6.2	1.5	7.3	1.7
CFF	FLEV	MH-DB004	12	947.1	20.9	2.2	0	0	0	0	7.5	0.8	19.3	2
CFF	FLEV	MH-WR001	12	377.4	0	0	0	0	0	0	6.5	1.7	6.5	1.7
CFF	FLEV	MH-WR002	12	450	1.6	0.4	5.2	1.2	0	0	6	1.3	7.7	1.7

Patient-Derived Hypo Samples (Dabigatran and Warfarin) – Table 2

Interference

Testing was performed in Coramed's laboratory for interference, using CLSI EP7-A2 as guidance.

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For CK, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Only Hemolysis and Hemodilution were found to be interferents.

For CRT, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Short Draw, Hemolysis and Hemodilution were found to be interferents.

For CKH, Protamine was tested for interference. Protamine was found to be an interferent for CKH at concentrations above 0.062 mg/ml.

For CFF, potential interferents tested were Na Heparin and Hemodilution. Heparin was found to be an interferent for CFF above Heparin concentrations of 1 IU/ml, and Hemodilution was found to be an interferent above hemodilution levels of 30%.

Linearity

Testing was performed in Coramed's laboratory for linearity, using CLSI EP6-A as guidance.

CFF was tested and found to be linear with varying concentrations of Fibrinogen (RiaSTAP) added. These concentrations ranged from 0 mg/dl to 565.5 mg/dl, over an FLEV range of 156 mg/dl to 1145 mg/dl. This corresponds to an MA range of 8.5 mm to 62.7 mm.

Sensitivity and Specificity

CK was tested for Sensitivity and Specificity with respect to Na Heparin, comparing R parameters of five blood samples with different clinically relevant concentrations of Heparin to five samples without heparin. Both Sensitivity and Specificity were found to be 100%.

Heparin Neutralization

Heparin Neutralization of CKH was tested using blood samples spiked with Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) and comparing these results to data obtained from testing CK with un-spiked blood samples. CKH was found to completely neutralize UFH levels of 5 IU/ml blood and LMWH levels of 0.013 mg/ml blood.

SUMMARY OF CLINICAL PERFORMANCE DATA

Testing was performed at three clinical sites for Reference Ranges and Method Comparison.

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Reference Ranges

Reference Ranges for the CORA assays were estimated using the CLSI C28-A3c Guideline on three reference sample groups. Blood samples from up to 55 normal volunteer subjects were taken at each of the three sites, for a total of 157 samples. There were at least 151 valid results for every parameter for all reagents. Samples were excluded on a per-parameter basis using standard outlier criteria. An alternative method would have been to exclude all parameters for any tests where one or more parameter results were determined to be outliers. However, it was decided to retain all valid parameter results in calculating reference ranges because a larger number of samples adds statistical credibility. Also, it does not appear that using the alternative approach would have any significant effect on the reference ranges. Subjects were chosen representing demographic populations of the three areas, regarding age, race and gender. These reference ranges are shown below.

Reagent ↓	N	R (min)	N	K (min)	N	Angle (deg)	N	MA (mm)	N	FLEV (mg/dl)
CK	157	4.6-9.1	157	0.8-2.1	155	63 - 78	151	52 - 69		
CRT							152	52 - 70		
CKH	155	4.3-8.3								
CFF							151	15 - 32	152	278-581

Reference Ranges for CKH are shown but not usually required because the only purpose is to neutralize the heparin in a patient's blood, regardless of the patient's hemostasis condition. Comparing results from the CK and CKH tests for the R parameter can assist in determining whether or not there is heparin in the blood sample.

Reference Ranges for Wet Quality Control (WQC) Abnormal material when used in CORA assay cartridges were estimated. Using three lots of Abnormal Quality Control and three citrated reagent lots, a total of over 135 test results were obtained.

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (deg)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563-873

Method Comparison

Method Comparison studies were conducted at three clinical sites on patient samples following CLSI EP09-A3 Guideline. The subjects enrolled were patients undergoing cardiovascular surgery or cardiology procedures, with blood samples drawn pre- and post-surgery and in the ICU. In order to broaden the range of comparisons, up to 10% artificially derived samples were added. Statistics are presented below.

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Method Comparison Statistics Summary – All Clinical Sites					
Parameter	**R**	**Intercept**	**95% CI**	**Slope**	**95% CI**
CK – R (min)	0.868	-0.325	-0.425	1.069	1.034
			-0.225		1.103
CK – K (min)	0.740	-0.097	-0.292	0.906	0.769
			0.098		1.042
CK – Alpha (deg)	0.680	7.305	-13.160	0.940	0.640
			27.769		1.240
CK – MA (mm)	0.924	2.351	0.166	0.948	0.912
			4.536		0.983
CKH – R (min)	0.812	-0.329	-0.393	1.057	1.026
			-0.265		1.089
CRT|CK – MA (mm)	0.929	-0.126	-1.909	0.978	0.948
			1.656		1.007
CFF – MA (mm)	0.938	-0.774	-1.836	1.126	1.072
			0.289		1.180
CFF – FLEV (mg/dl)	0.928	-12.495	-36.810	1.127	1.059
			11.819		1.194

In addition, a Reader Study was conducted to assess the comparison of CORA System and TEG 5000 results based on reading printed test outcomes. The study was performed at three sites, using three experienced TEG 5000 doctors as readers at each site, for a total of nine readers. 30 test outcomes were compared for each of the reagent test categories, for a total of 270 reading comparisons per reader. Excellent agreement between the two devices was demonstrated.

In both the Method Comparison Study and Reader Study, the CORA RapidTEG (CRT) MA parameter was compared to the TEG 5000 Kaolin (CK) MA parameter, to demonstrate that the CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTING

The data and information provided in this submission support a substantial equivalence determination for the CORA System and the TEG 5000 predicate device.

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Coramed Technologies, LLC
6225 W. Howard Street, Niles, Illinois 60714
847-647-8800 | 847-510-0502 FAX

CORA|MED

CORA® System 510(k) Summary

APPLICANT INFORMATION

Name of Manufacturer: Coramed Technologies, LLC

Manufacturer Street Address: 6225 W. Howard St.

City, State, Zip: Niles, IL 60714

Phone Number: (847) 647-8800

FAX Number: (847) 510-0502

Contact person for all communications: Norman E. Brunner

Email for contact person: nbrunner@coramedtech.com

Date that Summary was prepared: June 23, 2015

DEVICE INFORMATION

Trade name (proprietary name): CORA® (Coagulation Resonance Analysis) System and the following assays and reagents

- Citrated Assays and Reagents
  - CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
  - CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
  - CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
  - CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent

Common name (usual name): Whole Blood Hemostasis System

Classification Name: 21CFR 864.5425 Multipurpose System for *in vitro* Coagulation Studies

PREDICATE DEVICE

- Thrombelastograph® Coagulation Analyzer (TEG®) – 5000 Series, K002177, Product Code JPA (System, Multipurpose, for In Vitro Coagulation Studies), Haemoscope Corporation

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DESCRIPTION OF THE DEVICE

System Description

The CORA System consists of a four-channel diagnostic analyzer with integrated computer module, system reagents (CK, CRT, CKH, and CFF), and Abnormal Quality Control material and microfluidic test cartridges. See below for a description of system reagents. Reagents are dried-in-place within the cartridges during manufacturing. Abnormal Quality Control material is lyophilized and can be reconstituted with water as needed for WQC testing with reagent cartridges.

To perform a test, a disposable CORA Cartridge is inserted into the analyzer. Blood or WQC material is added to an entry port on the cartridge and drawn into the cartridge under analyzer control. The amount of the sample drawn into the cartridge is automatically determined by the volume of the blood chambers in the cartridge. Once in the disposable, the sample is metered into as many as four separate analysis channels, depending upon the assays being performed. Reconstitution of reagents dried within the cartridge is accomplished by moving the sample back and forth through reagent chambers, under the control of microfluidic valves and bellows (pumps) within the cartridge. After each sample has been mixed with reagent, it is delivered to a test cell where it is monitored for visco-elastic changes due to coagulation. Excess sample material is moved under microfluidic control into an enclosed waste chamber within the cartridge.

The CORA Measurement Technique

The CORA technology is based on a disposable containing up to four independent measurement cells. Each cell consists of a short vertically-oriented injection molded tube (ring) with a diameter of 2.5mm and a length of 4.5mm. Detection of clotting in the CORA System is performed optically. Under control of the analyzer, approximately 20µl of prepared sample is delivered to the tube, where a meniscus naturally forms at each end of the tube. The tube is positioned so that the lower meniscus partially blocks light traveling from a collimated source toward a photodiode.

During testing, a piezoelectric actuator drives the measurement cell(s) through a motion profile composed of summed sinusoids at different frequencies. The profile has a maximum amplitude of under 10µm and contains frequencies from 10-500Hz. Some, but not all, of the measurement cell motion will induce motion in the sample meniscus, which will be detected by the photodiode. The resulting motion of the meniscus is monitored optically and recorded by the analyzer to calculate the resonant frequency and modulus of elasticity (stiffness) of the sample. By performing a Fast Fourier Transform (FFT) on meniscus motion data, it is possible to determine the frequencies of input motion that caused the greatest deflection of the sample (these are called the resonant frequencies).

Resonance is the tendency of a material or structure to oscillate with greater amplitude at some frequencies than others. The exact frequencies at which resonance occurs will depend on the stiffness and mass of the sample. Stiffness, in turn, is a function of a material's modulus of elasticity and the boundary conditions to which the material is exposed, such as the geometry and materials of a test cell. By holding these boundary conditions and sample mass constant from run to run, the CORA System allows direct comparison of elasticity between samples.

In a typical test, blood that has been delivered to the measurement cell will not clot for several minutes. During this time the sample has no inherent stiffness except that provided by surface tension, and since this remains constant the measured resonant frequencies will not change. Once clotting begins, however, the elastic modulus and thus the resonant frequencies increase rapidly. During fibrinolysis, the process is reversed, with elastic modulus and resonant frequencies decreasing. In tests where clotting does not occur, the resonant frequency of the sample will not change. During coagulation, however, a clot will bind to the test tube (ring) and the resonant frequency will rise with increasing firmness of the clot. The

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CORA Analyzer collects meniscus motion data, tracks changing resonant frequencies and analyzes the frequency data to provide semi-quantitative parameters describing the clot. Results are presented in a format similar to the TEG 5000.

Both the TEG 5000 and CORA System monitor the elastic modulus of clots. Method Comparison testing has been performed, yielding data from approximately 300 patients from three sites (Mayo Clinic, University of Pittsburgh Medical Center, and Sinai Hospital, Baltimore). These data include all applicable parameters from the four citrated tests (CK, CKH, CRT and CFF). The TEG 5000 measures the changes of the linkage forces of the clot between the cup and pin over time, while the CORA System measures the changes of the resonant frequency of the clot over time. Despite the difference in the way the two analyzers measure the changes in the modulus of elasticity of the clot over time, they measure the same physical phenomenon and produce the same result when converted from their specific units of measurement (forces for the TEG5000 and frequency for the CORA System) to millimeters. The fact that these results are similar across all reagents used in both technologies is demonstration that the two technologies measure the same phenomenon, the changes in elastic modulus.

The following definitions apply to calculated parameters in the CORA System:

CORA Parameter	Definition	Parameter Relation to Hemostasis
R	R is the time from the start of the test until initial fibrin formation. This represents the enzymatic portion of coagulation.	Normal / reduced / increased speed of coagulation initiation
K	K is the time after R needed to reach a certain level of clot strength. This represents clot kinetics.	Normal / reduced / increased speed of coagulation amplification and propagation
Alpha α (angle)	Alpha is the angle representing the rate increase in the clot strength and the rapidity of fibrin build-up and cross-linking.	Normal / reduced / increased speed of coagulation amplification and propagation
MA	MA, or Maximum Amplitude, represents the maximum firmness of the clot during the test.	Normal / reduced / increased clot elasticity/strength
FLEV	FLEV is an estimate of the fibrinogen level in the blood sample.	Estimated Functional Fibrinogen Level

Citrated Assays

The CK assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle), and Maximum Clot Strength (MA). K and Alpha are complementary parameters and should be used in conjunction with Clotting Time (R) and Maximum Clot Strength (MA).

The CRT assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via both the intrinsic and extrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CFF assay is a semi-quantitative *in vitro* diagnostic assay for monitoring hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. CFF is used in conjunction with CK and clotting characteristics are described by the functional parameter Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

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The CKH assay is a semi-quantitative *in vitro* diagnostic assay used in conjunction with the CORA System to monitor the effects of heparin in the blood stream of a patient. CKH is used in conjunction with CK and heparin influence is determined by comparing Clotting Times (R) between the two tests.

Wet Quality Control (WQC)

Abnormal Wet Quality Control (WQC) material consists of bovine plasma with buffers and stabilizers, and is used instead of hypocoagulable blood, in conjunction with the Citrated Multichannel system cartridge. When used with the Citrated Multichannel cartridge, this material provides consistent and repeatable values for CORA parameters to confirm reagent quality and viability.

Abnormal WQC Intended Use

The Abnormal WQC (Wet Quality Control) Material is intended to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

INTENDED USE AND INDICATIONS FOR USE

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The CORA System records the kinetic changes in a sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARING THE CORA SYSTEM TO THE TEG 5000 PREDICATE DEVICE

Table of Similarities

Item	TEG® 5000 Predicate	CORA® System
Analyzer		
Technological Purpose	Monitoring the response of a clot to low levels of applied strain	Monitoring the response of a clot to low levels of applied strain
What is measured	Changes in clot elasticity over time	Changes in clot elasticity over time
Initial Warm Up Time	5 min	5 min
Time to Complete a Test	Varies with assay	Same as TEG 5000
Assays and Reagents		
Intrinsic Contact Activation Reagent (CK)	Kaolin and $CaCl_2$	Kaolin and $CaCl_2$, same materials as TEG 5000

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Item	TEG® 5000 Predicate	CORA® System
Intrinsic Contact Activation Reagent with Heparinase for heparin reversal (CKH)	Kaolin and $CaCl_2$ with Heparinase	Kaolin, Heparinase and $CaCl_2$, same materials as TEG 5000
Citrated RapidTEG (CRT) (Tissue Factor and Kaolin Activation)	Tissue Factor (TF), Kaolin and $CaCl_2$	Tissue Factor (TF), Kaolin and $CaCl_2$, same materials as TEG5000
Citrated Functional Fibrinogen (CFF) / Platelet-Blocked (Tissue Factor Activation)	ReoPro®, Tissue Factor and $CaCl_2$, same materials as CORA	ReoPro®, Tissue Factor and $CaCl_2$, same materials as TEG 5000
Calcium Chloride Reagent (CC) (for re-calcification)	$CaCl_2$ reagent	$CaCl_2$ same materials as TEG 5000
Quality Control Material (WQC Abnormal Control)	TEG coagulation control – Level II	TEG coagulation control – Abnormal, same materials as TEG 5000

Table of Differences

Item	TEG® 5000 Predicate	CORA® System
Analyzer	Thrombelastography analyzer, separate computer and software	Fully integrated Thrombelastography analyzer
Measuring Technique	Direct-contact measurement of shear elasticity of a coagulating sample	Non-contact measurement of shear elasticity of a coagulating sample
Measuring Channels	Two, each independent and interchangeable (can be used with any approved reagent)	Four, each independent and interchangeable (can be used with any approved reagent)
Signal Transducer	Electromechanical detection (rotary variable inductive transformer) of rotary motion of a pin suspended in the sample	Optical detection (silicon photodiode) of the motion of a free surface of the sample
Temperature Control	20° to 40°C	20° to 50°C
Sample Volume (per channel)	360-380 µl	63 µl
Total Reaction Volume (single channel)	360-380 µl	20 µl
Mains Supply Voltage	120V, 60Hz and 220V, 50Hz model available	100-240V, 50-60Hz (international power supply)
Analyzer Input Voltage	24 volts AC, 30 watts max	12 volts DC, 60 watts max
Environment	Level and vibration free position, no solar radiation Operating temperature: 10° to 35 °C Storage Temperature: -30° to +50 °C (analyzer only) Relative humidity 20-80% (non-condensing)	Stable and level surface. Operating Temperature 10° to 32°C Storage Temperature: -20° to 50°C (analyzer only) Relative humidity 20 to 80% (non-condensing)

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Item	TEG® 5000 Predicate	CORA® System
Sample Preparation	Performed by the operator using pipettes to reconstitute reagents and mix reagents with the sample	Performed under analyzer control within the disposable cartridge
Pipetting	Manual accurate pipettes (10, 20, 50, 100, 340, 360, 500, 1000µl)	Unmetered transfer pipette or syringe; blood sample is added until it fills to a level above the line marked on the blood intake well of the cartridge
Consumables	Cups & Pins (acrylic plastic)	Carrier (acrylic plastic) with microfluidics laminate and test rings (acrylic plastic)

SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Analytical Precision

Testing was performed in Coramed's laboratory for precision, using CLSI EP5-A2 as guidance. Acceptance criteria for all reagents are: CV ≤ 15% for the R parameter, CV ≤ 25% for the K parameter, and CV ≤ 10% for the Alpha and MA parameters. Three types of donor citrated whole blood (CWB) were used in this precision testing:

- Hypo (donors with natural coagulation levels of R parameter near the upper limit of the reference range and MA parameter near the lower limit of the reference range);
- Normal (donors with natural coagulation levels of R and MA parameters near the center of the reference ranges):
- Hyper (donors with natural coagulation levels of R parameter near the lower limit of the reference range and MA parameter near the upper limit of the reference range

Testing was performed with blood draws from three donors (one Hypo, one Normal, and one Hyper) on each of five days (non-consecutive). Testing was performed by two operators using three reagent lots and twelve analyzers, two replicates. The structure of this precision test is shown below.

Sample Type (Hypo, Normal or Hyper)												
	Day 1 (Total of 5 days)											
Operator	Operator 1						Operator 2					
Reagent lot	1		2		3		1		2		3	
Analyzer	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2

Structure of Precision Testing

Precision test estimates by test, parameter and donor sample test level are shown in the table on the following page. All acceptance criteria were met.

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Test	Parameter	Level	n	Mean	Reagent Lot		Operator*		Analyzer (within Operator, Reagent Lot)		Day (within Analyzer, Operator, Reagent Lot)		Repeatability		Total		Total without Day (Within Day)	
					SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
CFF	FLEV	Hypo	120	269.8	2.36	0.9%	0	0.0%	0	0.0%	5.32	2.0%	5.87	2.2%	8.27	3.1%	6.33	2.3%
CFF	FLEV	Normal	120	376.8	0	0.0%	2.25	0.6%	0	0.0%	5.49	1.5%	3.98	1.1%	7.15	1.9%	4.57	1.2%
CFF	FLEV	Hyper	120	597.4	0	0.0%	0	0.0%	0	0.0%	49.38	8.3%	9.62	1.6%	50.31	8.4%	9.62	1.6%
CFF	MA	Hypo	120	14.8	0.11	0.8%	0	0.0%	0	0.0%	0.29	2.0%	0.33	2.2%	0.45	3.0%	0.35	2.3%
CFF	MA	Normal	120	20.6	0	0.0%	0.13	0.6%	0	0.0%	0.3	1.5%	0.22	1.1%	0.39	1.9%	0.25	1.2%
CFF	MA	Hyper	120	32.7	0	0.0%	0	0.0%	0	0.0%	2.71	8.3%	0.53	1.6%	2.76	8.4%	0.53	1.6%
CKH	R	Hypo	120	8.2	0	0.0%	0	0.0%	0.18	2.2%	0.36	4.3%	0.76	9.2%	0.86	10.0%	0.78	9.5%
CKH	R	Normal	120	6.0	0	0.0%	0.05	0.9%	0.09	1.6%	0.14	2.3%	0.42	7.1%	0.46	7.7%	0.44	7.3%
CKH	R	Hyper	120	4.9	0	0.0%	0.05	1.1%	0	0.0%	0.28	5.7%	0.5	10.0%	0.58	12.0%	0.5	10.0%
CK	Angle	Hypo	120	68.7	0	0.0%	1.09	1.6%	0	0.0%	1.61	2.3%	3.01	4.4%	3.59	5.2%	3.2	4.7%
CK	Angle	Normal	120	72.1	0	0.0%	0	0.0%	0	0.0%	1.14	1.6%	1.73	2.4%	2.07	2.9%	1.73	2.4%
CK	Angle	Hyper	120	76.7	0	0.0%	0	0.0%	0	0.0%	1.84	2.4%	1.77	2.3%	2.56	3.3%	1.77	2.3%
CK	K	Hypo	120	1.8	0.03	1.9%	0.06	3.6%	0	0.0%	0.13	7.2%	0.18	10.0%	0.23	13.0%	0.19	11.0%
CK	K	Normal	120	1.4	0	0.0%	0	0.0%	0	0.0%	0.09	6.7%	0.16	12.0%	0.19	13.0%	0.16	12.0%
CK	K	Hyper	120	0.9	0	0.0%	0	0.0%	0	0.0%	0.12	12.0%	0.18	20.0%	0.22	23.0%	0.18	20.0%
CK	MA	Hypo	120	52.4	0.33	0.6%	0.55	1.0%	0.26	0.5%	0.83	1.6%	0.77	1.5%	1.33	2.5%	1.03	2.0%
CK	MA	Normal	120	59.4	0	0.0%	0.5	0.8%	0.48	0.8%	0.57	1.0%	0.86	1.4%	1.24	2.1%	1.1	1.9%
CK	MA	Hyper	120	68.0	0	0.0%	0.2	0.3%	0	0.0%	0.9	1.3%	0.52	0.8%	1.06	1.6%	0.56	0.8%
CK	R	Hypo	120	8.9	0	0.0%	0.29	3.3%	0	0.0%	0.64	7.1%	0.85	9.5%	1.1	12.0%	0.9	10.0%
CK	R	Normal	120	6.5	0	0.0%	0	0.0%	0	0.0%	0.28	4.3%	0.49	7.6%	0.56	8.7%	0.49	7.6%
CK	R	Hyper	120	5.2	0.13	2.5%	0	0.0%	0	0.0%	0.31	5.8%	0.66	13.0%	0.74	14.0%	0.67	13.0%
CRT	MA	Hypo	120	52.4	0.39	0.7%	0.22	0.4%	0	0.0%	0.92	1.8%	0.59	1.1%	1.18	2.3%	0.74	1.4%
CRT	MA	Normal	120	62.7	0	0.0%	0.15	0.2%	0.14	0.2%	0.37	0.6%	0.31	0.5%	0.52	0.8%	0.37	0.6%
CRT	MA	Hyper	120	69.4	0	0.0%	0	0.0%	0	0.0%	0.91	1.3%	0.2	0.3%	0.93	1.3%	0.2	0.3%

*Operator = Operator + operator-by-reagent lot interaction

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In addition, Coramed's Citrated Reagent Precision Protocol Rev. 02 was written to supplement precision data originally provided to FDA in 510(k) K150041. This protocol specifies testing to be performed outside of reference range values but within the Analytical Measurement Range (AMR) limits. This report presents data and statistics resulting from the execution of this protocol.

The following pages contain tables of precision statistics. Table 1 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from normal donors but spiked to achieve hypocoagulable (hypo) and hypercoagulable (hyper) results. Three donors for each reagent-parameter and spiking type were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each donor-reagent-parameter-hypo/hyper type, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B
Sample	Hypercoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

The focus of this study was on achieving values for the primary coagulation parameters R, MA and FLEV outside the reference ranges but within AMR limits, and taking the resulting K and Alpha (angle) values as is. Total Precision %CV values were all within pre-established limits, except for one CFF MA hypo outcome (11.6% for a limit of 10%) and 2 outcomes for Angle. The K and Angle parameters indicate the kinetics of the clotting process, and are not clinically significant as the main parameters representing coagulation, platelet and fibrinogen activities and abnormalities. The CFF MA CV% is higher because the MA value is small (mean of 6.5 mm) and although the Standard Deviation is very small (0.8mm) the resulting CV% is just over the limit. When the SD is so small there is no clinical significance for the differences making this CV% acceptable.

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Table 2 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from patients taking anticoagulants Dabigatran and Warfarin. Four Dabigatran patients and two Warfarin patients for each reagent-parameter were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each patient-reagent-parameter, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1		2		3		4		5		6	
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

Results for this testing were generally within limits, except for a few minor exceptions. As the data shows, all the MAs, for CK, CRT, and CFF, are within the specified expected CV% across the board while for the R parameter, there are no significant differences between lots, operators and devices and the only CVs (for CK and CKH – R parameter) somewhat exceeding 15% come from repeatability (16.9% for MH-DB003 for CK and 15.9% for MH-DB004 for CKH). Even though the, K and Angle are not parameters that are considered clinically significant the raw data indicates that the single angle CV% that is above the limit was due to an outlier while the K parameter has high CVs due to the fact that elongated coagulation results in higher CVs for that parameter.

Test	Param	Spiking	Patient ID	N	Mean	Lot		Operator		Instrument		Repetition		Total	
						StDev	CV	StDev	CV	StDev	CV	StDev	CV	StDev	CV

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CK	R	hyper	D101	12	2.1	0	0	0	0	0.1	4.5	0.1	3.1	0.1	5.5
CK	R	hyper	D108	12	2.7	0	0	0	1	0.1	3.5	0.1	2.4	0.1	4.3
CK	R	hyper	D169	12	2.2	0.1	2.8	0	0	0.1	3.1	0.1	2.5	0.1	4.6
CK	R	hypo	D141	12	16.1	0	0	1.1	6.9	1.3	8	0.7	4.3	1.7	10.8
CK	R	hypo	D169	12	15.3	0.8	5.3	0	0	1.6	10.2	1.1	7.1	2	13.2
CK	R	hypo	D108	12	12.1	0.1	1	0.1	0.9	0.9	7.2	0.7	5.6	1.1	9.3
CK	K	hyper	D101	12	0.5	0	0	0	0	0	3.9	0	4.1	0	5.7
CK	K	hyper	D108	12	0.4	0	3.8	0	3.8	0	7.2	0	6.5	0	10.7
CK	K	hyper	D169	12	0.5	0	0	0	0	0	8.2	0	8.2	0.1	11.6
CK	K	hypo	D141	12	3	0.2	5.2	0.2	6	0.3	9.9	0.2	8.2	0.4	14.6
CK	K	hypo	D169	12	3.1	0.5	16.4	0	0	0.5	14.8	0.3	10	0.7	22.7
CK	K	hypo	D108	12	2.2	0	0	0.1	6.4	0.3	12	0.1	6.2	0.3	14.6
CK	Angle	hyper	D101	12	80	0.8	1.1	1.5	1.8	7.2	9	6.9	8.7	10.1	12.6
CK	Angle	hyper	D108	12	85.1	0.1	0.2	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hyper	D169	12	84.3	0.1	0.1	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hypo	D141	12	54.7	0	0	0	0	8.4	15.4	5.4	9.9	10	18.3
CK	Angle	hypo	D169	12	42.7	1	2.4	1.9	4.5	1.8	4.3	1.6	3.7	3.1	7.2
CK	Angle	hypo	D108	12	66.7	3	4.4	0	0	4.8	7.2	3.3	5	6.3	9.5
CK	MA	hyper	D108	12	71.6	0	0	0.5	0.7	0.3	0.4	0.3	0.4	0.5	0.8
CK	MA	hyper	D169	12	70	0	0	0.1	0.1	0.2	0.2	0.1	0.2	0.2	0.3
CK	MA	hyper	D121	12	71.1	0	0	0	0	0.9	1.3	0.6	0.8	1.1	1.5
CK	MA	hypo	D141	12	42	0.2	0.6	0	0	1.5	3.5	0.9	2.1	1.7	4.1
CK	MA	hypo	D169	12	46.6	0	0	0	0	0.8	1.8	0.5	1.1	1	2.1
CK	MA	hypo	D108	12	45.4	0	0	0.8	1.8	1.2	2.7	0.9	2	1.7	3.7
CKH	R	hyper	D101	12	2	0.1	4.8	0	0	0	2.4	0.1	2.8	0.1	5.5
CKH	R	hyper	D108	12	2.6	0	0	0	0	0.1	2.6	0	1.6	0.1	3.1
CKH	R	hyper	D169	12	2.2	0	0	0	0	0	1.5	0	1	0	1.8
CKH	R	hypo	D141	12	15.7	0	0	1	6.4	0.7	4.5	0.6	4.1	1.3	8.2
CKH	R	hypo	D169	12	14.5	0	0	0.8	5.2	0.8	5.7	0.5	3.2	1.1	7.9
CKH	R	hypo	D108	12	12.3	0.6	5	0	0	0.8	6.3	0.5	4.4	1.1	8.8
CRT	MA	hyper	D108	12	70.8	0.2	0.3	0	0	0.1	0.2	0.1	0.2	0.2	0.3
CRT	MA	hyper	D121	12	72.5	0.2	0.3	0	0	0.4	0.5	0.4	0.5	0.5	0.8
CRT	MA	hyper	D145	12	73	0.2	0.2	0	0	0.2	0.3	0.2	0.2	0.3	0.4
CRT	MA	hypo	D141	12	41.3	0	0	0	0	0.7	1.8	0.5	1.2	0.9	2.2
CRT	MA	hypo	D169	12	44.4	0	0	0.3	0.7	0.6	1.3	0.4	0.9	0.8	1.7
CRT	MA	hypo	D108	12	45.5	0	0	0.4	0.9	1	2.1	0.5	1.1	1.1	2.5
CFF	MA	hyper	D101	12	49.9	0.1	0.1	0	0	0.5	0.9	0.3	0.5	0.5	1.1
CFF	MA	hyper	D141	12	44.3	0	0	0	0	0.5	1.2	0.3	0.6	0.6	1.3
CFF	MA	hyper	D145	12	47	0	0	0	0	0.7	1.4	0.5	1	0.8	1.7
CFF	MA	hypo	D101	12	10.2	0.2	1.5	0	0	0.3	3	0.2	1.7	0.4	3.6
CFF	MA	hypo	D125	12	9.5	0	0	0.2	1.8	0.4	4	0.3	2.7	0.5	5
CFF	MA	hypo	D169	12	6.5	0	0	0.7	10.1	0.3	4.9	0.4	6	0.8	11.6
CFF	FLEV	hyper	D101	12	910.7	1.2	0.1	0	0	8.6	0.9	5	0.5	10	1.1
CFF	FLEV	hyper	D141	12	809	0	0	0	0	9.6	1.2	5.2	0.6	10.9	1.3
CFF	FLEV	hyper	D145	12	858.1	0	0	0	0	11.9	1.4	8.5	1	14.7	1.7
CFF	FLEV	hypo	D101	12	186.4	2.9	1.5	0	0	5.5	3	3.1	1.7	6.8	3.6
CFF	FLEV	hypo	D125	12	173.4	0	0	3.1	1.8	7	4	4.6	2.6	8.7	5
CFF	FLEV	hypo	D169	12	157.5	1.8	1.2	1.1	0.7	2	1.3	1.7	1.1	3.2	2.1

Spiked Precision – Table 1

Test	Param	PatientID	N	Mean	Lot		Operator		Instrument		Repetition		Total	
					StDev	CV	StDev	CV	StDev	CV	StDev	CV	StDev	CV
CK	R	MH-DB001	12	13	0	0	0	0	0.4	3.2	1.2	8.9	1.2	9.4
CK	R	MH-DB002	12	21.3	0	0	0	0	1	4.7	2.1	10.1	2.3	11

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CK	R	MH-DB003	12	14.4	0	0	0	0	0	0	2.4	16.9	2.4	16.9
CK	R	MH-DB004	12	11.8	0.5	4	0.5	4.3	0	0	1.6	13.9	1.7	14.8
CK	R	MH-WR001	12	9.9	0.7	7	0.3	2.7	0.3	2.6	0.5	4.9	0.8	8.5
CK	R	MH-WR002	12	10.1	1	10.2	0	0	0.3	3.2	1	10	1.4	13.6
CK	K	MH-DB001	12	1.3	0	0	0	0	0	0	0.2	18.2	0.2	18.2
CK	K	MH-DB002	12	2.4	0	0	0	0	0.4	15.4	1	42	1	44.5
CK	K	MH-DB003	12	1.3	0	0	0	0	0	0	0.3	19.8	0.3	19.8
CK	K	MH-DB004	12	0.9	0.1	11.4	0	0	0	0	0.3	33	0.3	34.4
CK	K	MH-WR001	12	2.2	0	0	0	0	0	0	0.2	8.2	0.2	8.2
CK	K	MH-WR002	12	2	0	0	0	0	0	0	0.4	19.1	0.4	19.1
CK	Angle	MH-DB001	12	72.5	0	0	0	0	0	0	3.6	5	3.6	5
CK	Angle	MH-DB002	12	55.5	0	0	0	0	10.3	18.6	11.6	20.8	15.2	27.4
CK	Angle	MH-DB003	12	72.7	0	0	0	0	0	0	3.2	4.3	3.2	4.3
CK	Angle	MH-DB004	12	79.5	0	0	0	0	0	0	3.4	4.3	3.4	4.3
CK	Angle	MH-WR001	12	65	0	0	0	0	0	0	1.1	1.7	1.1	1.7
CK	Angle	MH-WR002	12	67.1	0	0	1.1	1.6	0	0	3	4.4	3.1	4.6
CK	MA	MH-DB001	12	60.2	0	0	0	0	0	0	0.9	1.5	0.9	1.5
CK	MA	MH-DB002	12	64.5	0	0	0.2	0.4	0	0	0.6	1	0.7	1
CK	MA	MH-DB003	12	64.1	0	0	0.4	0.7	0	0	0.5	0.8	0.7	1
CK	MA	MH-DB004	12	71.9	0.1	0.1	0.5	0.6	0	0	0.5	0.7	0.7	0.9
CK	MA	MH-WR001	12	60.6	0	0	0	0	0	0	0.9	1.4	0.9	1.4
CK	MA	MH-WR002	12	59.7	0	0	0	0	1	1.6	0.8	1.3	1.2	2
CKH	R	MH-DB001	12	12.2	0.8	6.8	0	0	0	0	0.7	5.8	1	8.2
CKH	R	MH-DB002	12	19.3	0	0	1.6	8.4	0	0	2.2	11.4	2.6	13.5
CKH	R	MH-DB003	12	13.5	0	0	0.5	4	0	0	1.4	10.6	1.5	11.1
CKH	R	MH-DB004	12	11.3	0	0	0	0	0	0	1.8	15.9	1.8	15.9
CKH	R	MH-WR001	12	8.4	0	0	0.1	0.8	0	0	0.8	9.7	0.8	9.8
CKH	R	MH-WR002	12	9.1	0.5	5.1	0	0	0	0	0.7	7.4	0.8	8.6
CRT	MA	MH-DB001	12	64.9	0.1	0.1	0	0	0.1	0.1	0.1	0.2	0.1	0.2
CRT	MA	MH-DB002	12	67.7	0.1	0.1	0	0	0	0	0.2	0.2	0.2	0.2
CRT	MA	MH-DB003	12	66	0	0	0	0	0	0	0.1	0.2	0.1	0.2
CRT	MA	MH-DB004	12	73.8	0.1	0.1	0	0	0.1	0.1	0.2	0.2	0.2	0.3
CRT	MA	MH-WR001	12	64	0.1	0.1	0	0	0	0	0.2	0.3	0.2	0.3
CRT	MA	MH-WR002	12	64.7	0	0	0	0	0	0	0.3	0.4	0.3	0.4
CFF	MA	MH-DB001	12	20.7	0.1	0.4	0	0	0.3	1.3	0.1	0.6	0.3	1.4
CFF	MA	MH-DB002	12	23.7	0.3	1.3	0.3	1.4	0	0	0.2	0.7	0.4	1.6
CFF	MA	MH-DB003	12	23.4	0.2	1	0	0	0	0	0.3	1.5	0.4	1.7
CFF	MA	MH-DB004	12	51.9	1.1	2.2	0	0	0	0	0.4	0.8	1.1	2
CFF	MA	MH-WR001	12	20.7	0	0	0	0	0	0	0.4	1.7	0.4	1.7
CFF	MA	MH-WR002	12	24.7	0.1	0.4	0.3	1.2	0	0	0.3	1.3	0.4	1.7
CFF	FLEV	MH-DB001	12	377.3	1.4	0.4	0	0	4.8	1.3	2.4	0.6	5.3	1.4
CFF	FLEV	MH-DB002	12	432.2	5.8	1.3	6.2	1.4	0	0	3	0.7	6.8	1.6
CFF	FLEV	MH-DB003	12	426.5	4.5	1	0	0	0	0	6.2	1.5	7.3	1.7
CFF	FLEV	MH-DB004	12	947.1	20.9	2.2	0	0	0	0	7.5	0.8	19.3	2
CFF	FLEV	MH-WR001	12	377.4	0	0	0	0	0	0	6.5	1.7	6.5	1.7
CFF	FLEV	MH-WR002	12	450	1.6	0.4	5.2	1.2	0	0	6	1.3	7.7	1.7

Patient-Derived Hypo Samples (Dabigatran and Warfarin) – Table 2

Interference

Testing was performed in Coramed's laboratory for interference, using CLSI EP7-A2 as guidance.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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For CK, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Only Hemolysis and Hemodilution were found to be interferents.

For CRT, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Short Draw, Hemolysis and Hemodilution were found to be interferents.

For CKH, Protamine was tested for interference. Protamine was found to be an interferent for CKH at concentrations above 0.062 mg/ml.

For CFF, potential interferents tested were Na Heparin and Hemodilution. Heparin was found to be an interferent for CFF above Heparin concentrations of 1 IU/ml, and Hemodilution was found to be an interferent above hemodilution levels of 30%.

Linearity

Testing was performed in Coramed's laboratory for linearity, using CLSI EP6-A as guidance.

CFF was tested and found to be linear with varying concentrations of Fibrinogen (RiaSTAP) added. These concentrations ranged from 0 mg/dl to 565.5 mg/dl, over an FLEV range of 156 mg/dl to 1145 mg/dl. This corresponds to an MA range of 8.5 mm to 62.7 mm.

Sensitivity and Specificity

CK was tested for Sensitivity and Specificity with respect to Na Heparin, comparing R parameters of five blood samples with different clinically relevant concentrations of Heparin to five samples without heparin. Both Sensitivity and Specificity were found to be 100%.

Heparin Neutralization

Heparin Neutralization of CKH was tested using blood samples spiked with Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) and comparing these results to data obtained from testing CK with un-spiked blood samples. CKH was found to completely neutralize UFH levels of 5 IU/ml blood and LMWH levels of 0.013 mg/ml blood.

SUMMARY OF CLINICAL PERFORMANCE DATA

Testing was performed at three clinical sites for Reference Ranges and Method Comparison.

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Reference Ranges

Reference Ranges for the CORA assays were estimated using the CLSI C28-A3c Guideline on three reference sample groups. Blood samples from up to 55 normal volunteer subjects were taken at each of the three sites, for a total of 157 samples. There were at least 151 valid results for every parameter for all reagents. Samples were excluded on a per-parameter basis using standard outlier criteria. An alternative method would have been to exclude all parameters for any tests where one or more parameter results were determined to be outliers. However, it was decided to retain all valid parameter results in calculating reference ranges because a larger number of samples adds statistical credibility. Also, it does not appear that using the alternative approach would have any significant effect on the reference ranges. Subjects were chosen representing demographic populations of the three areas, regarding age, race and gender. These reference ranges are shown below.

Reagent ↓	N	R (min)	N	K (min)	N	Angle (deg)	N	MA (mm)	N	FLEV (mg/dl)
CK	157	4.6-9.1	157	0.8-2.1	155	63 - 78	151	52 - 69		
CRT							152	52 - 70		
CKH	155	4.3-8.3								
CFF							151	15 - 32	152	278-581

Reference Ranges for CKH are shown but not usually required because the only purpose is to neutralize the heparin in a patient's blood, regardless of the patient's hemostasis condition. Comparing results from the CK and CKH tests for the R parameter can assist in determining whether or not there is heparin in the blood sample.

Reference Ranges for Wet Quality Control (WQC) Abnormal material when used in CORA assay cartridges were estimated. Using three lots of Abnormal Quality Control and three citrated reagent lots, a total of over 135 test results were obtained.

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (deg)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563-873

Method Comparison

Method Comparison studies were conducted at three clinical sites on patient samples following CLSI EP09-A3 Guideline. The subjects enrolled were patients undergoing cardiovascular surgery or cardiology procedures, with blood samples drawn pre- and post-surgery and in the ICU. In order to broaden the range of comparisons, up to 10% artificially derived samples were added. Statistics are presented below.

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Method Comparison Statistics Summary – All Clinical Sites					
Parameter	**R**	**Intercept**	**95% CI**	**Slope**	**95% CI**
CK – R (min)	0.868	-0.325	-0.425	1.069	1.034
			-0.225		1.103
CK – K (min)	0.740	-0.097	-0.292	0.906	0.769
			0.098		1.042
CK – Alpha (deg)	0.680	7.305	-13.160	0.940	0.640
			27.769		1.240
CK – MA (mm)	0.924	2.351	0.166	0.948	0.912
			4.536		0.983
CKH – R (min)	0.812	-0.329	-0.393	1.057	1.026
			-0.265		1.089
CRT|CK – MA (mm)	0.929	-0.126	-1.909	0.978	0.948
			1.656		1.007
CFF – MA (mm)	0.938	-0.774	-1.836	1.126	1.072
			0.289		1.180
CFF – FLEV (mg/dl)	0.928	-12.495	-36.810	1.127	1.059
			11.819		1.194

In addition, a Reader Study was conducted to assess the comparison of CORA System and TEG 5000 results based on reading printed test outcomes. The study was performed at three sites, using three experienced TEG 5000 doctors as readers at each site, for a total of nine readers. 30 test outcomes were compared for each of the reagent test categories, for a total of 270 reading comparisons per reader. Excellent agreement between the two devices was demonstrated.

In both the Method Comparison Study and Reader Study, the CORA RapidTEG (CRT) MA parameter was compared to the TEG 5000 Kaolin (CK) MA parameter, to demonstrate that the CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTING

The data and information provided in this submission support a substantial equivalence determination for the CORA System and the TEG 5000 predicate device.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*
K150041

Device Name
CORA Hemostasis System

Indications for Use *(Describe)*
The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The CORA System records the kinetic changes in a venous sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

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510(k) Number *(if known)*
K150041

Device Name
CORA Citrated Multichannel Cartridge

Indications for Use *(Describe)*
The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The Citrated Multichannel Cartridge, to be used with the CORA System instrument, contains four independent assays (CK, CRT, CKH and CFF), described below.

The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).
The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.
The CKH assay monitors the effects of heparin in 3.2% citrated whole blood specimens on the CORA System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests.
The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

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Device Name
CORA Hemostasis System - Abnormal Wet Quality Control (WQC) Material

Indications for Use *(Describe)*

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample.

The Abnormal Wet Quality Control Material is to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

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510(k) Number *(if known)*
K150041

Device Name
CORA Hemostasis System

Indications for Use *(Describe)*
The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The CORA System records the kinetic changes in a venous sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

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Device Name
CORA Citrated Multichannel Cartridge

Indications for Use *(Describe)*
The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The Citrated Multichannel Cartridge, to be used with the CORA System instrument, contains four independent assays (CK, CRT, CKH and CFF), described below.

The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).
The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.
The CKH assay monitors the effects of heparin in 3.2% citrated whole blood specimens on the CORA System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests.
The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

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Device Name
CORA Hemostasis System - Abnormal Wet Quality Control (WQC) Material

Indications for Use *(Describe)*

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The Abnormal Wet Quality Control Material is to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

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The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center WO66 G609
Silver Spring, MD 20993 0002

June 26, 2015

Coramed Technologies, LLC
Mr. Norman Brunner
Director of RA/QA
6225 W. Howard Street
Niles, IL 60714

Re: K150041
Trade/Device Name: CORA® (Coagulation Resonance Analysis) System
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: II
Product Code: JPA
Dated: May 21, 2015
Received: May 22, 2015

Dear Mr. Brunner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

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Indications for Use

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The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*
K150041

Device Name
CORA Citrated Multichannel Cartridge

Indications for Use *(Describe)*
The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The Citrated Multichannel Cartridge, to be used with the CORA System instrument, contains four independent assays (CK, CRT, CKH and CFF), described below.

The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).
The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.
The CKH assay monitors the effects of heparin in 3.2% citrated whole blood specimens on the CORA System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests.
The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*
K150041

Device Name
CORA Hemostasis System - Abnormal Wet Quality Control (WQC) Material

Indications for Use *(Describe)*

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample.

The Abnormal Wet Quality Control Material is to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

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Coramed Technologies, LLC
6225 W. Howard Street, Niles, Illinois 60714
847-647-8800 | 847-510-0502 FAX

CORA|MED

CORA® System 510(k) Summary

APPLICANT INFORMATION

Name of Manufacturer: Coramed Technologies, LLC

Manufacturer Street Address: 6225 W. Howard St.

City, State, Zip: Niles, IL 60714

Phone Number: (847) 647-8800

FAX Number: (847) 510-0502

Contact person for all communications: Norman E. Brunner

Email for contact person: nbrunner@coramedtech.com

Date that Summary was prepared: June 23, 2015

DEVICE INFORMATION

Trade name (proprietary name): CORA® (Coagulation Resonance Analysis) System and the following assays and reagents

- Citrated Assays and Reagents
  - CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
  - CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
  - CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
  - CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent

Common name (usual name): Whole Blood Hemostasis System

Classification Name: 21CFR 864.5425 Multipurpose System for *in vitro* Coagulation Studies

PREDICATE DEVICE

- Thrombelastograph® Coagulation Analyzer (TEG®) – 5000 Series, K002177, Product Code JPA (System, Multipurpose, for In Vitro Coagulation Studies), Haemoscope Corporation

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DESCRIPTION OF THE DEVICE

System Description

The CORA System consists of a four-channel diagnostic analyzer with integrated computer module, system reagents (CK, CRT, CKH, and CFF), and Abnormal Quality Control material and microfluidic test cartridges. See below for a description of system reagents. Reagents are dried-in-place within the cartridges during manufacturing. Abnormal Quality Control material is lyophilized and can be reconstituted with water as needed for WQC testing with reagent cartridges.

To perform a test, a disposable CORA Cartridge is inserted into the analyzer. Blood or WQC material is added to an entry port on the cartridge and drawn into the cartridge under analyzer control. The amount of the sample drawn into the cartridge is automatically determined by the volume of the blood chambers in the cartridge. Once in the disposable, the sample is metered into as many as four separate analysis channels, depending upon the assays being performed. Reconstitution of reagents dried within the cartridge is accomplished by moving the sample back and forth through reagent chambers, under the control of microfluidic valves and bellows (pumps) within the cartridge. After each sample has been mixed with reagent, it is delivered to a test cell where it is monitored for visco-elastic changes due to coagulation. Excess sample material is moved under microfluidic control into an enclosed waste chamber within the cartridge.

The CORA Measurement Technique

The CORA technology is based on a disposable containing up to four independent measurement cells. Each cell consists of a short vertically-oriented injection molded tube (ring) with a diameter of 2.5mm and a length of 4.5mm. Detection of clotting in the CORA System is performed optically. Under control of the analyzer, approximately 20µl of prepared sample is delivered to the tube, where a meniscus naturally forms at each end of the tube. The tube is positioned so that the lower meniscus partially blocks light traveling from a collimated source toward a photodiode.

During testing, a piezoelectric actuator drives the measurement cell(s) through a motion profile composed of summed sinusoids at different frequencies. The profile has a maximum amplitude of under 10µm and contains frequencies from 10-500Hz. Some, but not all, of the measurement cell motion will induce motion in the sample meniscus, which will be detected by the photodiode. The resulting motion of the meniscus is monitored optically and recorded by the analyzer to calculate the resonant frequency and modulus of elasticity (stiffness) of the sample. By performing a Fast Fourier Transform (FFT) on meniscus motion data, it is possible to determine the frequencies of input motion that caused the greatest deflection of the sample (these are called the resonant frequencies).

Resonance is the tendency of a material or structure to oscillate with greater amplitude at some frequencies than others. The exact frequencies at which resonance occurs will depend on the stiffness and mass of the sample. Stiffness, in turn, is a function of a material's modulus of elasticity and the boundary conditions to which the material is exposed, such as the geometry and materials of a test cell. By holding these boundary conditions and sample mass constant from run to run, the CORA System allows direct comparison of elasticity between samples.

In a typical test, blood that has been delivered to the measurement cell will not clot for several minutes. During this time the sample has no inherent stiffness except that provided by surface tension, and since this remains constant the measured resonant frequencies will not change. Once clotting begins, however, the elastic modulus and thus the resonant frequencies increase rapidly. During fibrinolysis, the process is reversed, with elastic modulus and resonant frequencies decreasing. In tests where clotting does not occur, the resonant frequency of the sample will not change. During coagulation, however, a clot will bind to the test tube (ring) and the resonant frequency will rise with increasing firmness of the clot. The

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CORA Analyzer collects meniscus motion data, tracks changing resonant frequencies and analyzes the frequency data to provide semi-quantitative parameters describing the clot. Results are presented in a format similar to the TEG 5000.

Both the TEG 5000 and CORA System monitor the elastic modulus of clots. Method Comparison testing has been performed, yielding data from approximately 300 patients from three sites (Mayo Clinic, University of Pittsburgh Medical Center, and Sinai Hospital, Baltimore). These data include all applicable parameters from the four citrated tests (CK, CKH, CRT and CFF). The TEG 5000 measures the changes of the linkage forces of the clot between the cup and pin over time, while the CORA System measures the changes of the resonant frequency of the clot over time. Despite the difference in the way the two analyzers measure the changes in the modulus of elasticity of the clot over time, they measure the same physical phenomenon and produce the same result when converted from their specific units of measurement (forces for the TEG5000 and frequency for the CORA System) to millimeters. The fact that these results are similar across all reagents used in both technologies is demonstration that the two technologies measure the same phenomenon, the changes in elastic modulus.

The following definitions apply to calculated parameters in the CORA System:

CORA Parameter	Definition	Parameter Relation to Hemostasis
R	R is the time from the start of the test until initial fibrin formation. This represents the enzymatic portion of coagulation.	Normal / reduced / increased speed of coagulation initiation
K	K is the time after R needed to reach a certain level of clot strength. This represents clot kinetics.	Normal / reduced / increased speed of coagulation amplification and propagation
Alpha α (angle)	Alpha is the angle representing the rate increase in the clot strength and the rapidity of fibrin build-up and cross-linking.	Normal / reduced / increased speed of coagulation amplification and propagation
MA	MA, or Maximum Amplitude, represents the maximum firmness of the clot during the test.	Normal / reduced / increased clot elasticity/strength
FLEV	FLEV is an estimate of the fibrinogen level in the blood sample.	Estimated Functional Fibrinogen Level

Citrated Assays

The CK assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle), and Maximum Clot Strength (MA). K and Alpha are complementary parameters and should be used in conjunction with Clotting Time (R) and Maximum Clot Strength (MA).

The CRT assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via both the intrinsic and extrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CFF assay is a semi-quantitative *in vitro* diagnostic assay for monitoring hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. CFF is used in conjunction with CK and clotting characteristics are described by the functional parameter Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

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The CKH assay is a semi-quantitative *in vitro* diagnostic assay used in conjunction with the CORA System to monitor the effects of heparin in the blood stream of a patient. CKH is used in conjunction with CK and heparin influence is determined by comparing Clotting Times (R) between the two tests.

Wet Quality Control (WQC)

Abnormal Wet Quality Control (WQC) material consists of bovine plasma with buffers and stabilizers, and is used instead of hypocoagulable blood, in conjunction with the Citrated Multichannel system cartridge. When used with the Citrated Multichannel cartridge, this material provides consistent and repeatable values for CORA parameters to confirm reagent quality and viability.

Abnormal WQC Intended Use

The Abnormal WQC (Wet Quality Control) Material is intended to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

INTENDED USE AND INDICATIONS FOR USE

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The CORA System records the kinetic changes in a sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARING THE CORA SYSTEM TO THE TEG 5000 PREDICATE DEVICE

Table of Similarities

Item	TEG® 5000 Predicate	CORA® System
Analyzer		
Technological Purpose	Monitoring the response of a clot to low levels of applied strain	Monitoring the response of a clot to low levels of applied strain
What is measured	Changes in clot elasticity over time	Changes in clot elasticity over time
Initial Warm Up Time	5 min	5 min
Time to Complete a Test	Varies with assay	Same as TEG 5000
Assays and Reagents		
Intrinsic Contact Activation Reagent (CK)	Kaolin and $CaCl_2$	Kaolin and $CaCl_2$, same materials as TEG 5000

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Item	TEG® 5000 Predicate	CORA® System
Intrinsic Contact Activation Reagent with Heparinase for heparin reversal (CKH)	Kaolin and $CaCl_2$ with Heparinase	Kaolin, Heparinase and $CaCl_2$, same materials as TEG 5000
Citrated RapidTEG (CRT) (Tissue Factor and Kaolin Activation)	Tissue Factor (TF), Kaolin and $CaCl_2$	Tissue Factor (TF), Kaolin and $CaCl_2$, same materials as TEG5000
Citrated Functional Fibrinogen (CFF) / Platelet-Blocked (Tissue Factor Activation)	ReoPro®, Tissue Factor and $CaCl_2$, same materials as CORA	ReoPro®, Tissue Factor and $CaCl_2$, same materials as TEG 5000
Calcium Chloride Reagent (CC) (for re-calcification)	$CaCl_2$ reagent	$CaCl_2$ same materials as TEG 5000
Quality Control Material (WQC Abnormal Control)	TEG coagulation control – Level II	TEG coagulation control – Abnormal, same materials as TEG 5000

Table of Differences

Item	TEG® 5000 Predicate	CORA® System
Analyzer	Thrombelastography analyzer, separate computer and software	Fully integrated Thrombelastography analyzer
Measuring Technique	Direct-contact measurement of shear elasticity of a coagulating sample	Non-contact measurement of shear elasticity of a coagulating sample
Measuring Channels	Two, each independent and interchangeable (can be used with any approved reagent)	Four, each independent and interchangeable (can be used with any approved reagent)
Signal Transducer	Electromechanical detection (rotary variable inductive transformer) of rotary motion of a pin suspended in the sample	Optical detection (silicon photodiode) of the motion of a free surface of the sample
Temperature Control	20° to 40°C	20° to 50°C
Sample Volume (per channel)	360-380 µl	63 µl
Total Reaction Volume (single channel)	360-380 µl	20 µl
Mains Supply Voltage	120V, 60Hz and 220V, 50Hz model available	100-240V, 50-60Hz (international power supply)
Analyzer Input Voltage	24 volts AC, 30 watts max	12 volts DC, 60 watts max
Environment	Level and vibration free position, no solar radiation Operating temperature: 10° to 35 °C Storage Temperature: -30° to +50 °C (analyzer only) Relative humidity 20-80% (non-condensing)	Stable and level surface. Operating Temperature 10° to 32°C Storage Temperature: -20° to 50°C (analyzer only) Relative humidity 20 to 80% (non-condensing)

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Item	TEG® 5000 Predicate	CORA® System
Sample Preparation	Performed by the operator using pipettes to reconstitute reagents and mix reagents with the sample	Performed under analyzer control within the disposable cartridge
Pipetting	Manual accurate pipettes (10, 20, 50, 100, 340, 360, 500, 1000µl)	Unmetered transfer pipette or syringe; blood sample is added until it fills to a level above the line marked on the blood intake well of the cartridge
Consumables	Cups & Pins (acrylic plastic)	Carrier (acrylic plastic) with microfluidics laminate and test rings (acrylic plastic)

SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Analytical Precision

Testing was performed in Coramed's laboratory for precision, using CLSI EP5-A2 as guidance. Acceptance criteria for all reagents are: CV ≤ 15% for the R parameter, CV ≤ 25% for the K parameter, and CV ≤ 10% for the Alpha and MA parameters. Three types of donor citrated whole blood (CWB) were used in this precision testing:

- Hypo (donors with natural coagulation levels of R parameter near the upper limit of the reference range and MA parameter near the lower limit of the reference range);
- Normal (donors with natural coagulation levels of R and MA parameters near the center of the reference ranges):
- Hyper (donors with natural coagulation levels of R parameter near the lower limit of the reference range and MA parameter near the upper limit of the reference range

Testing was performed with blood draws from three donors (one Hypo, one Normal, and one Hyper) on each of five days (non-consecutive). Testing was performed by two operators using three reagent lots and twelve analyzers, two replicates. The structure of this precision test is shown below.

Sample Type (Hypo, Normal or Hyper)												
	Day 1 (Total of 5 days)											
Operator	Operator 1						Operator 2					
Reagent lot	1		2		3		1		2		3	
Analyzer	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2

Structure of Precision Testing

Precision test estimates by test, parameter and donor sample test level are shown in the table on the following page. All acceptance criteria were met.

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Test	Parameter	Level	n	Mean	Reagent Lot		Operator*		Analyzer (within Operator, Reagent Lot)		Day (within Analyzer, Operator, Reagent Lot)		Repeatability		Total		Total without Day (Within Day)	
					SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
CFF	FLEV	Hypo	120	269.8	2.36	0.9%	0	0.0%	0	0.0%	5.32	2.0%	5.87	2.2%	8.27	3.1%	6.33	2.3%
CFF	FLEV	Normal	120	376.8	0	0.0%	2.25	0.6%	0	0.0%	5.49	1.5%	3.98	1.1%	7.15	1.9%	4.57	1.2%
CFF	FLEV	Hyper	120	597.4	0	0.0%	0	0.0%	0	0.0%	49.38	8.3%	9.62	1.6%	50.31	8.4%	9.62	1.6%
CFF	MA	Hypo	120	14.8	0.11	0.8%	0	0.0%	0	0.0%	0.29	2.0%	0.33	2.2%	0.45	3.0%	0.35	2.3%
CFF	MA	Normal	120	20.6	0	0.0%	0.13	0.6%	0	0.0%	0.3	1.5%	0.22	1.1%	0.39	1.9%	0.25	1.2%
CFF	MA	Hyper	120	32.7	0	0.0%	0	0.0%	0	0.0%	2.71	8.3%	0.53	1.6%	2.76	8.4%	0.53	1.6%
CKH	R	Hypo	120	8.2	0	0.0%	0	0.0%	0.18	2.2%	0.36	4.3%	0.76	9.2%	0.86	10.0%	0.78	9.5%
CKH	R	Normal	120	6.0	0	0.0%	0.05	0.9%	0.09	1.6%	0.14	2.3%	0.42	7.1%	0.46	7.7%	0.44	7.3%
CKH	R	Hyper	120	4.9	0	0.0%	0.05	1.1%	0	0.0%	0.28	5.7%	0.5	10.0%	0.58	12.0%	0.5	10.0%
CK	Angle	Hypo	120	68.7	0	0.0%	1.09	1.6%	0	0.0%	1.61	2.3%	3.01	4.4%	3.59	5.2%	3.2	4.7%
CK	Angle	Normal	120	72.1	0	0.0%	0	0.0%	0	0.0%	1.14	1.6%	1.73	2.4%	2.07	2.9%	1.73	2.4%
CK	Angle	Hyper	120	76.7	0	0.0%	0	0.0%	0	0.0%	1.84	2.4%	1.77	2.3%	2.56	3.3%	1.77	2.3%
CK	K	Hypo	120	1.8	0.03	1.9%	0.06	3.6%	0	0.0%	0.13	7.2%	0.18	10.0%	0.23	13.0%	0.19	11.0%
CK	K	Normal	120	1.4	0	0.0%	0	0.0%	0	0.0%	0.09	6.7%	0.16	12.0%	0.19	13.0%	0.16	12.0%
CK	K	Hyper	120	0.9	0	0.0%	0	0.0%	0	0.0%	0.12	12.0%	0.18	20.0%	0.22	23.0%	0.18	20.0%
CK	MA	Hypo	120	52.4	0.33	0.6%	0.55	1.0%	0.26	0.5%	0.83	1.6%	0.77	1.5%	1.33	2.5%	1.03	2.0%
CK	MA	Normal	120	59.4	0	0.0%	0.5	0.8%	0.48	0.8%	0.57	1.0%	0.86	1.4%	1.24	2.1%	1.1	1.9%
CK	MA	Hyper	120	68.0	0	0.0%	0.2	0.3%	0	0.0%	0.9	1.3%	0.52	0.8%	1.06	1.6%	0.56	0.8%
CK	R	Hypo	120	8.9	0	0.0%	0.29	3.3%	0	0.0%	0.64	7.1%	0.85	9.5%	1.1	12.0%	0.9	10.0%
CK	R	Normal	120	6.5	0	0.0%	0	0.0%	0	0.0%	0.28	4.3%	0.49	7.6%	0.56	8.7%	0.49	7.6%
CK	R	Hyper	120	5.2	0.13	2.5%	0	0.0%	0	0.0%	0.31	5.8%	0.66	13.0%	0.74	14.0%	0.67	13.0%
CRT	MA	Hypo	120	52.4	0.39	0.7%	0.22	0.4%	0	0.0%	0.92	1.8%	0.59	1.1%	1.18	2.3%	0.74	1.4%
CRT	MA	Normal	120	62.7	0	0.0%	0.15	0.2%	0.14	0.2%	0.37	0.6%	0.31	0.5%	0.52	0.8%	0.37	0.6%
CRT	MA	Hyper	120	69.4	0	0.0%	0	0.0%	0	0.0%	0.91	1.3%	0.2	0.3%	0.93	1.3%	0.2	0.3%

*Operator = Operator + operator-by-reagent lot interaction

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In addition, Coramed's Citrated Reagent Precision Protocol Rev. 02 was written to supplement precision data originally provided to FDA in 510(k) K150041. This protocol specifies testing to be performed outside of reference range values but within the Analytical Measurement Range (AMR) limits. This report presents data and statistics resulting from the execution of this protocol.

The following pages contain tables of precision statistics. Table 1 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from normal donors but spiked to achieve hypocoagulable (hypo) and hypercoagulable (hyper) results. Three donors for each reagent-parameter and spiking type were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each donor-reagent-parameter-hypo/hyper type, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B
Sample	Hypercoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

The focus of this study was on achieving values for the primary coagulation parameters R, MA and FLEV outside the reference ranges but within AMR limits, and taking the resulting K and Alpha (angle) values as is. Total Precision %CV values were all within pre-established limits, except for one CFF MA hypo outcome (11.6% for a limit of 10%) and 2 outcomes for Angle. The K and Angle parameters indicate the kinetics of the clotting process, and are not clinically significant as the main parameters representing coagulation, platelet and fibrinogen activities and abnormalities. The CFF MA CV% is higher because the MA value is small (mean of 6.5 mm) and although the Standard Deviation is very small (0.8mm) the resulting CV% is just over the limit. When the SD is so small there is no clinical significance for the differences making this CV% acceptable.

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Table 2 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from patients taking anticoagulants Dabigatran and Warfarin. Four Dabigatran patients and two Warfarin patients for each reagent-parameter were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each patient-reagent-parameter, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1		2		3		4		5		6	
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

Results for this testing were generally within limits, except for a few minor exceptions. As the data shows, all the MAs, for CK, CRT, and CFF, are within the specified expected CV% across the board while for the R parameter, there are no significant differences between lots, operators and devices and the only CVs (for CK and CKH – R parameter) somewhat exceeding 15% come from repeatability (16.9% for MH-DB003 for CK and 15.9% for MH-DB004 for CKH). Even though the, K and Angle are not parameters that are considered clinically significant the raw data indicates that the single angle CV% that is above the limit was due to an outlier while the K parameter has high CVs due to the fact that elongated coagulation results in higher CVs for that parameter.

Test	Param	Spiking	Patient ID	N	Mean	Lot		Operator		Instrument		Repetition		Total	
						StDev	CV	StDev	CV	StDev	CV	StDev	CV	StDev	CV

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CK	R	hyper	D101	12	2.1	0	0	0	0	0.1	4.5	0.1	3.1	0.1	5.5
CK	R	hyper	D108	12	2.7	0	0	0	1	0.1	3.5	0.1	2.4	0.1	4.3
CK	R	hyper	D169	12	2.2	0.1	2.8	0	0	0.1	3.1	0.1	2.5	0.1	4.6
CK	R	hypo	D141	12	16.1	0	0	1.1	6.9	1.3	8	0.7	4.3	1.7	10.8
CK	R	hypo	D169	12	15.3	0.8	5.3	0	0	1.6	10.2	1.1	7.1	2	13.2
CK	R	hypo	D108	12	12.1	0.1	1	0.1	0.9	0.9	7.2	0.7	5.6	1.1	9.3
CK	K	hyper	D101	12	0.5	0	0	0	0	0	3.9	0	4.1	0	5.7
CK	K	hyper	D108	12	0.4	0	3.8	0	3.8	0	7.2	0	6.5	0	10.7
CK	K	hyper	D169	12	0.5	0	0	0	0	0	8.2	0	8.2	0.1	11.6
CK	K	hypo	D141	12	3	0.2	5.2	0.2	6	0.3	9.9	0.2	8.2	0.4	14.6
CK	K	hypo	D169	12	3.1	0.5	16.4	0	0	0.5	14.8	0.3	10	0.7	22.7
CK	K	hypo	D108	12	2.2	0	0	0.1	6.4	0.3	12	0.1	6.2	0.3	14.6
CK	Angle	hyper	D101	12	80	0.8	1.1	1.5	1.8	7.2	9	6.9	8.7	10.1	12.6
CK	Angle	hyper	D108	12	85.1	0.1	0.2	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hyper	D169	12	84.3	0.1	0.1	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hypo	D141	12	54.7	0	0	0	0	8.4	15.4	5.4	9.9	10	18.3
CK	Angle	hypo	D169	12	42.7	1	2.4	1.9	4.5	1.8	4.3	1.6	3.7	3.1	7.2
CK	Angle	hypo	D108	12	66.7	3	4.4	0	0	4.8	7.2	3.3	5	6.3	9.5
CK	MA	hyper	D108	12	71.6	0	0	0.5	0.7	0.3	0.4	0.3	0.4	0.5	0.8
CK	MA	hyper	D169	12	70	0	0	0.1	0.1	0.2	0.2	0.1	0.2	0.2	0.3
CK	MA	hyper	D121	12	71.1	0	0	0	0	0.9	1.3	0.6	0.8	1.1	1.5
CK	MA	hypo	D141	12	42	0.2	0.6	0	0	1.5	3.5	0.9	2.1	1.7	4.1
CK	MA	hypo	D169	12	46.6	0	0	0	0	0.8	1.8	0.5	1.1	1	2.1
CK	MA	hypo	D108	12	45.4	0	0	0.8	1.8	1.2	2.7	0.9	2	1.7	3.7
CKH	R	hyper	D101	12	2	0.1	4.8	0	0	0	2.4	0.1	2.8	0.1	5.5
CKH	R	hyper	D108	12	2.6	0	0	0	0	0.1	2.6	0	1.6	0.1	3.1
CKH	R	hyper	D169	12	2.2	0	0	0	0	0	1.5	0	1	0	1.8
CKH	R	hypo	D141	12	15.7	0	0	1	6.4	0.7	4.5	0.6	4.1	1.3	8.2
CKH	R	hypo	D169	12	14.5	0	0	0.8	5.2	0.8	5.7	0.5	3.2	1.1	7.9
CKH	R	hypo	D108	12	12.3	0.6	5	0	0	0.8	6.3	0.5	4.4	1.1	8.8
CRT	MA	hyper	D108	12	70.8	0.2	0.3	0	0	0.1	0.2	0.1	0.2	0.2	0.3
CRT	MA	hyper	D121	12	72.5	0.2	0.3	0	0	0.4	0.5	0.4	0.5	0.5	0.8
CRT	MA	hyper	D145	12	73	0.2	0.2	0	0	0.2	0.3	0.2	0.2	0.3	0.4
CRT	MA	hypo	D141	12	41.3	0	0	0	0	0.7	1.8	0.5	1.2	0.9	2.2
CRT	MA	hypo	D169	12	44.4	0	0	0.3	0.7	0.6	1.3	0.4	0.9	0.8	1.7
CRT	MA	hypo	D108	12	45.5	0	0	0.4	0.9	1	2.1	0.5	1.1	1.1	2.5
CFF	MA	hyper	D101	12	49.9	0.1	0.1	0	0	0.5	0.9	0.3	0.5	0.5	1.1
CFF	MA	hyper	D141	12	44.3	0	0	0	0	0.5	1.2	0.3	0.6	0.6	1.3
CFF	MA	hyper	D145	12	47	0	0	0	0	0.7	1.4	0.5	1	0.8	1.7
CFF	MA	hypo	D101	12	10.2	0.2	1.5	0	0	0.3	3	0.2	1.7	0.4	3.6
CFF	MA	hypo	D125	12	9.5	0	0	0.2	1.8	0.4	4	0.3	2.7	0.5	5
CFF	MA	hypo	D169	12	6.5	0	0	0.7	10.1	0.3	4.9	0.4	6	0.8	11.6
CFF	FLEV	hyper	D101	12	910.7	1.2	0.1	0	0	8.6	0.9	5	0.5	10	1.1
CFF	FLEV	hyper	D141	12	809	0	0	0	0	9.6	1.2	5.2	0.6	10.9	1.3
CFF	FLEV	hyper	D145	12	858.1	0	0	0	0	11.9	1.4	8.5	1	14.7	1.7
CFF	FLEV	hypo	D101	12	186.4	2.9	1.5	0	0	5.5	3	3.1	1.7	6.8	3.6
CFF	FLEV	hypo	D125	12	173.4	0	0	3.1	1.8	7	4	4.6	2.6	8.7	5
CFF	FLEV	hypo	D169	12	157.5	1.8	1.2	1.1	0.7	2	1.3	1.7	1.1	3.2	2.1

Spiked Precision – Table 1

Test	Param	PatientID	N	Mean	Lot		Operator		Instrument		Repetition		Total	
					StDev	CV	StDev	CV	StDev	CV	StDev	CV	StDev	CV
CK	R	MH-DB001	12	13	0	0	0	0	0.4	3.2	1.2	8.9	1.2	9.4
CK	R	MH-DB002	12	21.3	0	0	0	0	1	4.7	2.1	10.1	2.3	11

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CK	R	MH-DB003	12	14.4	0	0	0	0	0	0	2.4	16.9	2.4	16.9
CK	R	MH-DB004	12	11.8	0.5	4	0.5	4.3	0	0	1.6	13.9	1.7	14.8
CK	R	MH-WR001	12	9.9	0.7	7	0.3	2.7	0.3	2.6	0.5	4.9	0.8	8.5
CK	R	MH-WR002	12	10.1	1	10.2	0	0	0.3	3.2	1	10	1.4	13.6
CK	K	MH-DB001	12	1.3	0	0	0	0	0	0	0.2	18.2	0.2	18.2
CK	K	MH-DB002	12	2.4	0	0	0	0	0.4	15.4	1	42	1	44.5
CK	K	MH-DB003	12	1.3	0	0	0	0	0	0	0.3	19.8	0.3	19.8
CK	K	MH-DB004	12	0.9	0.1	11.4	0	0	0	0	0.3	33	0.3	34.4
CK	K	MH-WR001	12	2.2	0	0	0	0	0	0	0.2	8.2	0.2	8.2
CK	K	MH-WR002	12	2	0	0	0	0	0	0	0.4	19.1	0.4	19.1
CK	Angle	MH-DB001	12	72.5	0	0	0	0	0	0	3.6	5	3.6	5
CK	Angle	MH-DB002	12	55.5	0	0	0	0	10.3	18.6	11.6	20.8	15.2	27.4
CK	Angle	MH-DB003	12	72.7	0	0	0	0	0	0	3.2	4.3	3.2	4.3
CK	Angle	MH-DB004	12	79.5	0	0	0	0	0	0	3.4	4.3	3.4	4.3
CK	Angle	MH-WR001	12	65	0	0	0	0	0	0	1.1	1.7	1.1	1.7
CK	Angle	MH-WR002	12	67.1	0	0	1.1	1.6	0	0	3	4.4	3.1	4.6
CK	MA	MH-DB001	12	60.2	0	0	0	0	0	0	0.9	1.5	0.9	1.5
CK	MA	MH-DB002	12	64.5	0	0	0.2	0.4	0	0	0.6	1	0.7	1
CK	MA	MH-DB003	12	64.1	0	0	0.4	0.7	0	0	0.5	0.8	0.7	1
CK	MA	MH-DB004	12	71.9	0.1	0.1	0.5	0.6	0	0	0.5	0.7	0.7	0.9
CK	MA	MH-WR001	12	60.6	0	0	0	0	0	0	0.9	1.4	0.9	1.4
CK	MA	MH-WR002	12	59.7	0	0	0	0	1	1.6	0.8	1.3	1.2	2
CKH	R	MH-DB001	12	12.2	0.8	6.8	0	0	0	0	0.7	5.8	1	8.2
CKH	R	MH-DB002	12	19.3	0	0	1.6	8.4	0	0	2.2	11.4	2.6	13.5
CKH	R	MH-DB003	12	13.5	0	0	0.5	4	0	0	1.4	10.6	1.5	11.1
CKH	R	MH-DB004	12	11.3	0	0	0	0	0	0	1.8	15.9	1.8	15.9
CKH	R	MH-WR001	12	8.4	0	0	0.1	0.8	0	0	0.8	9.7	0.8	9.8
CKH	R	MH-WR002	12	9.1	0.5	5.1	0	0	0	0	0.7	7.4	0.8	8.6
CRT	MA	MH-DB001	12	64.9	0.1	0.1	0	0	0.1	0.1	0.1	0.2	0.1	0.2
CRT	MA	MH-DB002	12	67.7	0.1	0.1	0	0	0	0	0.2	0.2	0.2	0.2
CRT	MA	MH-DB003	12	66	0	0	0	0	0	0	0.1	0.2	0.1	0.2
CRT	MA	MH-DB004	12	73.8	0.1	0.1	0	0	0.1	0.1	0.2	0.2	0.2	0.3
CRT	MA	MH-WR001	12	64	0.1	0.1	0	0	0	0	0.2	0.3	0.2	0.3
CRT	MA	MH-WR002	12	64.7	0	0	0	0	0	0	0.3	0.4	0.3	0.4
CFF	MA	MH-DB001	12	20.7	0.1	0.4	0	0	0.3	1.3	0.1	0.6	0.3	1.4
CFF	MA	MH-DB002	12	23.7	0.3	1.3	0.3	1.4	0	0	0.2	0.7	0.4	1.6
CFF	MA	MH-DB003	12	23.4	0.2	1	0	0	0	0	0.3	1.5	0.4	1.7
CFF	MA	MH-DB004	12	51.9	1.1	2.2	0	0	0	0	0.4	0.8	1.1	2
CFF	MA	MH-WR001	12	20.7	0	0	0	0	0	0	0.4	1.7	0.4	1.7
CFF	MA	MH-WR002	12	24.7	0.1	0.4	0.3	1.2	0	0	0.3	1.3	0.4	1.7
CFF	FLEV	MH-DB001	12	377.3	1.4	0.4	0	0	4.8	1.3	2.4	0.6	5.3	1.4
CFF	FLEV	MH-DB002	12	432.2	5.8	1.3	6.2	1.4	0	0	3	0.7	6.8	1.6
CFF	FLEV	MH-DB003	12	426.5	4.5	1	0	0	0	0	6.2	1.5	7.3	1.7
CFF	FLEV	MH-DB004	12	947.1	20.9	2.2	0	0	0	0	7.5	0.8	19.3	2
CFF	FLEV	MH-WR001	12	377.4	0	0	0	0	0	0	6.5	1.7	6.5	1.7
CFF	FLEV	MH-WR002	12	450	1.6	0.4	5.2	1.2	0	0	6	1.3	7.7	1.7

Patient-Derived Hypo Samples (Dabigatran and Warfarin) – Table 2

Interference

Testing was performed in Coramed's laboratory for interference, using CLSI EP7-A2 as guidance.

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For CK, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Only Hemolysis and Hemodilution were found to be interferents.

For CRT, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Short Draw, Hemolysis and Hemodilution were found to be interferents.

For CKH, Protamine was tested for interference. Protamine was found to be an interferent for CKH at concentrations above 0.062 mg/ml.

For CFF, potential interferents tested were Na Heparin and Hemodilution. Heparin was found to be an interferent for CFF above Heparin concentrations of 1 IU/ml, and Hemodilution was found to be an interferent above hemodilution levels of 30%.

Linearity

Testing was performed in Coramed's laboratory for linearity, using CLSI EP6-A as guidance.

CFF was tested and found to be linear with varying concentrations of Fibrinogen (RiaSTAP) added. These concentrations ranged from 0 mg/dl to 565.5 mg/dl, over an FLEV range of 156 mg/dl to 1145 mg/dl. This corresponds to an MA range of 8.5 mm to 62.7 mm.

Sensitivity and Specificity

CK was tested for Sensitivity and Specificity with respect to Na Heparin, comparing R parameters of five blood samples with different clinically relevant concentrations of Heparin to five samples without heparin. Both Sensitivity and Specificity were found to be 100%.

Heparin Neutralization

Heparin Neutralization of CKH was tested using blood samples spiked with Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) and comparing these results to data obtained from testing CK with un-spiked blood samples. CKH was found to completely neutralize UFH levels of 5 IU/ml blood and LMWH levels of 0.013 mg/ml blood.

SUMMARY OF CLINICAL PERFORMANCE DATA

Testing was performed at three clinical sites for Reference Ranges and Method Comparison.

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Reference Ranges

Reference Ranges for the CORA assays were estimated using the CLSI C28-A3c Guideline on three reference sample groups. Blood samples from up to 55 normal volunteer subjects were taken at each of the three sites, for a total of 157 samples. There were at least 151 valid results for every parameter for all reagents. Samples were excluded on a per-parameter basis using standard outlier criteria. An alternative method would have been to exclude all parameters for any tests where one or more parameter results were determined to be outliers. However, it was decided to retain all valid parameter results in calculating reference ranges because a larger number of samples adds statistical credibility. Also, it does not appear that using the alternative approach would have any significant effect on the reference ranges. Subjects were chosen representing demographic populations of the three areas, regarding age, race and gender. These reference ranges are shown below.

Reagent ↓	N	R (min)	N	K (min)	N	Angle (deg)	N	MA (mm)	N	FLEV (mg/dl)
CK	157	4.6-9.1	157	0.8-2.1	155	63 - 78	151	52 - 69		
CRT							152	52 - 70		
CKH	155	4.3-8.3								
CFF							151	15 - 32	152	278-581

Reference Ranges for CKH are shown but not usually required because the only purpose is to neutralize the heparin in a patient's blood, regardless of the patient's hemostasis condition. Comparing results from the CK and CKH tests for the R parameter can assist in determining whether or not there is heparin in the blood sample.

Reference Ranges for Wet Quality Control (WQC) Abnormal material when used in CORA assay cartridges were estimated. Using three lots of Abnormal Quality Control and three citrated reagent lots, a total of over 135 test results were obtained.

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (deg)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563-873

Method Comparison

Method Comparison studies were conducted at three clinical sites on patient samples following CLSI EP09-A3 Guideline. The subjects enrolled were patients undergoing cardiovascular surgery or cardiology procedures, with blood samples drawn pre- and post-surgery and in the ICU. In order to broaden the range of comparisons, up to 10% artificially derived samples were added. Statistics are presented below.

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Method Comparison Statistics Summary – All Clinical Sites					
Parameter	**R**	**Intercept**	**95% CI**	**Slope**	**95% CI**
CK – R (min)	0.868	-0.325	-0.425	1.069	1.034
			-0.225		1.103
CK – K (min)	0.740	-0.097	-0.292	0.906	0.769
			0.098		1.042
CK – Alpha (deg)	0.680	7.305	-13.160	0.940	0.640
			27.769		1.240
CK – MA (mm)	0.924	2.351	0.166	0.948	0.912
			4.536		0.983
CKH – R (min)	0.812	-0.329	-0.393	1.057	1.026
			-0.265		1.089
CRT|CK – MA (mm)	0.929	-0.126	-1.909	0.978	0.948
			1.656		1.007
CFF – MA (mm)	0.938	-0.774	-1.836	1.126	1.072
			0.289		1.180
CFF – FLEV (mg/dl)	0.928	-12.495	-36.810	1.127	1.059
			11.819		1.194

In addition, a Reader Study was conducted to assess the comparison of CORA System and TEG 5000 results based on reading printed test outcomes. The study was performed at three sites, using three experienced TEG 5000 doctors as readers at each site, for a total of nine readers. 30 test outcomes were compared for each of the reagent test categories, for a total of 270 reading comparisons per reader. Excellent agreement between the two devices was demonstrated.

In both the Method Comparison Study and Reader Study, the CORA RapidTEG (CRT) MA parameter was compared to the TEG 5000 Kaolin (CK) MA parameter, to demonstrate that the CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTING

The data and information provided in this submission support a substantial equivalence determination for the CORA System and the TEG 5000 predicate device.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*
Not known

Device Name
CORA Hemostasis System - Abnormal Quality Control Material

Indications for Use *(Describe)*
The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample.

The Abnormal QC Material is to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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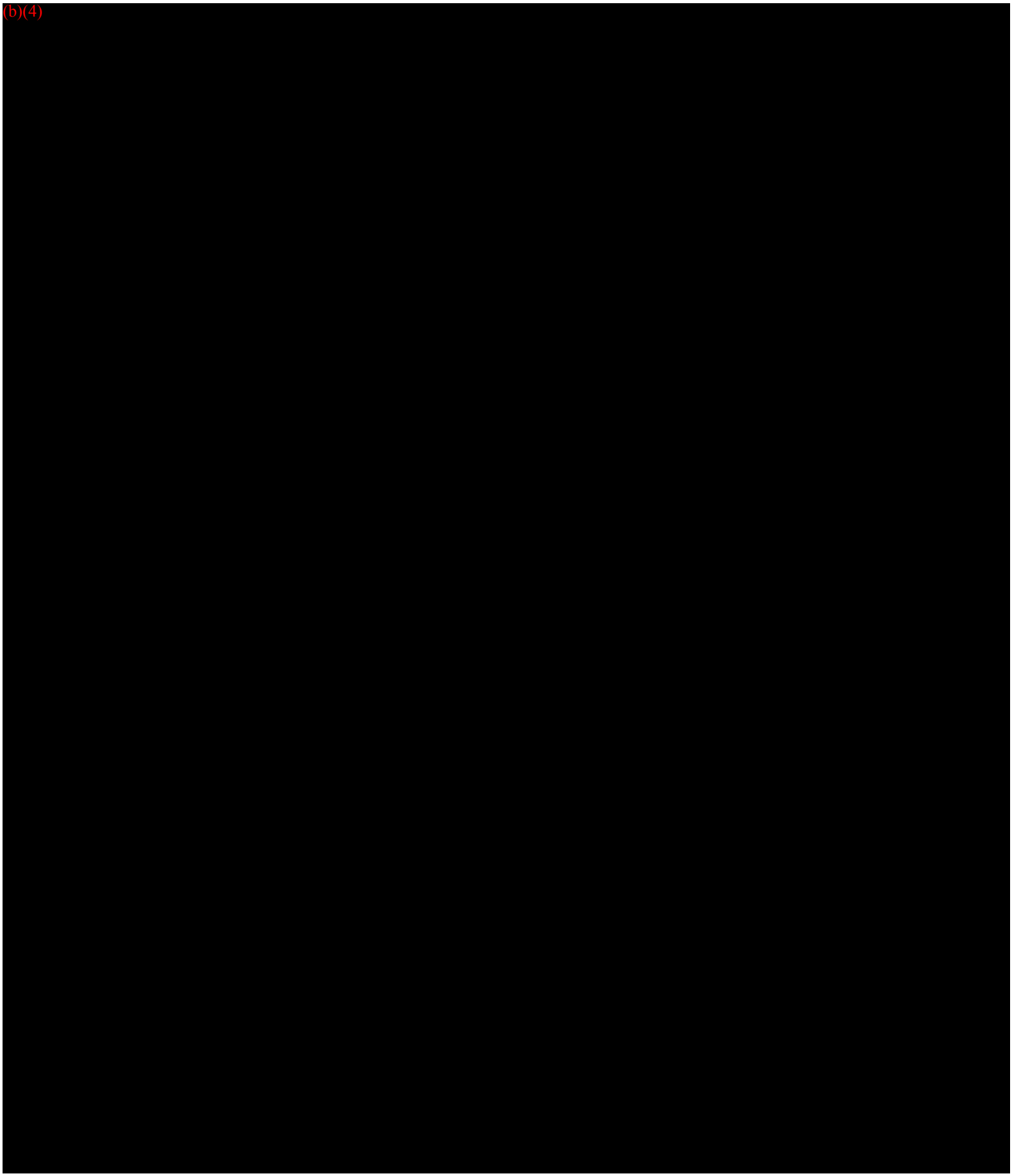
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1. **FDA Comments: Thank you for the clarification. We agree with your proposed study design for your contrived samples. Please note that we have corrected your table according to the study design you proposed, where duplicates per samples, replicates A and B, will be tested on unique instruments in parallel.**

Our proposal is to perform this for blood from three normal subjects; blood will not be pooled prior to spiking. Rather, the blood will be spiked separately, once to cause hypercoagulability and once to cause hypocoagulability.

The following is our response to FDA point number 2 in the document accompanying the 4/3/2015 email. The reason we proposed the below table to execute in our patient study is that this number of runs is equivalent to the numbers used in the November study as well as the proposal from point 1 above. In addition, what the FDA requested in their email from 4/3/2015, is not feasible because it requires that each instrument execute 6 consecutive tests with the same blood while the blood is only good for two consecutive runs.

Sample	Hypocoagulable – Sample A											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1		2		3		4		5		6	
Replicates	1	2	1	2	1	2	1	2	1	2	1	2

This will be repeated for each of five test subjects (Samples B through E).

2. **FDA Comments: With respect to your patient derived samples, we agree with your proposed study design, however we request that you include a patient on Warfarin therapy in your study design.**

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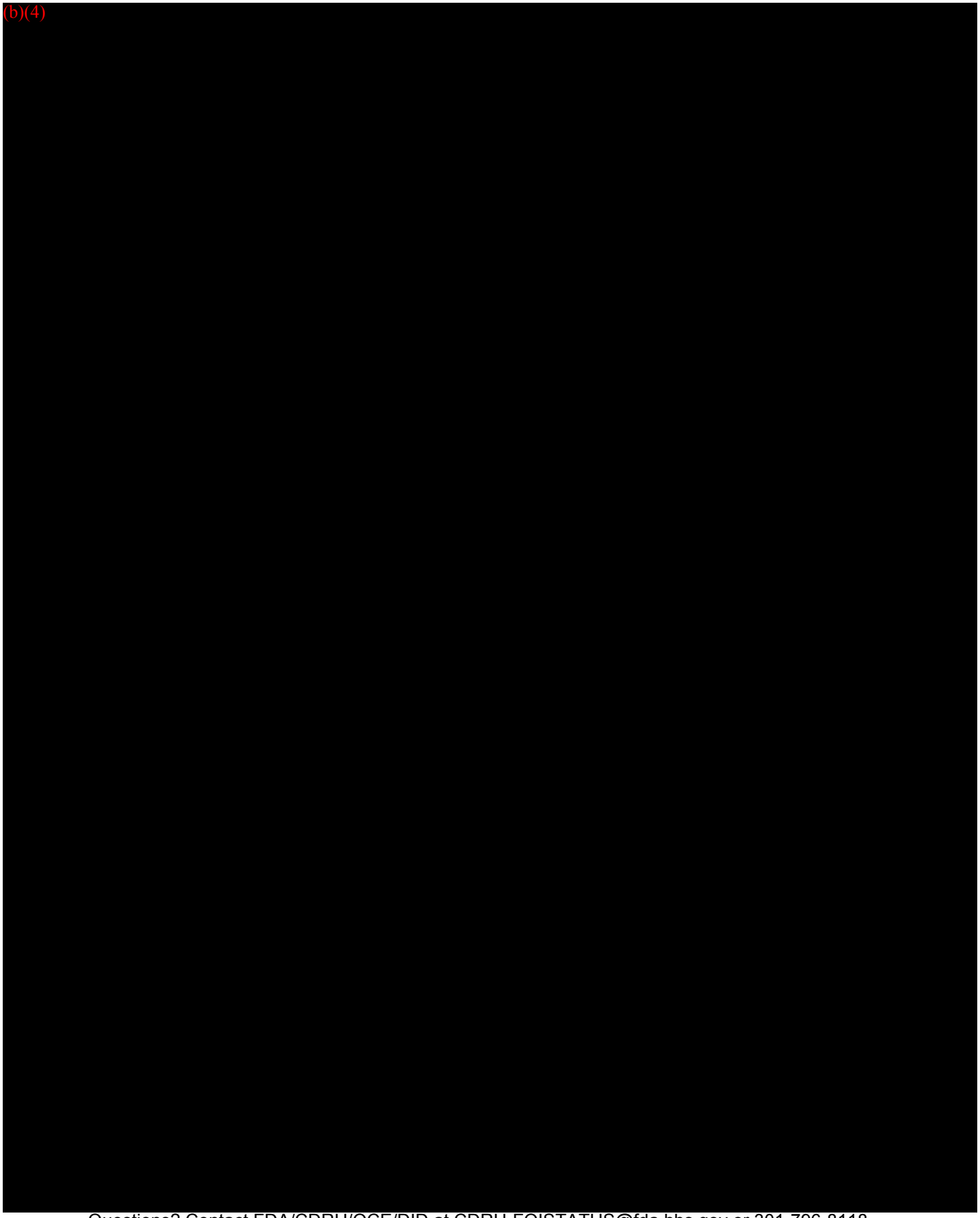
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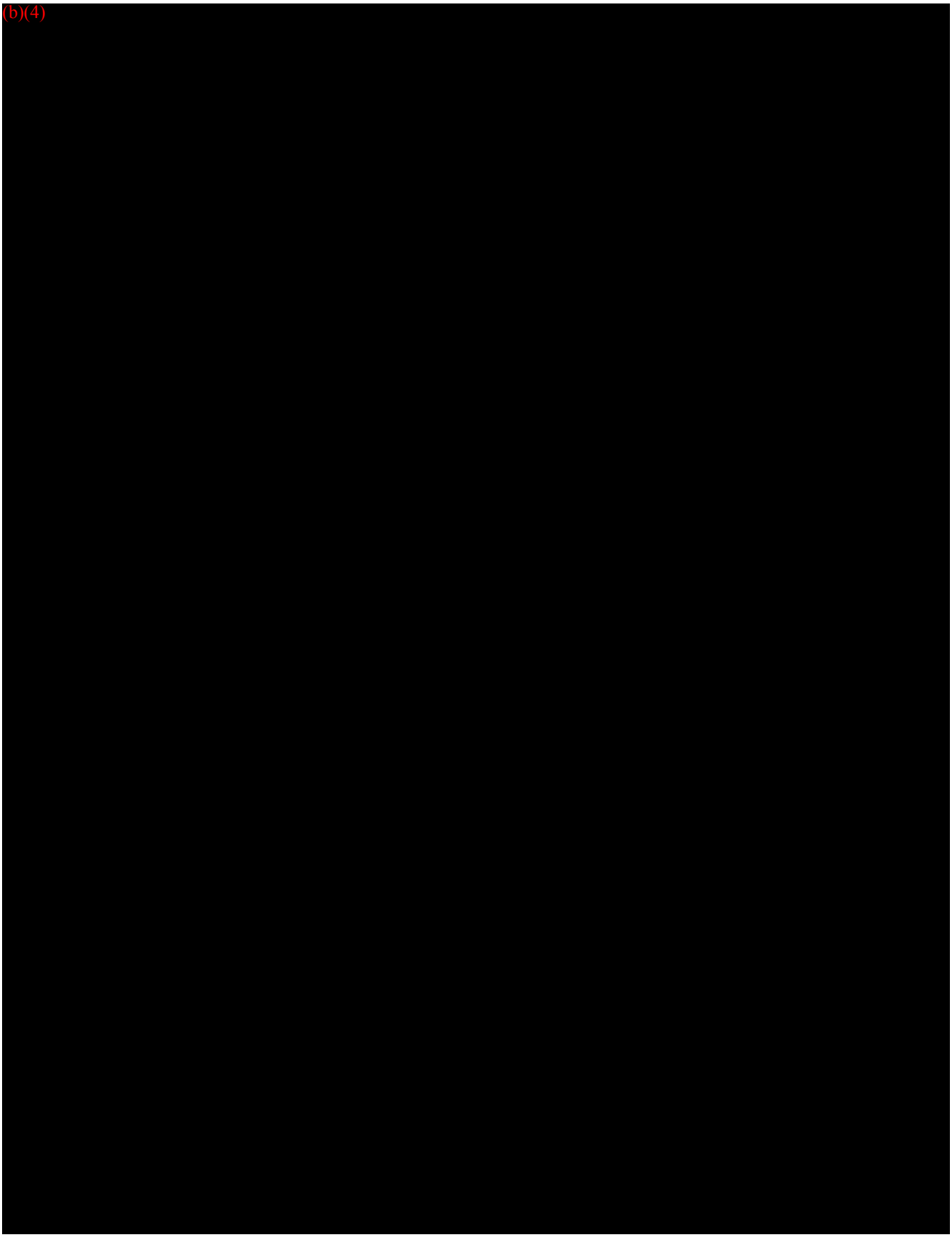
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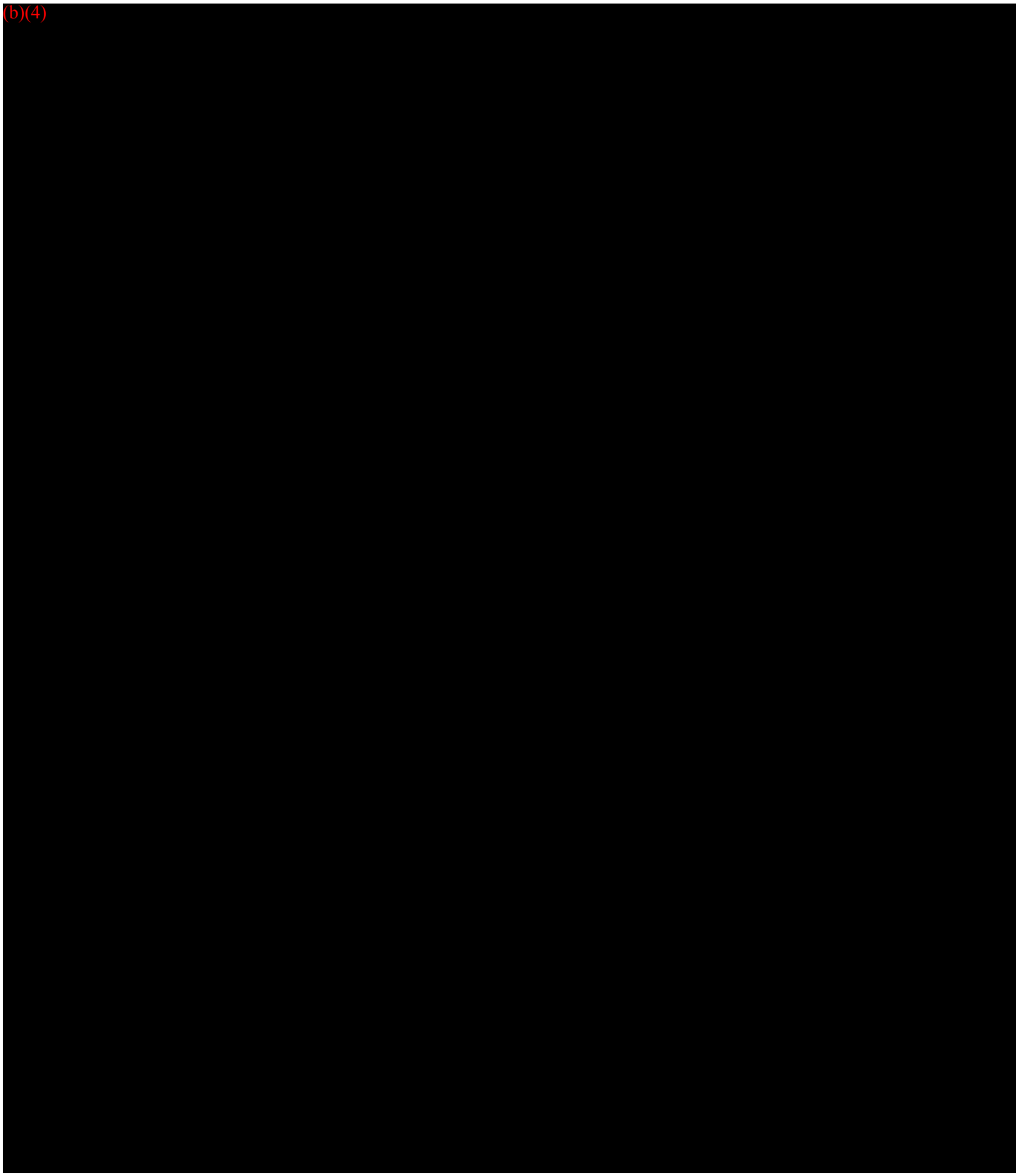
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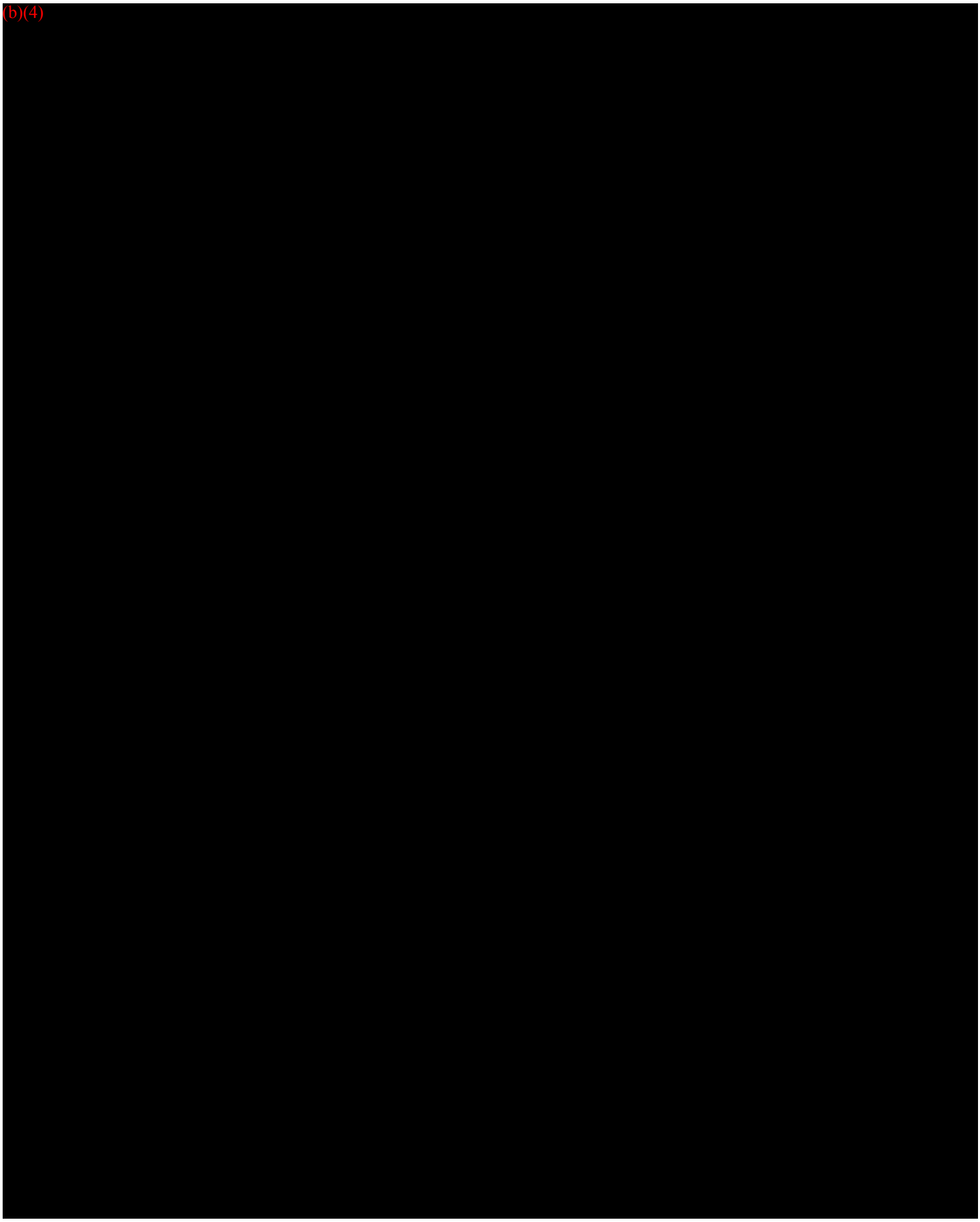
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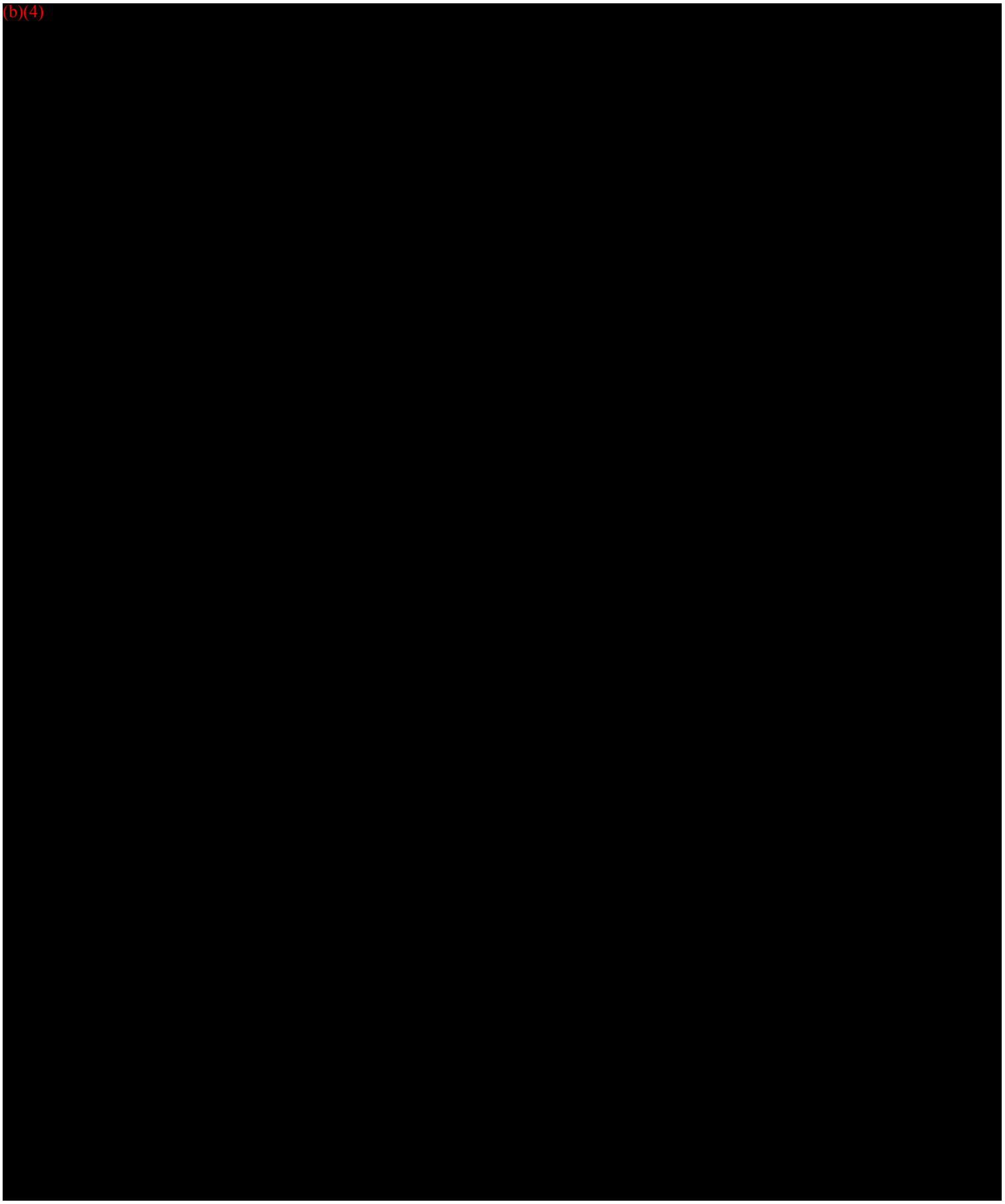
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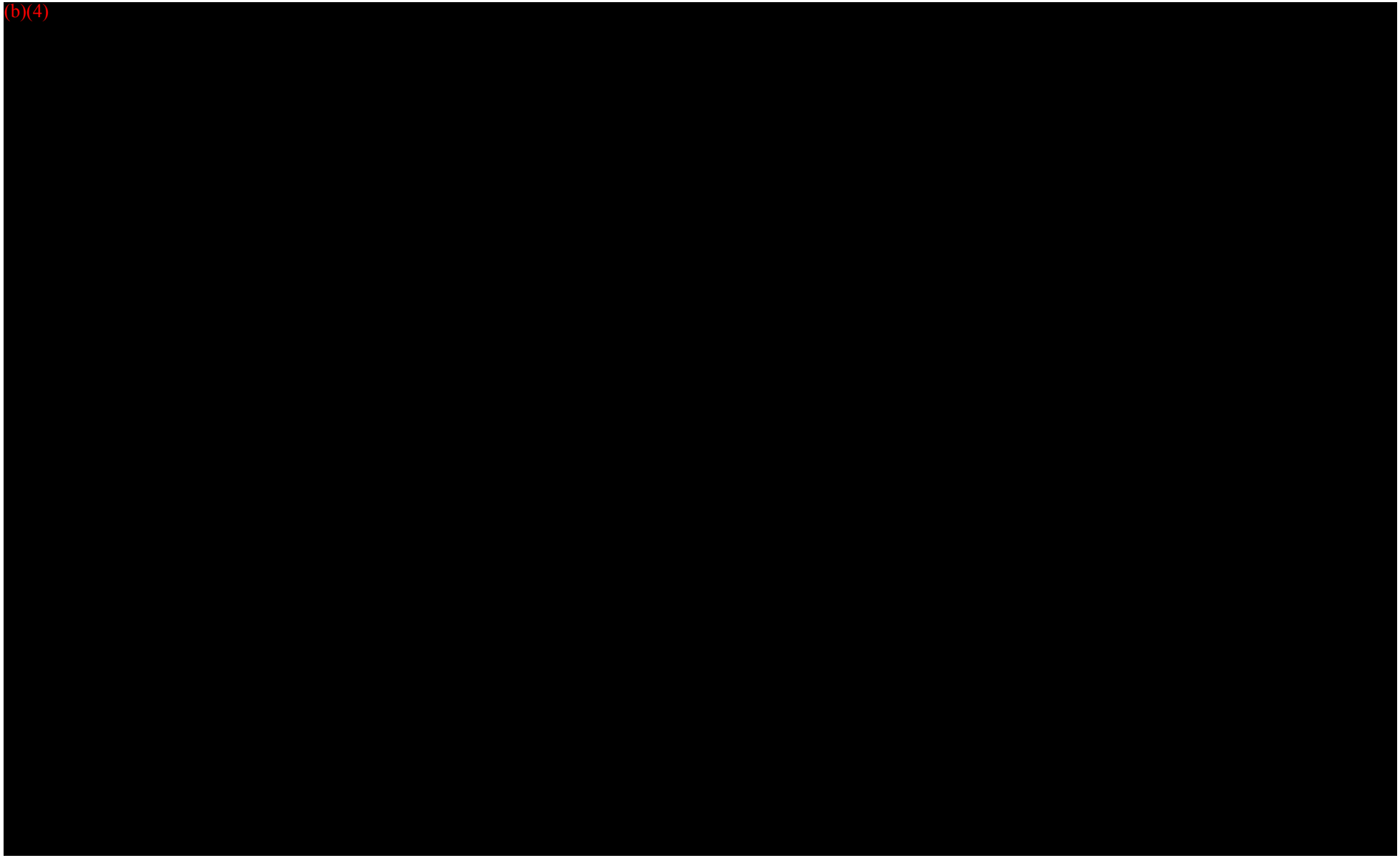
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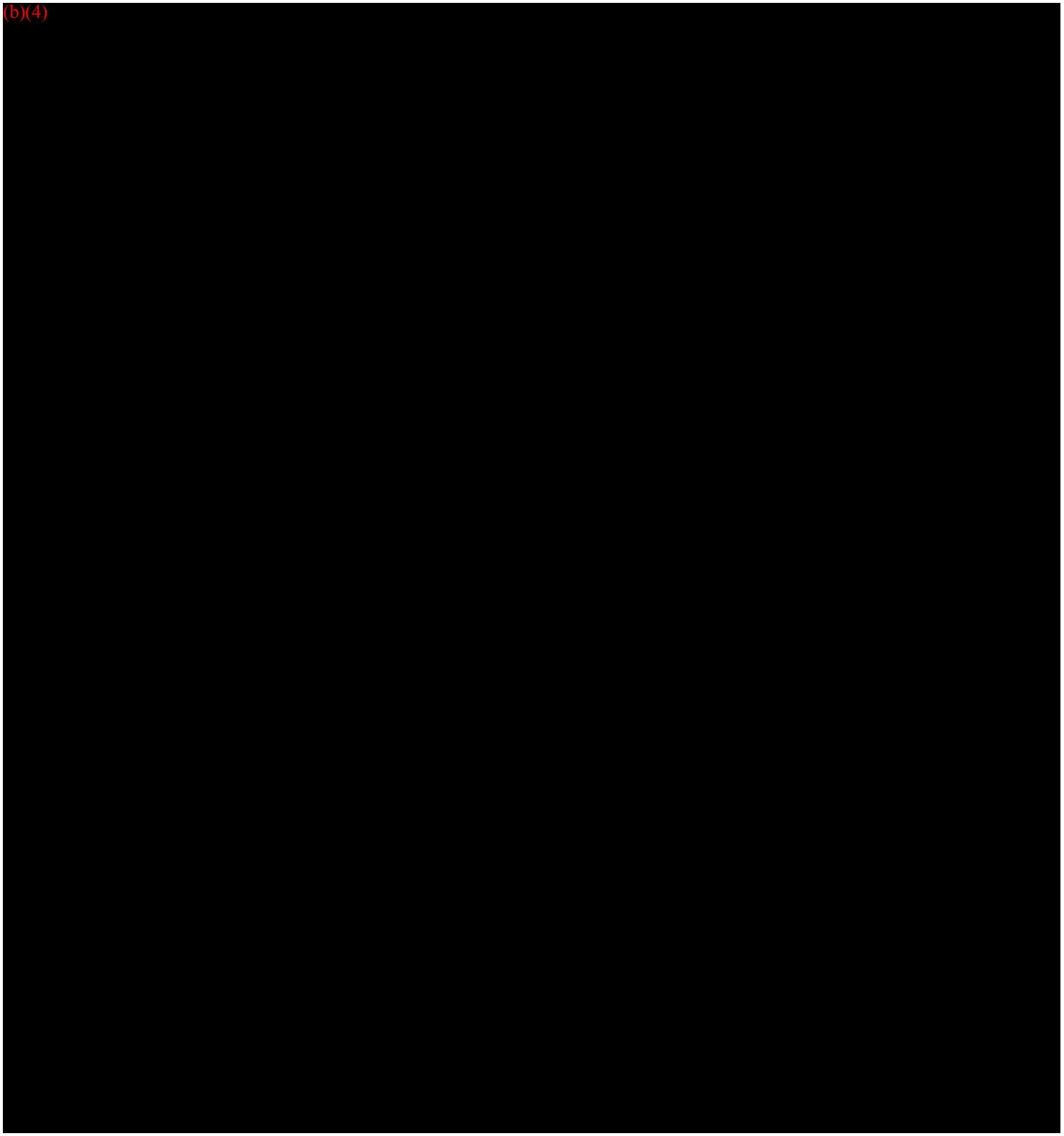
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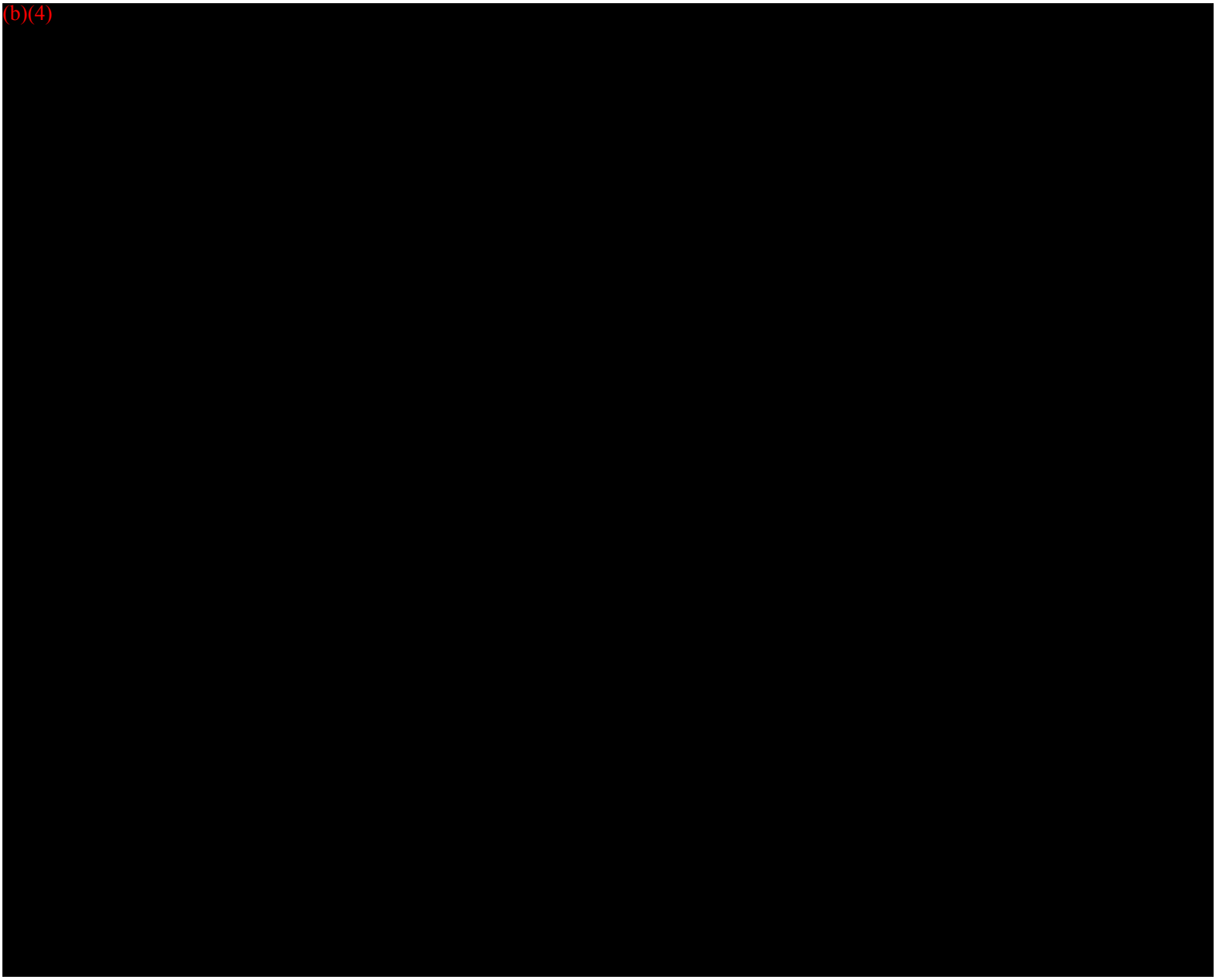
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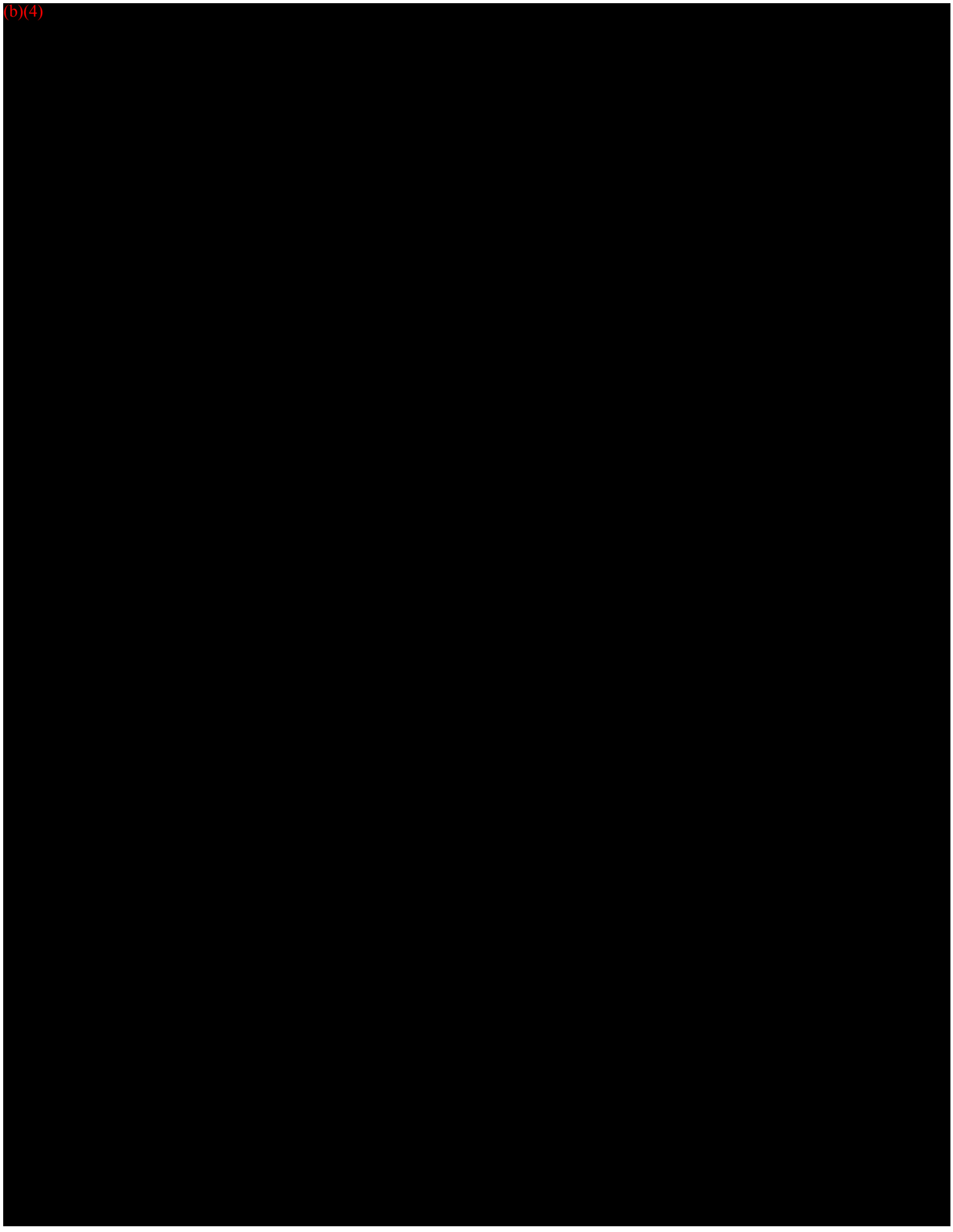
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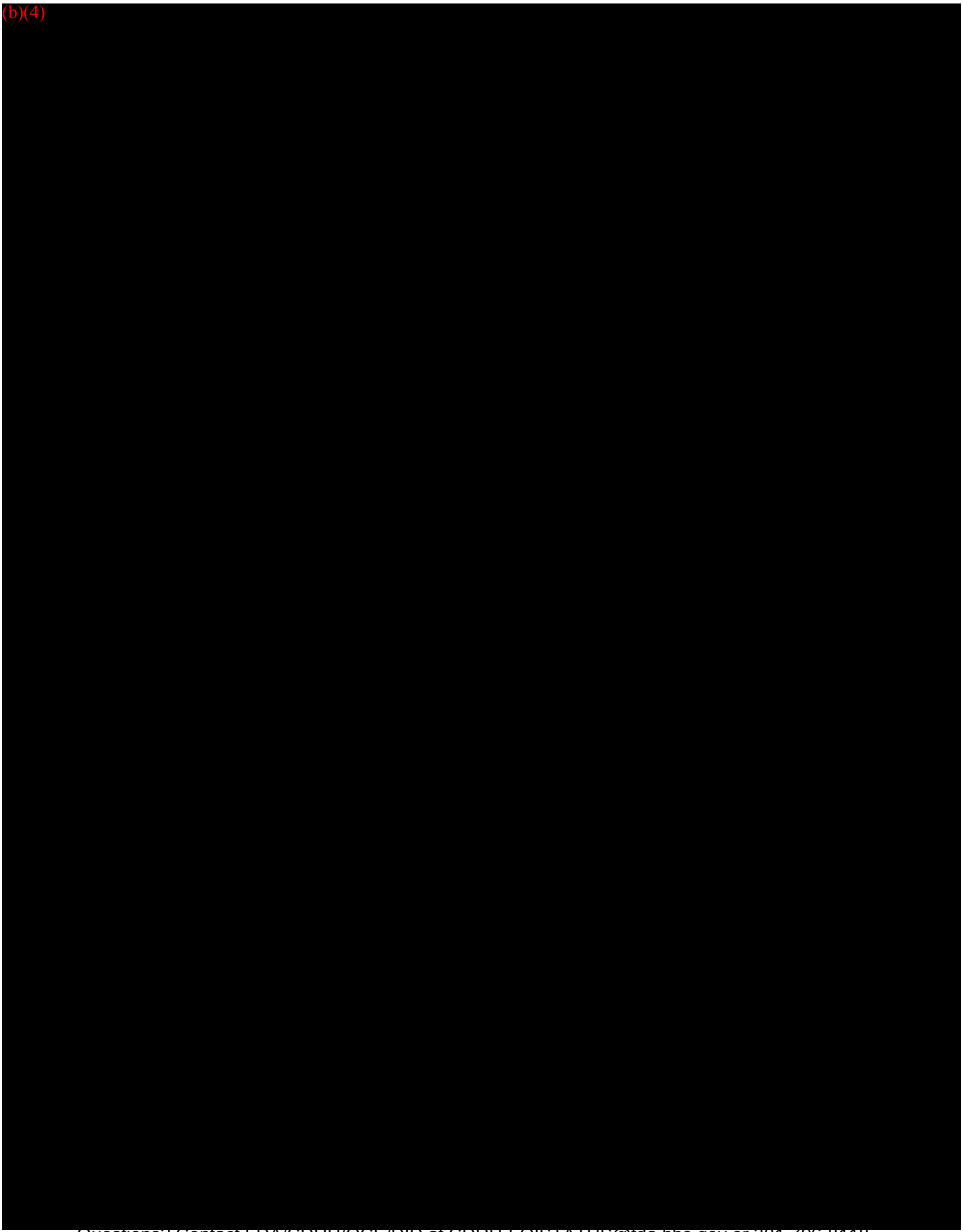
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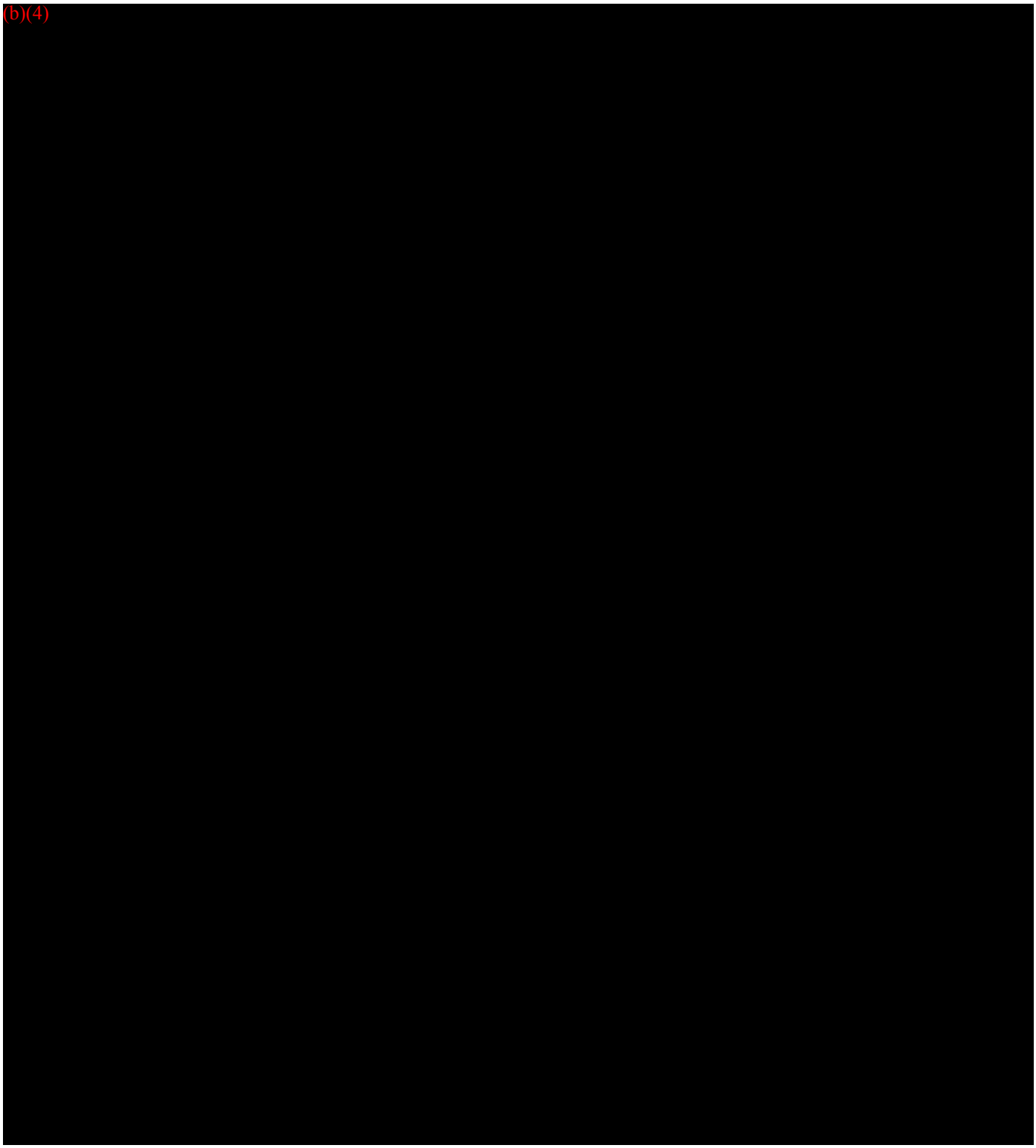
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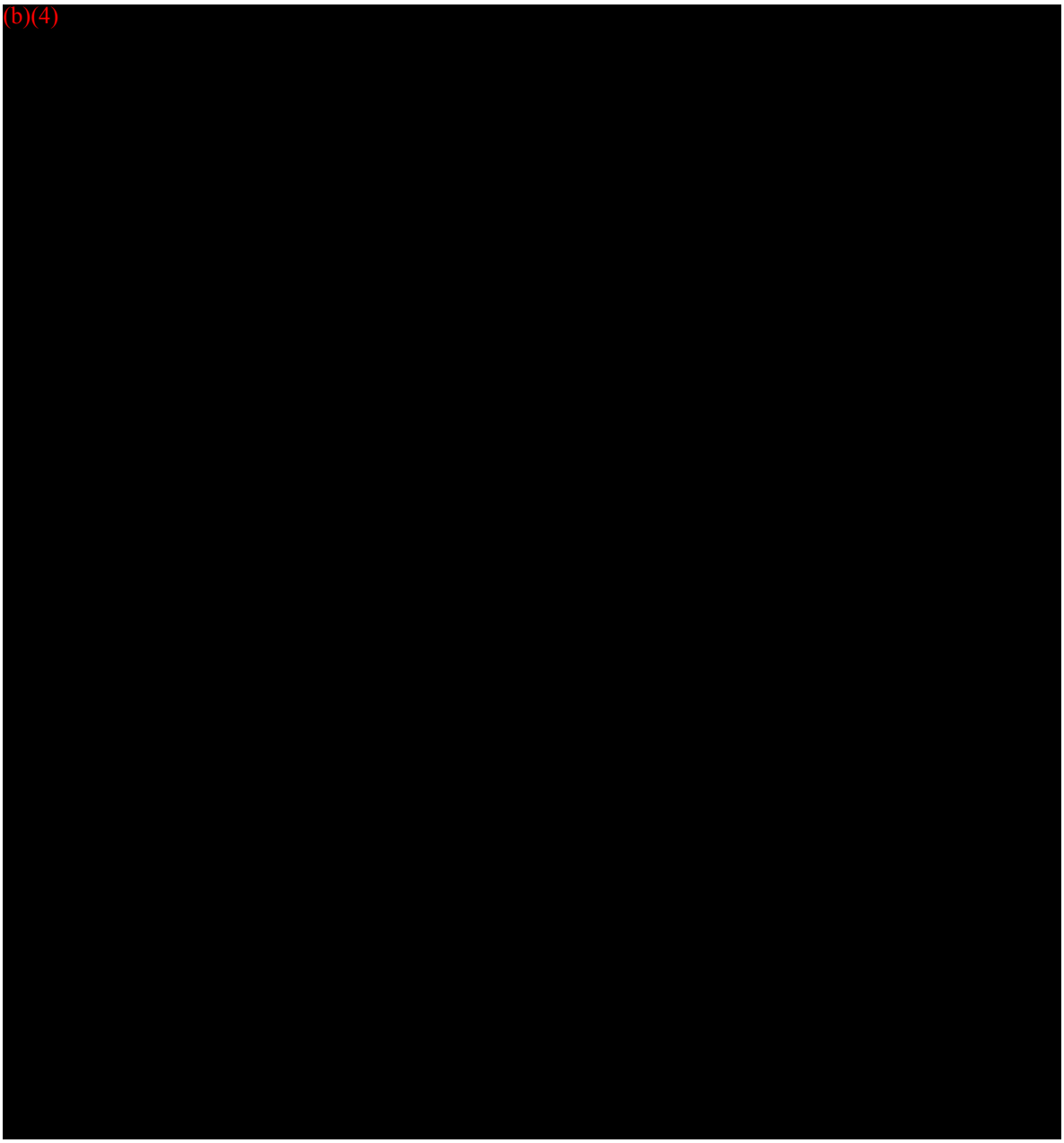
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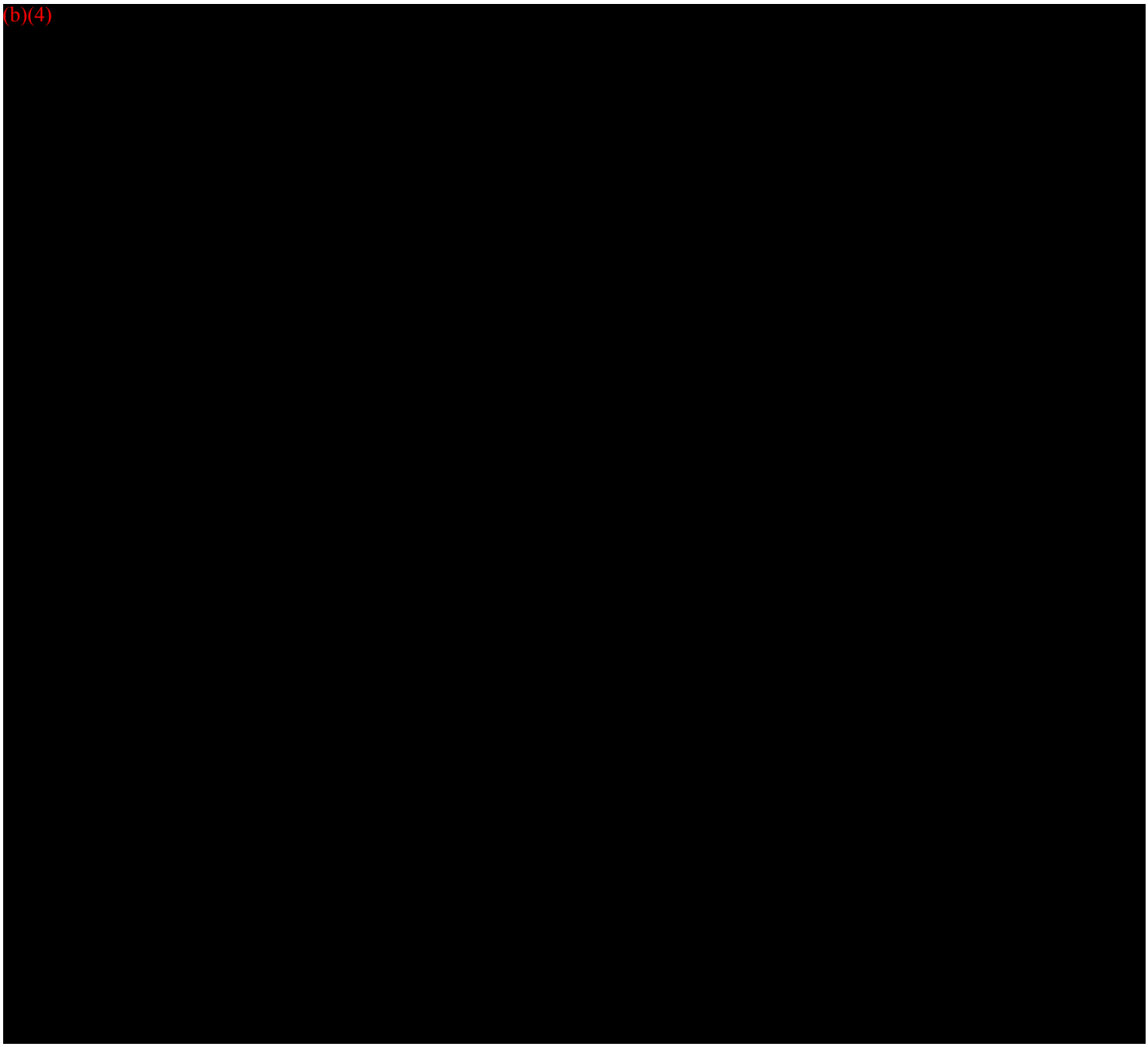
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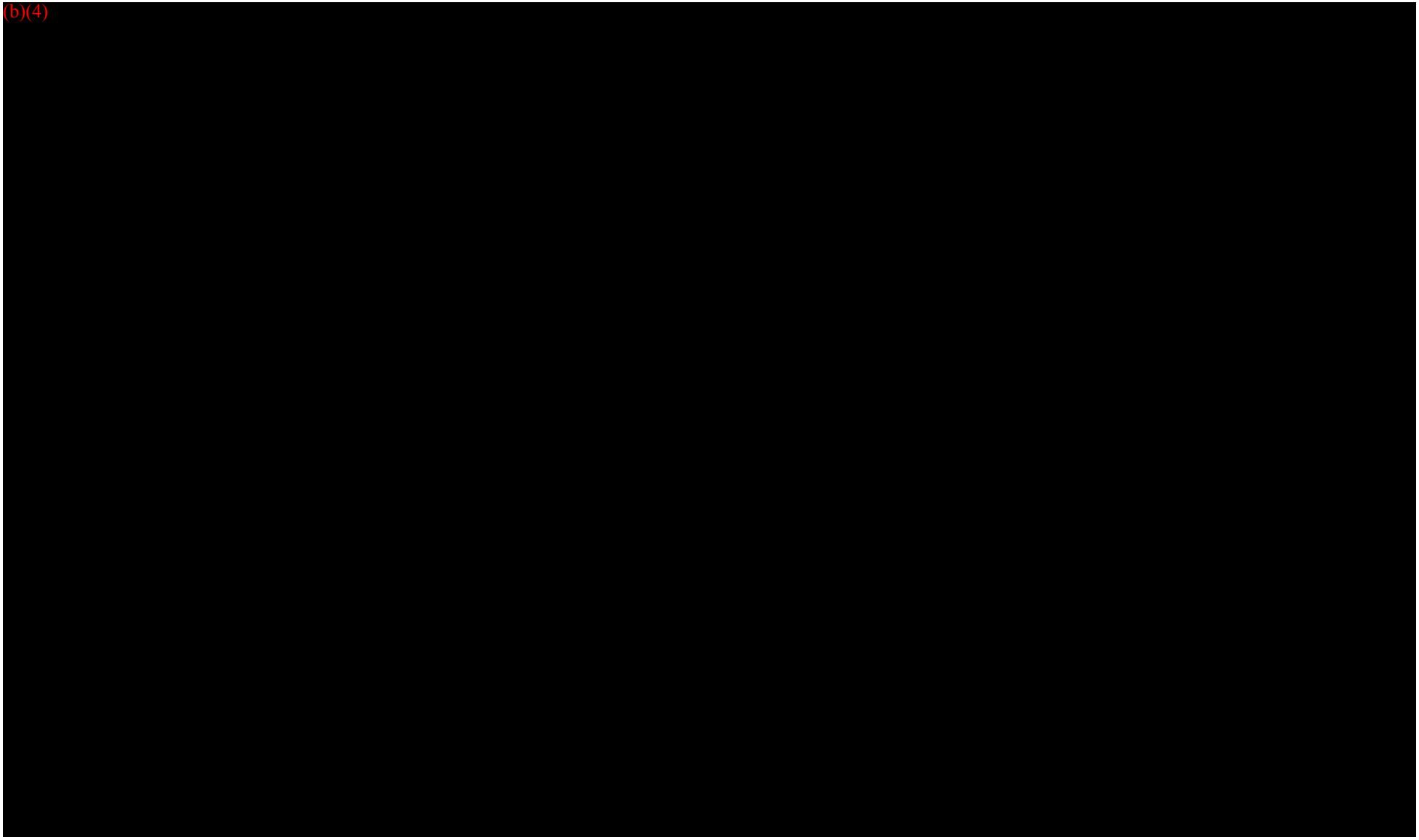
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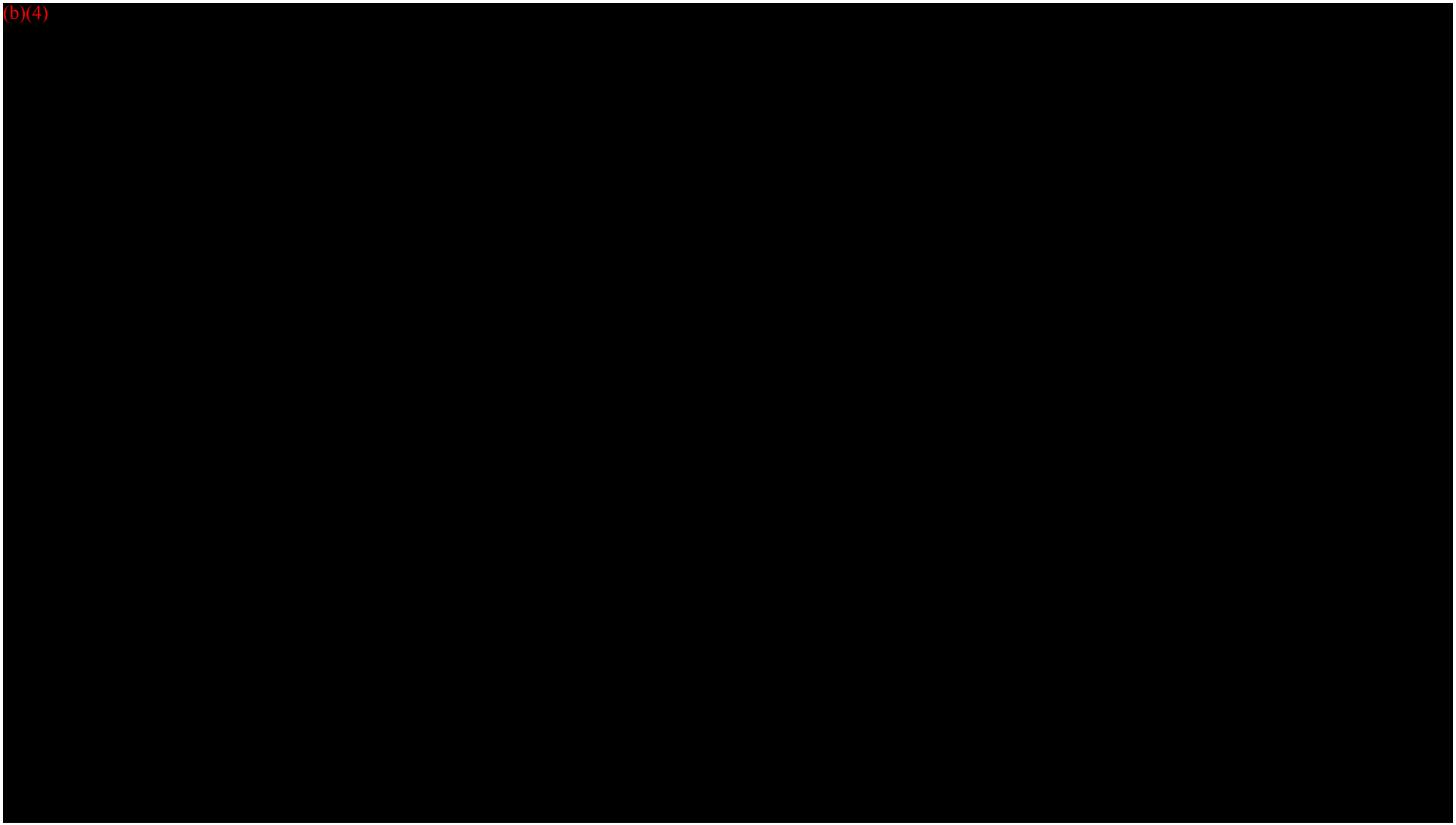
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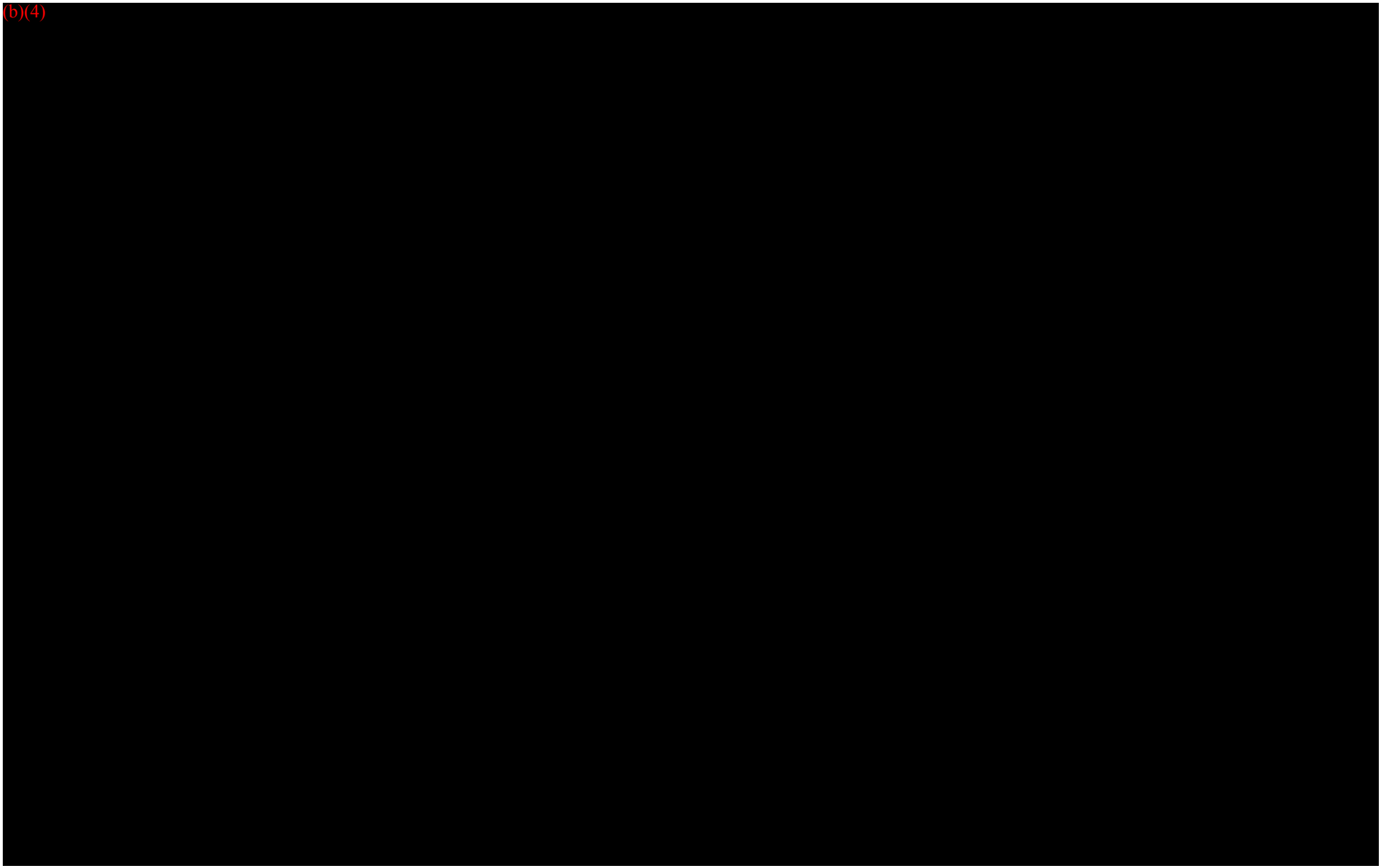
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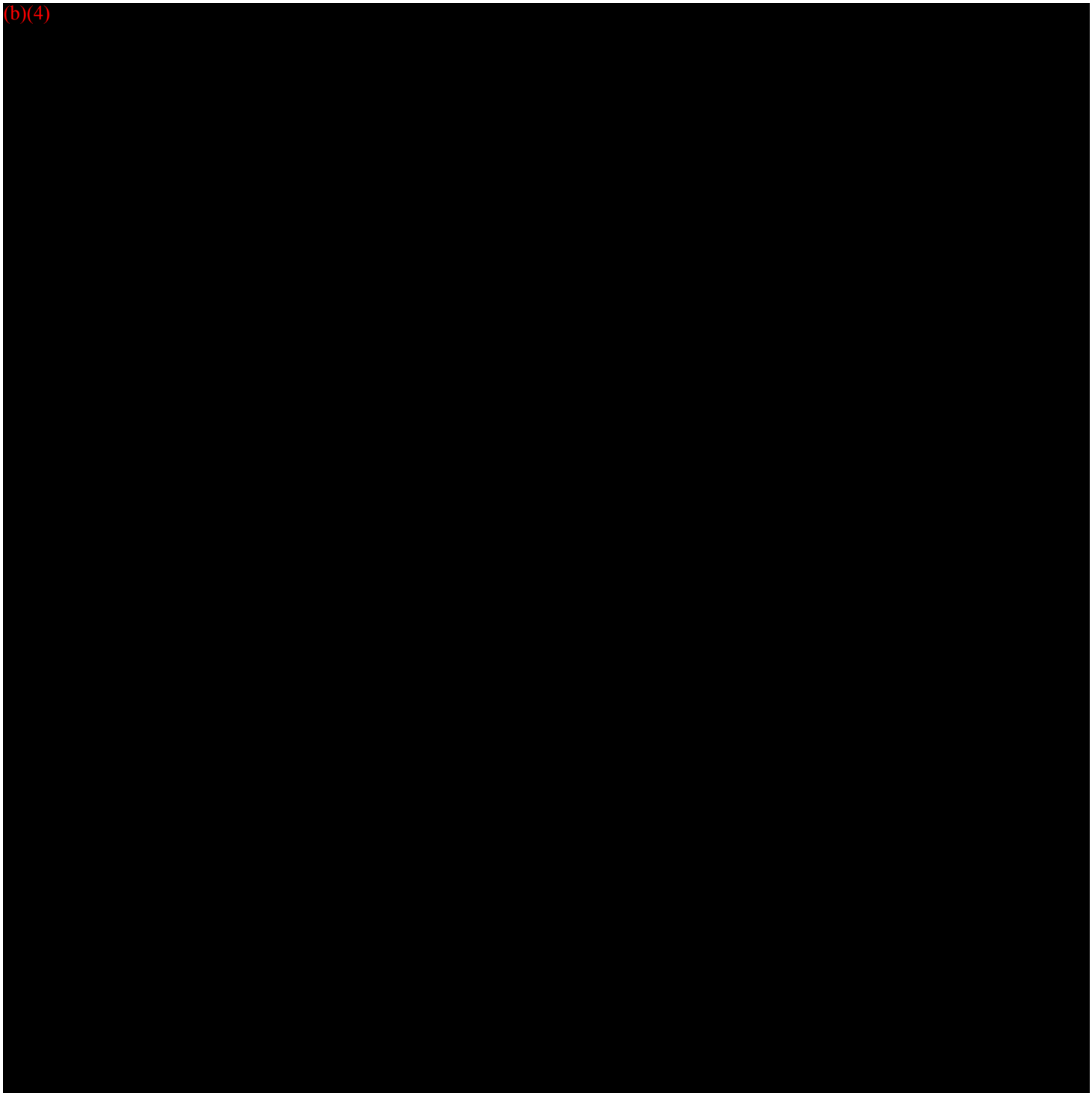
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Coramed Technologies, LLC
6225 W. Howard Street, Niles, Illinois 60714
847-647-8800 | 847-510-0502 FAX

CORA|MED

CORA® System 510(k) Summary

APPLICANT INFORMATION

Name of Manufacturer: Coramed Technologies, LLC

Manufacturer Street Address: 6225 W. Howard St.

City, State, Zip: Niles, IL 60714

Phone Number: (847) 647-8800

FAX Number: (847) 510-0502

Contact person for all communications: Norman E. Brunner

Email for contact person: nbrunner@coramedtech.com

Date that Summary was prepared: June 22, 2015

DEVICE INFORMATION

Trade name (proprietary name): CORA® (Coagulation Resonance Analysis) System and the following assays and reagents

- Citrated Assays and Reagents
  - CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
  - CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
  - CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
  - CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent

Common name (usual name): Whole Blood Hemostasis System

Classification Name: 21CFR 864.5425 Multipurpose System for *in vitro* Coagulation Studies

PREDICATE DEVICE

- Thrombelastograph® Coagulation Analyzer (TEG®) – 5000 Series, K002177, Product Code JPA (System, Multipurpose, for In Vitro Coagulation Studies), Haemoscope Corporation

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DESCRIPTION OF THE DEVICE

System Description

The CORA System consists of a four-channel diagnostic analyzer with integrated computer module, system reagents (CK, CRT, CKH, and CFF), and Abnormal Quality Control material and microfluidic test cartridges. See below for a description of system reagents. Reagents are dried-in-place within the cartridges during manufacturing. Abnormal Quality Control material is lyophilized and can be reconstituted with water as needed for WQC testing with reagent cartridges.

To perform a test, a disposable CORA Cartridge is inserted into the analyzer. Blood or WQC material is added to an entry port on the cartridge and drawn into the cartridge under analyzer control. The amount of the sample drawn into the cartridge is automatically determined by the volume of the blood chambers in the cartridge. Once in the disposable, the sample is metered into as many as four separate analysis channels, depending upon the assays being performed. Reconstitution of reagents dried within the cartridge is accomplished by moving the sample back and forth through reagent chambers, under the control of microfluidic valves and bellows (pumps) within the cartridge. After each sample has been mixed with reagent, it is delivered to a test cell where it is monitored for visco-elastic changes due to coagulation. Excess sample material is moved under microfluidic control into an enclosed waste chamber within the cartridge.

The CORA Measurement Technique

The CORA technology is based on a disposable containing up to four independent measurement cells. Each cell consists of a short vertically-oriented injection molded tube (ring) with a diameter of 2.5mm and a length of 4.5mm. Detection of clotting in the CORA System is performed optically. Under control of the analyzer, approximately 20µl of prepared sample is delivered to the tube, where a meniscus naturally forms at each end of the tube. The tube is positioned so that the lower meniscus partially blocks light traveling from a collimated source toward a photodiode.

During testing, a piezoelectric actuator drives the measurement cell(s) through a motion profile composed of summed sinusoids at different frequencies. The profile has a maximum amplitude of under 10µm and contains frequencies from 10-500Hz. Some, but not all, of the measurement cell motion will induce motion in the sample meniscus, which will be detected by the photodiode. The resulting motion of the meniscus is monitored optically and recorded by the analyzer to calculate the resonant frequency and modulus of elasticity (stiffness) of the sample. By performing a Fast Fourier Transform (FFT) on meniscus motion data, it is possible to determine the frequencies of input motion that caused the greatest deflection of the sample (these are called the resonant frequencies).

Resonance is the tendency of a material or structure to oscillate with greater amplitude at some frequencies than others. The exact frequencies at which resonance occurs will depend on the stiffness and mass of the sample. Stiffness, in turn, is a function of a material's modulus of elasticity and the boundary conditions to which the material is exposed, such as the geometry and materials of a test cell. By holding these boundary conditions and sample mass constant from run to run, the CORA System allows direct comparison of elasticity between samples.

In a typical test, blood that has been delivered to the measurement cell will not clot for several minutes. During this time the sample has no inherent stiffness except that provided by surface tension, and since this remains constant the measured resonant frequencies will not change. Once clotting begins, however, the elastic modulus and thus the resonant frequencies increase rapidly. During fibrinolysis, the process is reversed, with elastic modulus and resonant frequencies decreasing. In tests where clotting does not occur, the resonant frequency of the sample will not change. During coagulation, however, a clot will bind to the test tube (ring) and the resonant frequency will rise with increasing firmness of the clot. The

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CORA Analyzer collects meniscus motion data, tracks changing resonant frequencies and analyzes the frequency data to provide semi-quantitative parameters describing the clot. Results are presented in a format similar to the TEG 5000.

Both the TEG 5000 and CORA System monitor the elastic modulus of clots. Method Comparison testing has been performed, yielding data from approximately 300 patients from three sites (Mayo Clinic, University of Pittsburgh Medical Center, and Sinai Hospital, Baltimore). These data include all applicable parameters from the four citrated tests (CK, CKH, CRT and CFF). The TEG 5000 measures the changes of the linkage forces of the clot between the cup and pin over time, while the CORA System measures the changes of the resonant frequency of the clot over time. Despite the difference in the way the two analyzers measure the changes in the modulus of elasticity of the clot over time, they measure the same physical phenomenon and produce the same result when converted from their specific units of measurement (forces for the TEG5000 and frequency for the CORA System) to millimeters. The fact that these results are similar across all reagents used in both technologies is demonstration that the two technologies measure the same phenomenon, the changes in elastic modulus.

The following definitions apply to calculated parameters in the CORA System:

CORA Parameter	Definition	Parameter Relation to Hemostasis
R	R is the time from the start of the test until initial fibrin formation. This represents the enzymatic portion of coagulation.	Normal / reduced / increased speed of coagulation initiation
K	K is the time after R needed to reach a certain level of clot strength. This represents clot kinetics.	Normal / reduced / increased speed of coagulation amplification and propagation
Alpha α (angle)	Alpha is the angle representing the rate increase in the clot strength and the rapidity of fibrin build-up and cross-linking.	Normal / reduced / increased speed of coagulation amplification and propagation
MA	MA, or Maximum Amplitude, represents the maximum firmness of the clot during the test.	Normal / reduced / increased clot elasticity/strength
FLEV	FLEV is an estimate of the fibrinogen level in the blood sample.	Estimated Functional Fibrinogen Level

Citrated Assays

The CK assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle), and Maximum Clot Strength (MA). K and Alpha are complementary parameters and should be used in conjunction with Clotting Time (R) and Maximum Clot Strength (MA).

The CRT assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via both the intrinsic and extrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CFF assay is a semi-quantitative *in vitro* diagnostic assay for monitoring hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. CFF is used in conjunction with CK and clotting characteristics are described by the functional parameter Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

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The CKH assay is a semi-quantitative *in vitro* diagnostic assay used in conjunction with the CORA System to monitor the effects of heparin in the blood stream of a patient. CKH is used in conjunction with CK and heparin influence is determined by comparing Clotting Times (R) between the two tests.

Wet Quality Control (WQC)

Abnormal Wet Quality Control (WQC) material consists of bovine plasma with buffers and stabilizers, and is used instead of hypocoagulable blood, in conjunction with the Citrated Multichannel system cartridge. When used with the Citrated Multichannel cartridge, this material provides consistent and repeatable values for CORA parameters to confirm reagent quality and viability.

Abnormal WQC Intended Use

The Abnormal WQC (Wet Quality Control) Material is intended to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

INTENDED USE AND INDICATIONS FOR USE

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The CORA System records the kinetic changes in a sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARING THE CORA SYSTEM TO THE TEG 5000 PREDICATE DEVICE

Table of Similarities

Item	TEG® 5000 Predicate	CORA® System
Analyzer		
Technological Purpose	Monitoring the response of a clot to low levels of applied strain	Monitoring the response of a clot to low levels of applied strain
What is measured	Changes in clot elasticity over time	Changes in clot elasticity over time
Initial Warm Up Time	5 min	5 min
Time to Complete a Test	Varies with assay	Same as TEG 5000
Assays and Reagents		
Intrinsic Contact Activation Reagent (CK)	Kaolin and $CaCl_2$	Kaolin and $CaCl_2$, same materials as TEG 5000

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Item	TEG® 5000 Predicate	CORA® System
Intrinsic Contact Activation Reagent with Heparinase for heparin reversal (CKH)	Kaolin and $CaCl_2$ with Heparinase	Kaolin, Heparinase and $CaCl_2$, same materials as TEG 5000
Citrated RapidTEG (CRT) (Tissue Factor and Kaolin Activation)	Tissue Factor (TF), Kaolin and $CaCl_2$	Tissue Factor (TF), Kaolin and $CaCl_2$, same materials as TEG5000
Citrated Functional Fibrinogen (CFF) / Platelet-Blocked (Tissue Factor Activation)	ReoPro®, Tissue Factor and $CaCl_2$, same materials as CORA	ReoPro®, Tissue Factor and $CaCl_2$, same materials as TEG 5000
Calcium Chloride Reagent (CC) (for re-calcification)	$CaCl_2$ reagent	$CaCl_2$ same materials as TEG 5000
Quality Control Material (WQC Abnormal Control)	TEG coagulation control – Level II	TEG coagulation control – Abnormal, same materials as TEG 5000

Table of Differences

Item	TEG® 5000 Predicate	CORA® System
Analyzer	Thrombelastography analyzer, separate computer and software	Fully integrated Thrombelastography analyzer
Measuring Technique	Direct-contact measurement of shear elasticity of a coagulating sample	Non-contact measurement of shear elasticity of a coagulating sample
Measuring Channels	Two, each independent and interchangeable (can be used with any approved reagent)	Four, each independent and interchangeable (can be used with any approved reagent)
Signal Transducer	Electromechanical detection (rotary variable inductive transformer) of rotary motion of a pin suspended in the sample	Optical detection (silicon photodiode) of the motion of a free surface of the sample
Temperature Control	20° to 40°C	20° to 50°C
Sample Volume (per channel)	360-380 µl	63 µl
Total Reaction Volume (single channel)	360-380 µl	20 µl
Mains Supply Voltage	120V, 60Hz and 220V, 50Hz model available	100-240V, 50-60Hz (international power supply)
Analyzer Input Voltage	24 volts AC, 30 watts max	12 volts DC, 60 watts max
Environment	Level and vibration free position, no solar radiation Operating temperature: 10° to 35 °C Storage Temperature: -30° to +50 °C (analyzer only) Relative humidity 20-80% (non-condensing)	Stable and level surface. Operating Temperature 10° to 32°C Storage Temperature: -20° to 50°C (analyzer only) Relative humidity 20 to 80% (non-condensing)

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Item	TEG® 5000 Predicate	CORA® System
Sample Preparation	Performed by the operator using pipettes to reconstitute reagents and mix reagents with the sample	Performed under analyzer control within the disposable cartridge
Pipetting	Manual accurate pipettes (10, 20, 50, 100, 340, 360, 500, 1000µl)	Unmetered transfer pipette or syringe; blood sample is added until it fills to a level above the line marked on the blood intake well of the cartridge
Consumables	Cups & Pins (acrylic plastic)	Carrier (acrylic plastic) with microfluidics laminate and test rings (acrylic plastic)

SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Analytical Precision

Testing was performed in Coramed's laboratory for precision, using CLSI EP5-A2 as guidance. Acceptance criteria for all reagents are: CV ≤ 15% for the R parameter, CV ≤ 25% for the K parameter, and CV ≤ 10% for the Alpha and MA parameters. Three types of donor citrated whole blood (CWB) were used in this precision testing:

- Hypo (donors with natural coagulation levels of R parameter near the upper limit of the reference range and MA parameter near the lower limit of the reference range);
- Normal (donors with natural coagulation levels of R and MA parameters near the center of the reference ranges):
- Hyper (donors with natural coagulation levels of R parameter near the lower limit of the reference range and MA parameter near the upper limit of the reference range

Testing was performed with blood draws from three donors (one Hypo, one Normal, and one Hyper) on each of five days (non-consecutive). Testing was performed by two operators using three reagent lots and twelve analyzers, two replicates. The structure of this precision test is shown below.

Sample Type (Hypo, Normal or Hyper)												
	Day 1 (Total of 5 days)											
Operator	Operator 1						Operator 2					
Reagent lot	1		2		3		1		2		3	
Analyzer	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2

Structure of Precision Testing

Precision test estimates by test, parameter and donor sample test level are shown in the table on the following page. All acceptance criteria were met.

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Test	Parameter	Level	n	Mean	Reagent Lot		Operator*		Analyzer (within Operator, Reagent Lot)		Day (within Analyzer, Operator, Reagent Lot)		Repeatability		Total		Total without Day (Within Day)	
					SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
CFF	FLEV	Hypo	120	269.8	2.36	0.9%	0	0.0%	0	0.0%	5.32	2.0%	5.87	2.2%	8.27	3.1%	6.33	2.3%
CFF	FLEV	Normal	120	376.8	0	0.0%	2.25	0.6%	0	0.0%	5.49	1.5%	3.98	1.1%	7.15	1.9%	4.57	1.2%
CFF	FLEV	Hyper	120	597.4	0	0.0%	0	0.0%	0	0.0%	49.38	8.3%	9.62	1.6%	50.31	8.4%	9.62	1.6%
CFF	MA	Hypo	120	14.8	0.11	0.8%	0	0.0%	0	0.0%	0.29	2.0%	0.33	2.2%	0.45	3.0%	0.35	2.3%
CFF	MA	Normal	120	20.6	0	0.0%	0.13	0.6%	0	0.0%	0.3	1.5%	0.22	1.1%	0.39	1.9%	0.25	1.2%
CFF	MA	Hyper	120	32.7	0	0.0%	0	0.0%	0	0.0%	2.71	8.3%	0.53	1.6%	2.76	8.4%	0.53	1.6%
CKH	R	Hypo	120	8.2	0	0.0%	0	0.0%	0.18	2.2%	0.36	4.3%	0.76	9.2%	0.86	10.0%	0.78	9.5%
CKH	R	Normal	120	6.0	0	0.0%	0.05	0.9%	0.09	1.6%	0.14	2.3%	0.42	7.1%	0.46	7.7%	0.44	7.3%
CKH	R	Hyper	120	4.9	0	0.0%	0.05	1.1%	0	0.0%	0.28	5.7%	0.5	10.0%	0.58	12.0%	0.5	10.0%
CK	Angle	Hypo	120	68.7	0	0.0%	1.09	1.6%	0	0.0%	1.61	2.3%	3.01	4.4%	3.59	5.2%	3.2	4.7%
CK	Angle	Normal	120	72.1	0	0.0%	0	0.0%	0	0.0%	1.14	1.6%	1.73	2.4%	2.07	2.9%	1.73	2.4%
CK	Angle	Hyper	120	76.7	0	0.0%	0	0.0%	0	0.0%	1.84	2.4%	1.77	2.3%	2.56	3.3%	1.77	2.3%
CK	K	Hypo	120	1.8	0.03	1.9%	0.06	3.6%	0	0.0%	0.13	7.2%	0.18	10.0%	0.23	13.0%	0.19	11.0%
CK	K	Normal	120	1.4	0	0.0%	0	0.0%	0	0.0%	0.09	6.7%	0.16	12.0%	0.19	13.0%	0.16	12.0%
CK	K	Hyper	120	0.9	0	0.0%	0	0.0%	0	0.0%	0.12	12.0%	0.18	20.0%	0.22	23.0%	0.18	20.0%
CK	MA	Hypo	120	52.4	0.33	0.6%	0.55	1.0%	0.26	0.5%	0.83	1.6%	0.77	1.5%	1.33	2.5%	1.03	2.0%
CK	MA	Normal	120	59.4	0	0.0%	0.5	0.8%	0.48	0.8%	0.57	1.0%	0.86	1.4%	1.24	2.1%	1.1	1.9%
CK	MA	Hyper	120	68.0	0	0.0%	0.2	0.3%	0	0.0%	0.9	1.3%	0.52	0.8%	1.06	1.6%	0.56	0.8%
CK	R	Hypo	120	8.9	0	0.0%	0.29	3.3%	0	0.0%	0.64	7.1%	0.85	9.5%	1.1	12.0%	0.9	10.0%
CK	R	Normal	120	6.5	0	0.0%	0	0.0%	0	0.0%	0.28	4.3%	0.49	7.6%	0.56	8.7%	0.49	7.6%
CK	R	Hyper	120	5.2	0.13	2.5%	0	0.0%	0	0.0%	0.31	5.8%	0.66	13.0%	0.74	14.0%	0.67	13.0%
CRT	MA	Hypo	120	52.4	0.39	0.7%	0.22	0.4%	0	0.0%	0.92	1.8%	0.59	1.1%	1.18	2.3%	0.74	1.4%
CRT	MA	Normal	120	62.7	0	0.0%	0.15	0.2%	0.14	0.2%	0.37	0.6%	0.31	0.5%	0.52	0.8%	0.37	0.6%
CRT	MA	Hyper	120	69.4	0	0.0%	0	0.0%	0	0.0%	0.91	1.3%	0.2	0.3%	0.93	1.3%	0.2	0.3%

*Operator = Operator + operator-by-reagent lot interaction

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In addition, Coramed's Citrated Reagent Precision Protocol Rev. 02 was written to supplement precision data originally provided to FDA in 510(k) K150041. This protocol specifies testing to be performed outside of reference range values but within the Analytical Measurement Range (AMR) limits. This report presents data and statistics resulting from the execution of this protocol.

The following pages contain tables of precision statistics. Table 1 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from normal donors but spiked to achieve hypocoagulable (hypo) and hypercoagulable (hyper) results. Three donors for each reagent-parameter and spiking type were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each donor-reagent-parameter-hypo/hyper type, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B
Sample	Hypercoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

The focus of this study was on achieving values for the primary coagulation parameters R, MA and FLEV outside the reference ranges but within AMR limits, and taking the resulting K and Alpha (angle) values as is. Total Precision %CV values were all within pre-established limits, except for one CFF MA hypo outcome (11.6% for a limit of 10%) and 2 outcomes for Angle. The K and Angle parameters indicate the kinetics of the clotting process, and are not clinically significant as the main parameters representing coagulation, platelet and fibrinogen activities and abnormalities. The CFF MA CV% is higher because the MA value is small (mean of 6.5 mm) and although the Standard Deviation is very small (0.8mm) the resulting CV% is just over the limit. When the SD is so small there is no clinical significance for the differences making this CV% acceptable.

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Table 2 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from patients taking anticoagulants Dabigatran and Warfarin. Four Dabigatran patients and two Warfarin patients for each reagent-parameter were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each patient-reagent-parameter, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1		2		3		4		5		6	
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

Results for this testing were generally within limits, except for a few minor exceptions. As the data shows, all the MAs, for CK, CRT, and CFF, are within the specified expected CV% across the board while for the R parameter, there are no significant differences between lots, operators and devices and the only CVs (for CK and CKH – R parameter) somewhat exceeding 15% come from repeatability (16.9% for MH-DB003 for CK and 15.9% for MH-DB004 for CKH). Even though the, K and Angle are not parameters that are considered clinically significant the raw data indicates that the single angle CV% that is above the limit was due to an outlier while the K parameter has high CVs due to the fact that elongated coagulation results in higher CVs for that parameter.

Test	Param	Spiking	Patient ID	N	Mean	Lot		Operator		Instrument		Repetition		Total	
						StDev	CV	StDev	CV	StDev	CV	StDev	CV	StDev	CV

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CK	R	hyper	D101	12	2.1	0	0	0	0	0.1	4.5	0.1	3.1	0.1	5.5
CK	R	hyper	D108	12	2.7	0	0	0	1	0.1	3.5	0.1	2.4	0.1	4.3
CK	R	hyper	D169	12	2.2	0.1	2.8	0	0	0.1	3.1	0.1	2.5	0.1	4.6
CK	R	hypo	D141	12	16.1	0	0	1.1	6.9	1.3	8	0.7	4.3	1.7	10.8
CK	R	hypo	D169	12	15.3	0.8	5.3	0	0	1.6	10.2	1.1	7.1	2	13.2
CK	R	hypo	D108	12	12.1	0.1	1	0.1	0.9	0.9	7.2	0.7	5.6	1.1	9.3
CK	K	hyper	D101	12	0.5	0	0	0	0	0	3.9	0	4.1	0	5.7
CK	K	hyper	D108	12	0.4	0	3.8	0	3.8	0	7.2	0	6.5	0	10.7
CK	K	hyper	D169	12	0.5	0	0	0	0	0	8.2	0	8.2	0.1	11.6
CK	K	hypo	D141	12	3	0.2	5.2	0.2	6	0.3	9.9	0.2	8.2	0.4	14.6
CK	K	hypo	D169	12	3.1	0.5	16.4	0	0	0.5	14.8	0.3	10	0.7	22.7
CK	K	hypo	D108	12	2.2	0	0	0.1	6.4	0.3	12	0.1	6.2	0.3	14.6
CK	Angle	hyper	D101	12	80	0.8	1.1	1.5	1.8	7.2	9	6.9	8.7	10.1	12.6
CK	Angle	hyper	D108	12	85.1	0.1	0.2	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hyper	D169	12	84.3	0.1	0.1	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hypo	D141	12	54.7	0	0	0	0	8.4	15.4	5.4	9.9	10	18.3
CK	Angle	hypo	D169	12	42.7	1	2.4	1.9	4.5	1.8	4.3	1.6	3.7	3.1	7.2
CK	Angle	hypo	D108	12	66.7	3	4.4	0	0	4.8	7.2	3.3	5	6.3	9.5
CK	MA	hyper	D108	12	71.6	0	0	0.5	0.7	0.3	0.4	0.3	0.4	0.5	0.8
CK	MA	hyper	D169	12	70	0	0	0.1	0.1	0.2	0.2	0.1	0.2	0.2	0.3
CK	MA	hyper	D121	12	71.1	0	0	0	0	0.9	1.3	0.6	0.8	1.1	1.5
CK	MA	hypo	D141	12	42	0.2	0.6	0	0	1.5	3.5	0.9	2.1	1.7	4.1
CK	MA	hypo	D169	12	46.6	0	0	0	0	0.8	1.8	0.5	1.1	1	2.1
CK	MA	hypo	D108	12	45.4	0	0	0.8	1.8	1.2	2.7	0.9	2	1.7	3.7
CKH	R	hyper	D101	12	2	0.1	4.8	0	0	0	2.4	0.1	2.8	0.1	5.5
CKH	R	hyper	D108	12	2.6	0	0	0	0	0.1	2.6	0	1.6	0.1	3.1
CKH	R	hyper	D169	12	2.2	0	0	0	0	0	1.5	0	1	0	1.8
CKH	R	hypo	D141	12	15.7	0	0	1	6.4	0.7	4.5	0.6	4.1	1.3	8.2
CKH	R	hypo	D169	12	14.5	0	0	0.8	5.2	0.8	5.7	0.5	3.2	1.1	7.9
CKH	R	hypo	D108	12	12.3	0.6	5	0	0	0.8	6.3	0.5	4.4	1.1	8.8
CRT	MA	hyper	D108	12	70.8	0.2	0.3	0	0	0.1	0.2	0.1	0.2	0.2	0.3
CRT	MA	hyper	D121	12	72.5	0.2	0.3	0	0	0.4	0.5	0.4	0.5	0.5	0.8
CRT	MA	hyper	D145	12	73	0.2	0.2	0	0	0.2	0.3	0.2	0.2	0.3	0.4
CRT	MA	hypo	D141	12	41.3	0	0	0	0	0.7	1.8	0.5	1.2	0.9	2.2
CRT	MA	hypo	D169	12	44.4	0	0	0.3	0.7	0.6	1.3	0.4	0.9	0.8	1.7
CRT	MA	hypo	D108	12	45.5	0	0	0.4	0.9	1	2.1	0.5	1.1	1.1	2.5
CFF	MA	hyper	D101	12	49.9	0.1	0.1	0	0	0.5	0.9	0.3	0.5	0.5	1.1
CFF	MA	hyper	D141	12	44.3	0	0	0	0	0.5	1.2	0.3	0.6	0.6	1.3
CFF	MA	hyper	D145	12	47	0	0	0	0	0.7	1.4	0.5	1	0.8	1.7
CFF	MA	hypo	D101	12	10.2	0.2	1.5	0	0	0.3	3	0.2	1.7	0.4	3.6
CFF	MA	hypo	D125	12	9.5	0	0	0.2	1.8	0.4	4	0.3	2.7	0.5	5
CFF	MA	hypo	D169	12	6.5	0	0	0.7	10.1	0.3	4.9	0.4	6	0.8	11.6
CFF	FLEV	hyper	D101	12	910.7	1.2	0.1	0	0	8.6	0.9	5	0.5	10	1.1
CFF	FLEV	hyper	D141	12	809	0	0	0	0	9.6	1.2	5.2	0.6	10.9	1.3
CFF	FLEV	hyper	D145	12	858.1	0	0	0	0	11.9	1.4	8.5	1	14.7	1.7
CFF	FLEV	hypo	D101	12	186.4	2.9	1.5	0	0	5.5	3	3.1	1.7	6.8	3.6
CFF	FLEV	hypo	D125	12	173.4	0	0	3.1	1.8	7	4	4.6	2.6	8.7	5
CFF	FLEV	hypo	D169	12	157.5	1.8	1.2	1.1	0.7	2	1.3	1.7	1.1	3.2	2.1

Spiked Precision – Table 1

Test	Param	PatientID	N	Mean	Lot		Operator		Instrument		Repetition		Total	
					StDev	CV	StDev	CV	StDev	CV	StDev	CV	StDev	CV
CK	R	MH-DB001	12	13	0	0	0	0	0.4	3.2	1.2	8.9	1.2	9.4
CK	R	MH-DB002	12	21.3	0	0	0	0	1	4.7	2.1	10.1	2.3	11

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CK	R	MH-DB003	12	14.4	0	0	0	0	0	0	2.4	16.9	2.4	16.9
CK	R	MH-DB004	12	11.8	0.5	4	0.5	4.3	0	0	1.6	13.9	1.7	14.8
CK	R	MH-WR001	12	9.9	0.7	7	0.3	2.7	0.3	2.6	0.5	4.9	0.8	8.5
CK	R	MH-WR002	12	10.1	1	10.2	0	0	0.3	3.2	1	10	1.4	13.6
CK	K	MH-DB001	12	1.3	0	0	0	0	0	0	0.2	18.2	0.2	18.2
CK	K	MH-DB002	12	2.4	0	0	0	0	0.4	15.4	1	42	1	44.5
CK	K	MH-DB003	12	1.3	0	0	0	0	0	0	0.3	19.8	0.3	19.8
CK	K	MH-DB004	12	0.9	0.1	11.4	0	0	0	0	0.3	33	0.3	34.4
CK	K	MH-WR001	12	2.2	0	0	0	0	0	0	0.2	8.2	0.2	8.2
CK	K	MH-WR002	12	2	0	0	0	0	0	0	0.4	19.1	0.4	19.1
CK	Angle	MH-DB001	12	72.5	0	0	0	0	0	0	3.6	5	3.6	5
CK	Angle	MH-DB002	12	55.5	0	0	0	0	10.3	18.6	11.6	20.8	15.2	27.4
CK	Angle	MH-DB003	12	72.7	0	0	0	0	0	0	3.2	4.3	3.2	4.3
CK	Angle	MH-DB004	12	79.5	0	0	0	0	0	0	3.4	4.3	3.4	4.3
CK	Angle	MH-WR001	12	65	0	0	0	0	0	0	1.1	1.7	1.1	1.7
CK	Angle	MH-WR002	12	67.1	0	0	1.1	1.6	0	0	3	4.4	3.1	4.6
CK	MA	MH-DB001	12	60.2	0	0	0	0	0	0	0.9	1.5	0.9	1.5
CK	MA	MH-DB002	12	64.5	0	0	0.2	0.4	0	0	0.6	1	0.7	1
CK	MA	MH-DB003	12	64.1	0	0	0.4	0.7	0	0	0.5	0.8	0.7	1
CK	MA	MH-DB004	12	71.9	0.1	0.1	0.5	0.6	0	0	0.5	0.7	0.7	0.9
CK	MA	MH-WR001	12	60.6	0	0	0	0	0	0	0.9	1.4	0.9	1.4
CK	MA	MH-WR002	12	59.7	0	0	0	0	1	1.6	0.8	1.3	1.2	2
CKH	R	MH-DB001	12	12.2	0.8	6.8	0	0	0	0	0.7	5.8	1	8.2
CKH	R	MH-DB002	12	19.3	0	0	1.6	8.4	0	0	2.2	11.4	2.6	13.5
CKH	R	MH-DB003	12	13.5	0	0	0.5	4	0	0	1.4	10.6	1.5	11.1
CKH	R	MH-DB004	12	11.3	0	0	0	0	0	0	1.8	15.9	1.8	15.9
CKH	R	MH-WR001	12	8.4	0	0	0.1	0.8	0	0	0.8	9.7	0.8	9.8
CKH	R	MH-WR002	12	9.1	0.5	5.1	0	0	0	0	0.7	7.4	0.8	8.6
CRT	MA	MH-DB001	12	64.9	0.1	0.1	0	0	0.1	0.1	0.1	0.2	0.1	0.2
CRT	MA	MH-DB002	12	67.7	0.1	0.1	0	0	0	0	0.2	0.2	0.2	0.2
CRT	MA	MH-DB003	12	66	0	0	0	0	0	0	0.1	0.2	0.1	0.2
CRT	MA	MH-DB004	12	73.8	0.1	0.1	0	0	0.1	0.1	0.2	0.2	0.2	0.3
CRT	MA	MH-WR001	12	64	0.1	0.1	0	0	0	0	0.2	0.3	0.2	0.3
CRT	MA	MH-WR002	12	64.7	0	0	0	0	0	0	0.3	0.4	0.3	0.4
CFF	MA	MH-DB001	12	20.7	0.1	0.4	0	0	0.3	1.3	0.1	0.6	0.3	1.4
CFF	MA	MH-DB002	12	23.7	0.3	1.3	0.3	1.4	0	0	0.2	0.7	0.4	1.6
CFF	MA	MH-DB003	12	23.4	0.2	1	0	0	0	0	0.3	1.5	0.4	1.7
CFF	MA	MH-DB004	12	51.9	1.1	2.2	0	0	0	0	0.4	0.8	1.1	2
CFF	MA	MH-WR001	12	20.7	0	0	0	0	0	0	0.4	1.7	0.4	1.7
CFF	MA	MH-WR002	12	24.7	0.1	0.4	0.3	1.2	0	0	0.3	1.3	0.4	1.7
CFF	FLEV	MH-DB001	12	377.3	1.4	0.4	0	0	4.8	1.3	2.4	0.6	5.3	1.4
CFF	FLEV	MH-DB002	12	432.2	5.8	1.3	6.2	1.4	0	0	3	0.7	6.8	1.6
CFF	FLEV	MH-DB003	12	426.5	4.5	1	0	0	0	0	6.2	1.5	7.3	1.7
CFF	FLEV	MH-DB004	12	947.1	20.9	2.2	0	0	0	0	7.5	0.8	19.3	2
CFF	FLEV	MH-WR001	12	377.4	0	0	0	0	0	0	6.5	1.7	6.5	1.7
CFF	FLEV	MH-WR002	12	450	1.6	0.4	5.2	1.2	0	0	6	1.3	7.7	1.7

Patient-Derived Hypo Samples (Dabigatran and Warfarin) – Table 2

Interference

Testing was performed in Coramed's laboratory for interference, using CLSI EP7-A2 as guidance.

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For CK, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Only Hemolysis and Hemodilution were found to be interferents.

For CRT, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Short Draw, Hemolysis and Hemodilution were found to be interferents.

For CKH, Protamine was tested for interference. Protamine was found to be an interferent for CKH at concentrations above 0.062 mg/ml.

For CFF, potential interferents tested were Na Heparin and Hemodilution. Heparin was found to be an interferent for CFF above Heparin concentrations of 1 IU/ml, and Hemodilution was found to be an interferent above hemodilution levels of 30%.

Linearity

Testing was performed in Coramed's laboratory for linearity, using CLSI EP6-A as guidance.

CFF was tested and found to be linear with varying concentrations of Fibrinogen (RiaSTAP) added. These concentrations ranged from 0 mg/dl to 565.5 mg/dl, over an FLEV range of 156 mg/dl to 1145 mg/dl. This corresponds to an MA range of 8.5 mm to 62.7 mm.

Sensitivity and Specificity

CK was tested for Sensitivity and Specificity with respect to Na Heparin, comparing R parameters of five blood samples with different clinically relevant concentrations of Heparin to five samples without heparin. Both Sensitivity and Specificity were found to be 100%.

Heparin Neutralization

Heparin Neutralization of CKH was tested using blood samples spiked with Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) and comparing these results to data obtained from testing CK with un-spiked blood samples. CKH was found to completely neutralize UFH levels of 6 IU/ml blood and LMWH levels of 0.016 mg/ml blood.

SUMMARY OF CLINICAL PERFORMANCE DATA

Testing was performed at three clinical sites for Reference Ranges and Method Comparison.

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Reference Ranges

Reference Ranges for the CORA assays were estimated using the CLSI C28-A3c Guideline on three reference sample groups. Blood samples from up to 55 normal volunteer subjects were taken at each of the three sites, for a total of 157 samples. There were at least 151 valid results for every parameter for all reagents. Samples were excluded on a per-parameter basis using standard outlier criteria. An alternative method would have been to exclude all parameters for any tests where one or more parameter results were determined to be outliers. However, it was decided to retain all valid parameter results in calculating reference ranges because a larger number of samples adds statistical credibility. Also, it does not appear that using the alternative approach would have any significant effect on the reference ranges. Subjects were chosen representing demographic populations of the three areas, regarding age, race and gender. These reference ranges are shown below.

Reagent ↓	N	R (min)	N	K (min)	N	Angle (deg)	N	MA (mm)	N	FLEV (mg/dl)
CK	157	4.6-9.1	157	0.8-2.1	155	63 - 78	151	52 - 69		
CRT							152	52 - 70		
CKH	155	4.3-8.3								
CFF							151	15 - 32	152	278-581

Reference Ranges for CKH are shown but not usually required because the only purpose is to neutralize the heparin in a patient's blood, regardless of the patient's hemostasis condition. Comparing results from the CK and CKH tests for the R parameter can assist in determining whether or not there is heparin in the blood sample.

Reference Ranges for Wet Quality Control (WQC) Abnormal material when used in CORA assay cartridges were estimated. Using three lots of Abnormal Quality Control and three citrated reagent lots, a total of over 135 test results were obtained.

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (deg)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563-873

Method Comparison

Method Comparison studies were conducted at three clinical sites on patient samples following CLSI EP09-A3 Guideline. The subjects enrolled were patients undergoing cardiovascular surgery or cardiology procedures, with blood samples drawn pre- and post-surgery and in the ICU. In order to broaden the range of comparisons, up to 10% contrived samples were added. Key statistics are presented below.

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Method Comparison Statistics Summary – All Clinical Sites					
Parameter	**R**	**Intercept**	**95% CI**	**Slope**	**95% CI**
CK – R (min)	0.868	-0.325	-0.425	1.069	1.034
			-0.225		1.103
CK – K (min)	0.740	-0.097	-0.292	0.906	0.769
			0.098		1.042
CK – Alpha (deg)	0.680	7.305	-13.160	0.940	0.640
			27.769		1.240
CK – MA (mm)	0.924	2.351	0.166	0.948	0.912
			4.536		0.983
CKH – R (min)	0.812	-0.329	-0.393	1.057	1.026
			-0.265		1.089
CRT|CK – MA (mm)	0.929	-0.126	-1.909	0.978	0.948
			1.656		1.007
CFF – MA (mm)	0.938	-0.774	-1.836	1.126	1.072
			0.289		1.180
CFF – FLEV (mg/dl)	0.928	-12.495	-36.810	1.127	1.059
			11.819		1.194

In addition, a Reader Study was conducted to assess the comparison of CORA System and TEG 5000 results based on reading printed test outcomes. The study was performed at three sites, using three experienced TEG 5000 doctors as readers at each site, for a total of nine readers. 30 test outcomes were compared for each of the reagent test categories, for a total of 270 reading comparisons per reader. Excellent agreement between the two devices was demonstrated.

In both the Method Comparison Study and Reader Study, the CORA RapidTEG (CRT) MA parameter was compared to the TEG 5000 Kaolin (CK) MA parameter, to demonstrate that the CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTING

The data and information provided in this submission support a substantial equivalence determination for the CORA System and the TEG 5000 predicate device.

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Coramed Technologies, LLC
6225 W. Howard Street, Niles, Illinois 60714
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CORA|MED

CORA® System 510(k) Summary

APPLICANT INFORMATION

Name of Manufacturer: Coramed Technologies, LLC

Manufacturer Street Address: 6225 W. Howard St.

City, State, Zip: Niles, IL 60714

Phone Number: (847) 647-8800

FAX Number: (847) 510-0502

Contact person for all communications: Norman E. Brunner

Email for contact person: nbrunner@coramedtech.com

Date that Summary was prepared: June 23, 2015

DEVICE INFORMATION

Trade name (proprietary name): CORA® (Coagulation Resonance Analysis) System and the following assays and reagents

- Citrated Assays and Reagents
  - CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
  - CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
  - CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
  - CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent

Common name (usual name): Whole Blood Hemostasis System

Classification Name: 21CFR 864.5425 Multipurpose System for *in vitro* Coagulation Studies

PREDICATE DEVICE

- Thrombelastograph® Coagulation Analyzer (TEG®) – 5000 Series, K002177, Product Code JPA (System, Multipurpose, for In Vitro Coagulation Studies), Haemoscope Corporation

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DESCRIPTION OF THE DEVICE

System Description

The CORA System consists of a four-channel diagnostic analyzer with integrated computer module, system reagents (CK, CRT, CKH, and CFF), and Abnormal Quality Control material and microfluidic test cartridges. See below for a description of system reagents. Reagents are dried-in-place within the cartridges during manufacturing. Abnormal Quality Control material is lyophilized and can be reconstituted with water as needed for WQC testing with reagent cartridges.

To perform a test, a disposable CORA Cartridge is inserted into the analyzer. Blood or WQC material is added to an entry port on the cartridge and drawn into the cartridge under analyzer control. The amount of the sample drawn into the cartridge is automatically determined by the volume of the blood chambers in the cartridge. Once in the disposable, the sample is metered into as many as four separate analysis channels, depending upon the assays being performed. Reconstitution of reagents dried within the cartridge is accomplished by moving the sample back and forth through reagent chambers, under the control of microfluidic valves and bellows (pumps) within the cartridge. After each sample has been mixed with reagent, it is delivered to a test cell where it is monitored for visco-elastic changes due to coagulation. Excess sample material is moved under microfluidic control into an enclosed waste chamber within the cartridge.

The CORA Measurement Technique

The CORA technology is based on a disposable containing up to four independent measurement cells. Each cell consists of a short vertically-oriented injection molded tube (ring) with a diameter of 2.5mm and a length of 4.5mm. Detection of clotting in the CORA System is performed optically. Under control of the analyzer, approximately 20µl of prepared sample is delivered to the tube, where a meniscus naturally forms at each end of the tube. The tube is positioned so that the lower meniscus partially blocks light traveling from a collimated source toward a photodiode.

During testing, a piezoelectric actuator drives the measurement cell(s) through a motion profile composed of summed sinusoids at different frequencies. The profile has a maximum amplitude of under 10µm and contains frequencies from 10-500Hz. Some, but not all, of the measurement cell motion will induce motion in the sample meniscus, which will be detected by the photodiode. The resulting motion of the meniscus is monitored optically and recorded by the analyzer to calculate the resonant frequency and modulus of elasticity (stiffness) of the sample. By performing a Fast Fourier Transform (FFT) on meniscus motion data, it is possible to determine the frequencies of input motion that caused the greatest deflection of the sample (these are called the resonant frequencies).

Resonance is the tendency of a material or structure to oscillate with greater amplitude at some frequencies than others. The exact frequencies at which resonance occurs will depend on the stiffness and mass of the sample. Stiffness, in turn, is a function of a material's modulus of elasticity and the boundary conditions to which the material is exposed, such as the geometry and materials of a test cell. By holding these boundary conditions and sample mass constant from run to run, the CORA System allows direct comparison of elasticity between samples.

In a typical test, blood that has been delivered to the measurement cell will not clot for several minutes. During this time the sample has no inherent stiffness except that provided by surface tension, and since this remains constant the measured resonant frequencies will not change. Once clotting begins, however, the elastic modulus and thus the resonant frequencies increase rapidly. During fibrinolysis, the process is reversed, with elastic modulus and resonant frequencies decreasing. In tests where clotting does not occur, the resonant frequency of the sample will not change. During coagulation, however, a clot will bind to the test tube (ring) and the resonant frequency will rise with increasing firmness of the clot. The

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CORA Analyzer collects meniscus motion data, tracks changing resonant frequencies and analyzes the frequency data to provide semi-quantitative parameters describing the clot. Results are presented in a format similar to the TEG 5000.

Both the TEG 5000 and CORA System monitor the elastic modulus of clots. Method Comparison testing has been performed, yielding data from approximately 300 patients from three sites (Mayo Clinic, University of Pittsburgh Medical Center, and Sinai Hospital, Baltimore). These data include all applicable parameters from the four citrated tests (CK, CKH, CRT and CFF). The TEG 5000 measures the changes of the linkage forces of the clot between the cup and pin over time, while the CORA System measures the changes of the resonant frequency of the clot over time. Despite the difference in the way the two analyzers measure the changes in the modulus of elasticity of the clot over time, they measure the same physical phenomenon and produce the same result when converted from their specific units of measurement (forces for the TEG5000 and frequency for the CORA System) to millimeters. The fact that these results are similar across all reagents used in both technologies is demonstration that the two technologies measure the same phenomenon, the changes in elastic modulus.

The following definitions apply to calculated parameters in the CORA System:

CORA Parameter	Definition	Parameter Relation to Hemostasis
R	R is the time from the start of the test until initial fibrin formation. This represents the enzymatic portion of coagulation.	Normal / reduced / increased speed of coagulation initiation
K	K is the time after R needed to reach a certain level of clot strength. This represents clot kinetics.	Normal / reduced / increased speed of coagulation amplification and propagation
Alpha α (angle)	Alpha is the angle representing the rate increase in the clot strength and the rapidity of fibrin build-up and cross-linking.	Normal / reduced / increased speed of coagulation amplification and propagation
MA	MA, or Maximum Amplitude, represents the maximum firmness of the clot during the test.	Normal / reduced / increased clot elasticity/strength
FLEV	FLEV is an estimate of the fibrinogen level in the blood sample.	Estimated Functional Fibrinogen Level

Citrated Assays

The CK assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle), and Maximum Clot Strength (MA). K and Alpha are complementary parameters and should be used in conjunction with Clotting Time (R) and Maximum Clot Strength (MA).

The CRT assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via both the intrinsic and extrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CFF assay is a semi-quantitative *in vitro* diagnostic assay for monitoring hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. CFF is used in conjunction with CK and clotting characteristics are described by the functional parameter Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

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The CKH assay is a semi-quantitative *in vitro* diagnostic assay used in conjunction with the CORA System to monitor the effects of heparin in the blood stream of a patient. CKH is used in conjunction with CK and heparin influence is determined by comparing Clotting Times (R) between the two tests.

Wet Quality Control (WQC)

Abnormal Wet Quality Control (WQC) material consists of bovine plasma with buffers and stabilizers, and is used instead of hypocoagulable blood, in conjunction with the Citrated Multichannel system cartridge. When used with the Citrated Multichannel cartridge, this material provides consistent and repeatable values for CORA parameters to confirm reagent quality and viability.

Abnormal WQC Intended Use

The Abnormal WQC (Wet Quality Control) Material is intended to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

INTENDED USE AND INDICATIONS FOR USE

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The CORA System records the kinetic changes in a sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARING THE CORA SYSTEM TO THE TEG 5000 PREDICATE DEVICE

Table of Similarities

Item	TEG® 5000 Predicate	CORA® System
Analyzer		
Technological Purpose	Monitoring the response of a clot to low levels of applied strain	Monitoring the response of a clot to low levels of applied strain
What is measured	Changes in clot elasticity over time	Changes in clot elasticity over time
Initial Warm Up Time	5 min	5 min
Time to Complete a Test	Varies with assay	Same as TEG 5000
Assays and Reagents		
Intrinsic Contact Activation Reagent (CK)	Kaolin and $CaCl_2$	Kaolin and $CaCl_2$, same materials as TEG 5000

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Item	TEG® 5000 Predicate	CORA® System
Intrinsic Contact Activation Reagent with Heparinase for heparin reversal (CKH)	Kaolin and $CaCl_2$ with Heparinase	Kaolin, Heparinase and $CaCl_2$, same materials as TEG 5000
Citrated RapidTEG (CRT) (Tissue Factor and Kaolin Activation)	Tissue Factor (TF), Kaolin and $CaCl_2$	Tissue Factor (TF), Kaolin and $CaCl_2$, same materials as TEG5000
Citrated Functional Fibrinogen (CFF) / Platelet-Blocked (Tissue Factor Activation)	ReoPro®, Tissue Factor and $CaCl_2$, same materials as CORA	ReoPro®, Tissue Factor and $CaCl_2$, same materials as TEG 5000
Calcium Chloride Reagent (CC) (for re-calcification)	$CaCl_2$ reagent	$CaCl_2$ same materials as TEG 5000
Quality Control Material (WQC Abnormal Control)	TEG coagulation control – Level II	TEG coagulation control – Abnormal, same materials as TEG 5000

Table of Differences

Item	TEG® 5000 Predicate	CORA® System
Analyzer	Thrombelastography analyzer, separate computer and software	Fully integrated Thrombelastography analyzer
Measuring Technique	Direct-contact measurement of shear elasticity of a coagulating sample	Non-contact measurement of shear elasticity of a coagulating sample
Measuring Channels	Two, each independent and interchangeable (can be used with any approved reagent)	Four, each independent and interchangeable (can be used with any approved reagent)
Signal Transducer	Electromechanical detection (rotary variable inductive transformer) of rotary motion of a pin suspended in the sample	Optical detection (silicon photodiode) of the motion of a free surface of the sample
Temperature Control	20° to 40°C	20° to 50°C
Sample Volume (per channel)	360-380 µl	63 µl
Total Reaction Volume (single channel)	360-380 µl	20 µl
Mains Supply Voltage	120V, 60Hz and 220V, 50Hz model available	100-240V, 50-60Hz (international power supply)
Analyzer Input Voltage	24 volts AC, 30 watts max	12 volts DC, 60 watts max
Environment	Level and vibration free position, no solar radiation Operating temperature: 10° to 35 °C Storage Temperature: -30° to +50 °C (analyzer only) Relative humidity 20-80% (non-condensing)	Stable and level surface. Operating Temperature 10° to 32°C Storage Temperature: -20° to 50°C (analyzer only) Relative humidity 20 to 80% (non-condensing)

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Item	TEG® 5000 Predicate	CORA® System
Sample Preparation	Performed by the operator using pipettes to reconstitute reagents and mix reagents with the sample	Performed under analyzer control within the disposable cartridge
Pipetting	Manual accurate pipettes (10, 20, 50, 100, 340, 360, 500, 1000µl)	Unmetered transfer pipette or syringe; blood sample is added until it fills to a level above the line marked on the blood intake well of the cartridge
Consumables	Cups & Pins (acrylic plastic)	Carrier (acrylic plastic) with microfluidics laminate and test rings (acrylic plastic)

SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Analytical Precision

Testing was performed in Coramed's laboratory for precision, using CLSI EP5-A2 as guidance. Acceptance criteria for all reagents are: CV ≤ 15% for the R parameter, CV ≤ 25% for the K parameter, and CV ≤ 10% for the Alpha and MA parameters. Three types of donor citrated whole blood (CWB) were used in this precision testing:

- Hypo (donors with natural coagulation levels of R parameter near the upper limit of the reference range and MA parameter near the lower limit of the reference range);
- Normal (donors with natural coagulation levels of R and MA parameters near the center of the reference ranges):
- Hyper (donors with natural coagulation levels of R parameter near the lower limit of the reference range and MA parameter near the upper limit of the reference range

Testing was performed with blood draws from three donors (one Hypo, one Normal, and one Hyper) on each of five days (non-consecutive). Testing was performed by two operators using three reagent lots and twelve analyzers, two replicates. The structure of this precision test is shown below.

Sample Type (Hypo, Normal or Hyper)												
	Day 1 (Total of 5 days)											
Operator	Operator 1						Operator 2					
Reagent lot	1		2		3		1		2		3	
Analyzer	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2

Structure of Precision Testing

Precision test estimates by test, parameter and donor sample test level are shown in the table on the following page. All acceptance criteria were met.

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Test	Parameter	Level	n	Mean	Reagent Lot		Operator*		Analyzer (within Operator, Reagent Lot)		Day (within Analyzer, Operator, Reagent Lot)		Repeatability		Total		Total without Day (Within Day)	
					SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
CFF	FLEV	Hypo	120	269.8	2.36	0.9%	0	0.0%	0	0.0%	5.32	2.0%	5.87	2.2%	8.27	3.1%	6.33	2.3%
CFF	FLEV	Normal	120	376.8	0	0.0%	2.25	0.6%	0	0.0%	5.49	1.5%	3.98	1.1%	7.15	1.9%	4.57	1.2%
CFF	FLEV	Hyper	120	597.4	0	0.0%	0	0.0%	0	0.0%	49.38	8.3%	9.62	1.6%	50.31	8.4%	9.62	1.6%
CFF	MA	Hypo	120	14.8	0.11	0.8%	0	0.0%	0	0.0%	0.29	2.0%	0.33	2.2%	0.45	3.0%	0.35	2.3%
CFF	MA	Normal	120	20.6	0	0.0%	0.13	0.6%	0	0.0%	0.3	1.5%	0.22	1.1%	0.39	1.9%	0.25	1.2%
CFF	MA	Hyper	120	32.7	0	0.0%	0	0.0%	0	0.0%	2.71	8.3%	0.53	1.6%	2.76	8.4%	0.53	1.6%
CKH	R	Hypo	120	8.2	0	0.0%	0	0.0%	0.18	2.2%	0.36	4.3%	0.76	9.2%	0.86	10.0%	0.78	9.5%
CKH	R	Normal	120	6.0	0	0.0%	0.05	0.9%	0.09	1.6%	0.14	2.3%	0.42	7.1%	0.46	7.7%	0.44	7.3%
CKH	R	Hyper	120	4.9	0	0.0%	0.05	1.1%	0	0.0%	0.28	5.7%	0.5	10.0%	0.58	12.0%	0.5	10.0%
CK	Angle	Hypo	120	68.7	0	0.0%	1.09	1.6%	0	0.0%	1.61	2.3%	3.01	4.4%	3.59	5.2%	3.2	4.7%
CK	Angle	Normal	120	72.1	0	0.0%	0	0.0%	0	0.0%	1.14	1.6%	1.73	2.4%	2.07	2.9%	1.73	2.4%
CK	Angle	Hyper	120	76.7	0	0.0%	0	0.0%	0	0.0%	1.84	2.4%	1.77	2.3%	2.56	3.3%	1.77	2.3%
CK	K	Hypo	120	1.8	0.03	1.9%	0.06	3.6%	0	0.0%	0.13	7.2%	0.18	10.0%	0.23	13.0%	0.19	11.0%
CK	K	Normal	120	1.4	0	0.0%	0	0.0%	0	0.0%	0.09	6.7%	0.16	12.0%	0.19	13.0%	0.16	12.0%
CK	K	Hyper	120	0.9	0	0.0%	0	0.0%	0	0.0%	0.12	12.0%	0.18	20.0%	0.22	23.0%	0.18	20.0%
CK	MA	Hypo	120	52.4	0.33	0.6%	0.55	1.0%	0.26	0.5%	0.83	1.6%	0.77	1.5%	1.33	2.5%	1.03	2.0%
CK	MA	Normal	120	59.4	0	0.0%	0.5	0.8%	0.48	0.8%	0.57	1.0%	0.86	1.4%	1.24	2.1%	1.1	1.9%
CK	MA	Hyper	120	68.0	0	0.0%	0.2	0.3%	0	0.0%	0.9	1.3%	0.52	0.8%	1.06	1.6%	0.56	0.8%
CK	R	Hypo	120	8.9	0	0.0%	0.29	3.3%	0	0.0%	0.64	7.1%	0.85	9.5%	1.1	12.0%	0.9	10.0%
CK	R	Normal	120	6.5	0	0.0%	0	0.0%	0	0.0%	0.28	4.3%	0.49	7.6%	0.56	8.7%	0.49	7.6%
CK	R	Hyper	120	5.2	0.13	2.5%	0	0.0%	0	0.0%	0.31	5.8%	0.66	13.0%	0.74	14.0%	0.67	13.0%
CRT	MA	Hypo	120	52.4	0.39	0.7%	0.22	0.4%	0	0.0%	0.92	1.8%	0.59	1.1%	1.18	2.3%	0.74	1.4%
CRT	MA	Normal	120	62.7	0	0.0%	0.15	0.2%	0.14	0.2%	0.37	0.6%	0.31	0.5%	0.52	0.8%	0.37	0.6%
CRT	MA	Hyper	120	69.4	0	0.0%	0	0.0%	0	0.0%	0.91	1.3%	0.2	0.3%	0.93	1.3%	0.2	0.3%

*Operator = Operator + operator-by-reagent lot interaction

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In addition, Coramed's Citrated Reagent Precision Protocol Rev. 02 was written to supplement precision data originally provided to FDA in 510(k) K150041. This protocol specifies testing to be performed outside of reference range values but within the Analytical Measurement Range (AMR) limits. This report presents data and statistics resulting from the execution of this protocol.

The following pages contain tables of precision statistics. Table 1 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from normal donors but spiked to achieve hypocoagulable (hypo) and hypercoagulable (hyper) results. Three donors for each reagent-parameter and spiking type were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each donor-reagent-parameter-hypo/hyper type, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B
Sample	Hypercoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

The focus of this study was on achieving values for the primary coagulation parameters R, MA and FLEV outside the reference ranges but within AMR limits, and taking the resulting K and Alpha (angle) values as is. Total Precision %CV values were all within pre-established limits, except for one CFF MA hypo outcome (11.6% for a limit of 10%) and 2 outcomes for Angle. The K and Angle parameters indicate the kinetics of the clotting process, and are not clinically significant as the main parameters representing coagulation, platelet and fibrinogen activities and abnormalities. The CFF MA CV% is higher because the MA value is small (mean of 6.5 mm) and although the Standard Deviation is very small (0.8mm) the resulting CV% is just over the limit. When the SD is so small there is no clinical significance for the differences making this CV% acceptable.

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Table 2 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from patients taking anticoagulants Dabigatran and Warfarin. Four Dabigatran patients and two Warfarin patients for each reagent-parameter were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each patient-reagent-parameter, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1		2		3		4		5		6	
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

Results for this testing were generally within limits, except for a few minor exceptions. As the data shows, all the MAs, for CK, CRT, and CFF, are within the specified expected CV% across the board while for the R parameter, there are no significant differences between lots, operators and devices and the only CVs (for CK and CKH – R parameter) somewhat exceeding 15% come from repeatability (16.9% for MH-DB003 for CK and 15.9% for MH-DB004 for CKH). Even though the, K and Angle are not parameters that are considered clinically significant the raw data indicates that the single angle CV% that is above the limit was due to an outlier while the K parameter has high CVs due to the fact that elongated coagulation results in higher CVs for that parameter.

Test	Param	Spiking	Patient ID	N	Mean	Lot		Operator		Instrument		Repetition		Total	
						StDev	CV	StDev	CV	StDev	CV	StDev	CV	StDev	CV

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CK	R	hyper	D101	12	2.1	0	0	0	0	0.1	4.5	0.1	3.1	0.1	5.5
CK	R	hyper	D108	12	2.7	0	0	0	1	0.1	3.5	0.1	2.4	0.1	4.3
CK	R	hyper	D169	12	2.2	0.1	2.8	0	0	0.1	3.1	0.1	2.5	0.1	4.6
CK	R	hypo	D141	12	16.1	0	0	1.1	6.9	1.3	8	0.7	4.3	1.7	10.8
CK	R	hypo	D169	12	15.3	0.8	5.3	0	0	1.6	10.2	1.1	7.1	2	13.2
CK	R	hypo	D108	12	12.1	0.1	1	0.1	0.9	0.9	7.2	0.7	5.6	1.1	9.3
CK	K	hyper	D101	12	0.5	0	0	0	0	0	3.9	0	4.1	0	5.7
CK	K	hyper	D108	12	0.4	0	3.8	0	3.8	0	7.2	0	6.5	0	10.7
CK	K	hyper	D169	12	0.5	0	0	0	0	0	8.2	0	8.2	0.1	11.6
CK	K	hypo	D141	12	3	0.2	5.2	0.2	6	0.3	9.9	0.2	8.2	0.4	14.6
CK	K	hypo	D169	12	3.1	0.5	16.4	0	0	0.5	14.8	0.3	10	0.7	22.7
CK	K	hypo	D108	12	2.2	0	0	0.1	6.4	0.3	12	0.1	6.2	0.3	14.6
CK	Angle	hyper	D101	12	80	0.8	1.1	1.5	1.8	7.2	9	6.9	8.7	10.1	12.6
CK	Angle	hyper	D108	12	85.1	0.1	0.2	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hyper	D169	12	84.3	0.1	0.1	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hypo	D141	12	54.7	0	0	0	0	8.4	15.4	5.4	9.9	10	18.3
CK	Angle	hypo	D169	12	42.7	1	2.4	1.9	4.5	1.8	4.3	1.6	3.7	3.1	7.2
CK	Angle	hypo	D108	12	66.7	3	4.4	0	0	4.8	7.2	3.3	5	6.3	9.5
CK	MA	hyper	D108	12	71.6	0	0	0.5	0.7	0.3	0.4	0.3	0.4	0.5	0.8
CK	MA	hyper	D169	12	70	0	0	0.1	0.1	0.2	0.2	0.1	0.2	0.2	0.3
CK	MA	hyper	D121	12	71.1	0	0	0	0	0.9	1.3	0.6	0.8	1.1	1.5
CK	MA	hypo	D141	12	42	0.2	0.6	0	0	1.5	3.5	0.9	2.1	1.7	4.1
CK	MA	hypo	D169	12	46.6	0	0	0	0	0.8	1.8	0.5	1.1	1	2.1
CK	MA	hypo	D108	12	45.4	0	0	0.8	1.8	1.2	2.7	0.9	2	1.7	3.7
CKH	R	hyper	D101	12	2	0.1	4.8	0	0	0	2.4	0.1	2.8	0.1	5.5
CKH	R	hyper	D108	12	2.6	0	0	0	0	0.1	2.6	0	1.6	0.1	3.1
CKH	R	hyper	D169	12	2.2	0	0	0	0	0	1.5	0	1	0	1.8
CKH	R	hypo	D141	12	15.7	0	0	1	6.4	0.7	4.5	0.6	4.1	1.3	8.2
CKH	R	hypo	D169	12	14.5	0	0	0.8	5.2	0.8	5.7	0.5	3.2	1.1	7.9
CKH	R	hypo	D108	12	12.3	0.6	5	0	0	0.8	6.3	0.5	4.4	1.1	8.8
CRT	MA	hyper	D108	12	70.8	0.2	0.3	0	0	0.1	0.2	0.1	0.2	0.2	0.3
CRT	MA	hyper	D121	12	72.5	0.2	0.3	0	0	0.4	0.5	0.4	0.5	0.5	0.8
CRT	MA	hyper	D145	12	73	0.2	0.2	0	0	0.2	0.3	0.2	0.2	0.3	0.4
CRT	MA	hypo	D141	12	41.3	0	0	0	0	0.7	1.8	0.5	1.2	0.9	2.2
CRT	MA	hypo	D169	12	44.4	0	0	0.3	0.7	0.6	1.3	0.4	0.9	0.8	1.7
CRT	MA	hypo	D108	12	45.5	0	0	0.4	0.9	1	2.1	0.5	1.1	1.1	2.5
CFF	MA	hyper	D101	12	49.9	0.1	0.1	0	0	0.5	0.9	0.3	0.5	0.5	1.1
CFF	MA	hyper	D141	12	44.3	0	0	0	0	0.5	1.2	0.3	0.6	0.6	1.3
CFF	MA	hyper	D145	12	47	0	0	0	0	0.7	1.4	0.5	1	0.8	1.7
CFF	MA	hypo	D101	12	10.2	0.2	1.5	0	0	0.3	3	0.2	1.7	0.4	3.6
CFF	MA	hypo	D125	12	9.5	0	0	0.2	1.8	0.4	4	0.3	2.7	0.5	5
CFF	MA	hypo	D169	12	6.5	0	0	0.7	10.1	0.3	4.9	0.4	6	0.8	11.6
CFF	FLEV	hyper	D101	12	910.7	1.2	0.1	0	0	8.6	0.9	5	0.5	10	1.1
CFF	FLEV	hyper	D141	12	809	0	0	0	0	9.6	1.2	5.2	0.6	10.9	1.3
CFF	FLEV	hyper	D145	12	858.1	0	0	0	0	11.9	1.4	8.5	1	14.7	1.7
CFF	FLEV	hypo	D101	12	186.4	2.9	1.5	0	0	5.5	3	3.1	1.7	6.8	3.6
CFF	FLEV	hypo	D125	12	173.4	0	0	3.1	1.8	7	4	4.6	2.6	8.7	5
CFF	FLEV	hypo	D169	12	157.5	1.8	1.2	1.1	0.7	2	1.3	1.7	1.1	3.2	2.1

Spiked Precision – Table 1

Test	Param	PatientID	N	Mean	Lot		Operator		Instrument		Repetition		Total	
					StDev	CV	StDev	CV	StDev	CV	StDev	CV	StDev	CV
CK	R	MH-DB001	12	13	0	0	0	0	0.4	3.2	1.2	8.9	1.2	9.4
CK	R	MH-DB002	12	21.3	0	0	0	0	1	4.7	2.1	10.1	2.3	11

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CK	R	MH-DB003	12	14.4	0	0	0	0	0	0	2.4	16.9	2.4	16.9
CK	R	MH-DB004	12	11.8	0.5	4	0.5	4.3	0	0	1.6	13.9	1.7	14.8
CK	R	MH-WR001	12	9.9	0.7	7	0.3	2.7	0.3	2.6	0.5	4.9	0.8	8.5
CK	R	MH-WR002	12	10.1	1	10.2	0	0	0.3	3.2	1	10	1.4	13.6
CK	K	MH-DB001	12	1.3	0	0	0	0	0	0	0.2	18.2	0.2	18.2
CK	K	MH-DB002	12	2.4	0	0	0	0	0.4	15.4	1	42	1	44.5
CK	K	MH-DB003	12	1.3	0	0	0	0	0	0	0.3	19.8	0.3	19.8
CK	K	MH-DB004	12	0.9	0.1	11.4	0	0	0	0	0.3	33	0.3	34.4
CK	K	MH-WR001	12	2.2	0	0	0	0	0	0	0.2	8.2	0.2	8.2
CK	K	MH-WR002	12	2	0	0	0	0	0	0	0.4	19.1	0.4	19.1
CK	Angle	MH-DB001	12	72.5	0	0	0	0	0	0	3.6	5	3.6	5
CK	Angle	MH-DB002	12	55.5	0	0	0	0	10.3	18.6	11.6	20.8	15.2	27.4
CK	Angle	MH-DB003	12	72.7	0	0	0	0	0	0	3.2	4.3	3.2	4.3
CK	Angle	MH-DB004	12	79.5	0	0	0	0	0	0	3.4	4.3	3.4	4.3
CK	Angle	MH-WR001	12	65	0	0	0	0	0	0	1.1	1.7	1.1	1.7
CK	Angle	MH-WR002	12	67.1	0	0	1.1	1.6	0	0	3	4.4	3.1	4.6
CK	MA	MH-DB001	12	60.2	0	0	0	0	0	0	0.9	1.5	0.9	1.5
CK	MA	MH-DB002	12	64.5	0	0	0.2	0.4	0	0	0.6	1	0.7	1
CK	MA	MH-DB003	12	64.1	0	0	0.4	0.7	0	0	0.5	0.8	0.7	1
CK	MA	MH-DB004	12	71.9	0.1	0.1	0.5	0.6	0	0	0.5	0.7	0.7	0.9
CK	MA	MH-WR001	12	60.6	0	0	0	0	0	0	0.9	1.4	0.9	1.4
CK	MA	MH-WR002	12	59.7	0	0	0	0	1	1.6	0.8	1.3	1.2	2
CKH	R	MH-DB001	12	12.2	0.8	6.8	0	0	0	0	0.7	5.8	1	8.2
CKH	R	MH-DB002	12	19.3	0	0	1.6	8.4	0	0	2.2	11.4	2.6	13.5
CKH	R	MH-DB003	12	13.5	0	0	0.5	4	0	0	1.4	10.6	1.5	11.1
CKH	R	MH-DB004	12	11.3	0	0	0	0	0	0	1.8	15.9	1.8	15.9
CKH	R	MH-WR001	12	8.4	0	0	0.1	0.8	0	0	0.8	9.7	0.8	9.8
CKH	R	MH-WR002	12	9.1	0.5	5.1	0	0	0	0	0.7	7.4	0.8	8.6
CRT	MA	MH-DB001	12	64.9	0.1	0.1	0	0	0.1	0.1	0.1	0.2	0.1	0.2
CRT	MA	MH-DB002	12	67.7	0.1	0.1	0	0	0	0	0.2	0.2	0.2	0.2
CRT	MA	MH-DB003	12	66	0	0	0	0	0	0	0.1	0.2	0.1	0.2
CRT	MA	MH-DB004	12	73.8	0.1	0.1	0	0	0.1	0.1	0.2	0.2	0.2	0.3
CRT	MA	MH-WR001	12	64	0.1	0.1	0	0	0	0	0.2	0.3	0.2	0.3
CRT	MA	MH-WR002	12	64.7	0	0	0	0	0	0	0.3	0.4	0.3	0.4
CFF	MA	MH-DB001	12	20.7	0.1	0.4	0	0	0.3	1.3	0.1	0.6	0.3	1.4
CFF	MA	MH-DB002	12	23.7	0.3	1.3	0.3	1.4	0	0	0.2	0.7	0.4	1.6
CFF	MA	MH-DB003	12	23.4	0.2	1	0	0	0	0	0.3	1.5	0.4	1.7
CFF	MA	MH-DB004	12	51.9	1.1	2.2	0	0	0	0	0.4	0.8	1.1	2
CFF	MA	MH-WR001	12	20.7	0	0	0	0	0	0	0.4	1.7	0.4	1.7
CFF	MA	MH-WR002	12	24.7	0.1	0.4	0.3	1.2	0	0	0.3	1.3	0.4	1.7
CFF	FLEV	MH-DB001	12	377.3	1.4	0.4	0	0	4.8	1.3	2.4	0.6	5.3	1.4
CFF	FLEV	MH-DB002	12	432.2	5.8	1.3	6.2	1.4	0	0	3	0.7	6.8	1.6
CFF	FLEV	MH-DB003	12	426.5	4.5	1	0	0	0	0	6.2	1.5	7.3	1.7
CFF	FLEV	MH-DB004	12	947.1	20.9	2.2	0	0	0	0	7.5	0.8	19.3	2
CFF	FLEV	MH-WR001	12	377.4	0	0	0	0	0	0	6.5	1.7	6.5	1.7
CFF	FLEV	MH-WR002	12	450	1.6	0.4	5.2	1.2	0	0	6	1.3	7.7	1.7

Patient-Derived Hypo Samples (Dabigatran and Warfarin) – Table 2

Interference

Testing was performed in Coramed's laboratory for interference, using CLSI EP7-A2 as guidance.

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For CK, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Only Hemolysis and Hemodilution were found to be interferents.

For CRT, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Short Draw, Hemolysis and Hemodilution were found to be interferents.

For CKH, Protamine was tested for interference. Protamine was found to be an interferent for CKH at concentrations above 0.062 mg/ml.

For CFF, potential interferents tested were Na Heparin and Hemodilution. Heparin was found to be an interferent for CFF above Heparin concentrations of 1 IU/ml, and Hemodilution was found to be an interferent above hemodilution levels of 30%.

Linearity

Testing was performed in Coramed's laboratory for linearity, using CLSI EP6-A as guidance.

CFF was tested and found to be linear with varying concentrations of Fibrinogen (RiaSTAP) added. These concentrations ranged from 0 mg/dl to 565.5 mg/dl, over an FLEV range of 156 mg/dl to 1145 mg/dl. This corresponds to an MA range of 8.5 mm to 62.7 mm.

Sensitivity and Specificity

CK was tested for Sensitivity and Specificity with respect to Na Heparin, comparing R parameters of five blood samples with different clinically relevant concentrations of Heparin to five samples without heparin. Both Sensitivity and Specificity were found to be 100%.

Heparin Neutralization

Heparin Neutralization of CKH was tested using blood samples spiked with Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) and comparing these results to data obtained from testing CK with un-spiked blood samples. CKH was found to completely neutralize UFH levels of 5 IU/ml blood and LMWH levels of 0.013 mg/ml blood.

SUMMARY OF CLINICAL PERFORMANCE DATA

Testing was performed at three clinical sites for Reference Ranges and Method Comparison.

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Reference Ranges

Reference Ranges for the CORA assays were estimated using the CLSI C28-A3c Guideline on three reference sample groups. Blood samples from up to 55 normal volunteer subjects were taken at each of the three sites, for a total of 157 samples. There were at least 151 valid results for every parameter for all reagents. Samples were excluded on a per-parameter basis using standard outlier criteria. An alternative method would have been to exclude all parameters for any tests where one or more parameter results were determined to be outliers. However, it was decided to retain all valid parameter results in calculating reference ranges because a larger number of samples adds statistical credibility. Also, it does not appear that using the alternative approach would have any significant effect on the reference ranges. Subjects were chosen representing demographic populations of the three areas, regarding age, race and gender. These reference ranges are shown below.

Reagent ↓	N	R (min)	N	K (min)	N	Angle (deg)	N	MA (mm)	N	FLEV (mg/dl)
CK	157	4.6-9.1	157	0.8-2.1	155	63 - 78	151	52 - 69		
CRT							152	52 - 70		
CKH	155	4.3-8.3								
CFF							151	15 - 32	152	278-581

Reference Ranges for CKH are shown but not usually required because the only purpose is to neutralize the heparin in a patient's blood, regardless of the patient's hemostasis condition. Comparing results from the CK and CKH tests for the R parameter can assist in determining whether or not there is heparin in the blood sample.

Reference Ranges for Wet Quality Control (WQC) Abnormal material when used in CORA assay cartridges were estimated. Using three lots of Abnormal Quality Control and three citrated reagent lots, a total of over 135 test results were obtained.

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (deg)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563-873

Method Comparison

Method Comparison studies were conducted at three clinical sites on patient samples following CLSI EP09-A3 Guideline. The subjects enrolled were patients undergoing cardiovascular surgery or cardiology procedures, with blood samples drawn pre- and post-surgery and in the ICU. In order to broaden the range of comparisons, up to 10% artificially derived samples were added. Statistics are presented below.

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Method Comparison Statistics Summary – All Clinical Sites					
Parameter	**R**	**Intercept**	**95% CI**	**Slope**	**95% CI**
CK – R (min)	0.868	-0.325	-0.425	1.069	1.034
			-0.225		1.103
CK – K (min)	0.740	-0.097	-0.292	0.906	0.769
			0.098		1.042
CK – Alpha (deg)	0.680	7.305	-13.160	0.940	0.640
			27.769		1.240
CK – MA (mm)	0.924	2.351	0.166	0.948	0.912
			4.536		0.983
CKH – R (min)	0.812	-0.329	-0.393	1.057	1.026
			-0.265		1.089
CRT|CK – MA (mm)	0.929	-0.126	-1.909	0.978	0.948
			1.656		1.007
CFF – MA (mm)	0.938	-0.774	-1.836	1.126	1.072
			0.289		1.180
CFF – FLEV (mg/dl)	0.928	-12.495	-36.810	1.127	1.059
			11.819		1.194

In addition, a Reader Study was conducted to assess the comparison of CORA System and TEG 5000 results based on reading printed test outcomes. The study was performed at three sites, using three experienced TEG 5000 doctors as readers at each site, for a total of nine readers. 30 test outcomes were compared for each of the reagent test categories, for a total of 270 reading comparisons per reader. Excellent agreement between the two devices was demonstrated.

In both the Method Comparison Study and Reader Study, the CORA RapidTEG (CRT) MA parameter was compared to the TEG 5000 Kaolin (CK) MA parameter, to demonstrate that the CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTING

The data and information provided in this submission support a substantial equivalence determination for the CORA System and the TEG 5000 predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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Silver Spring, MD 20993-0002

February 27, 2015

Coramed Technologies, LLC
c/o Mr. Norman E. Brunner
Director of RA/QA
6225 W. Howard Street
Niles, Illinois 60714

Re: k150041
Trade Name: CORA® System
Dated: 1-8-2015
Received: 1-9-2015

Dear Mr. Brunner:

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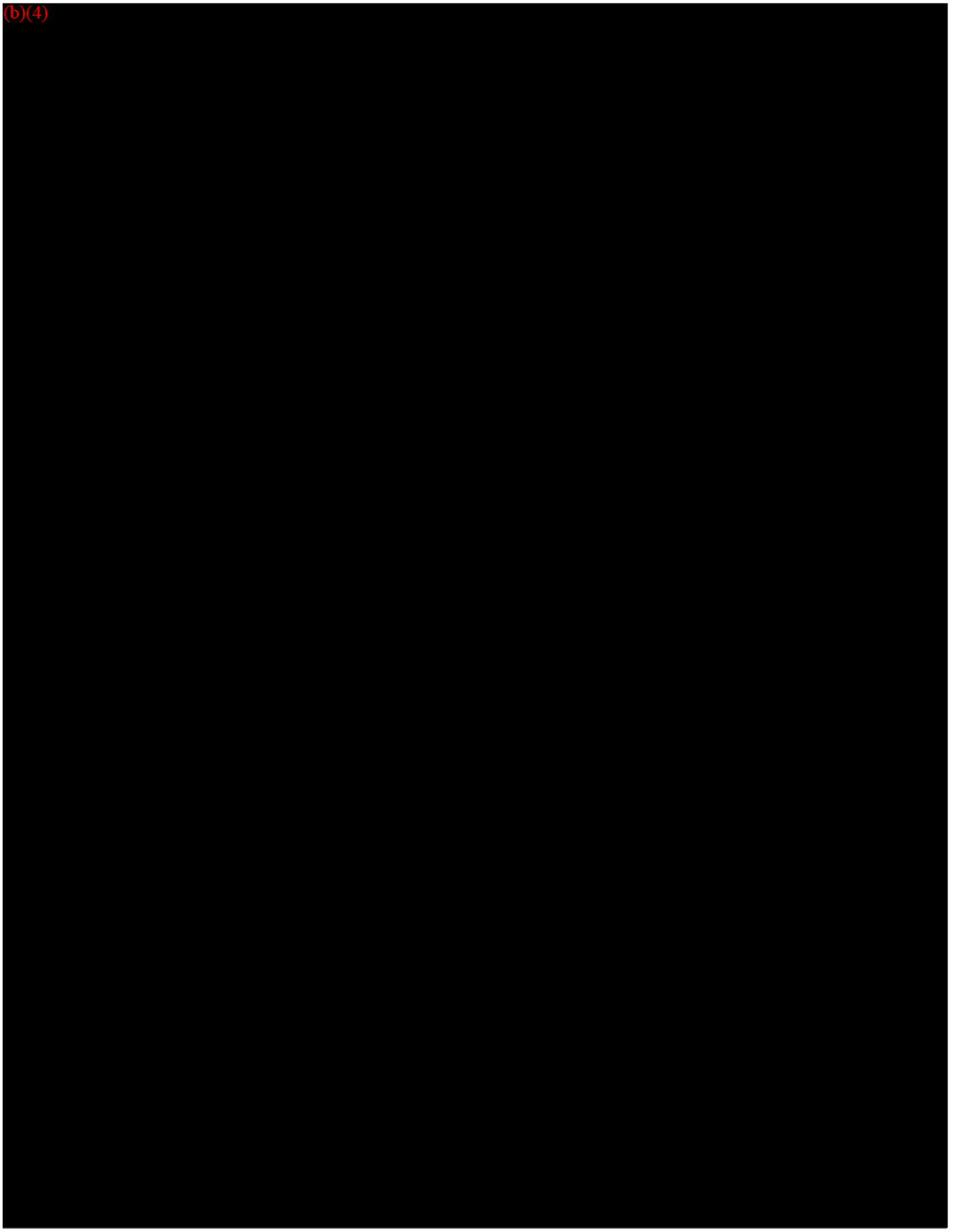
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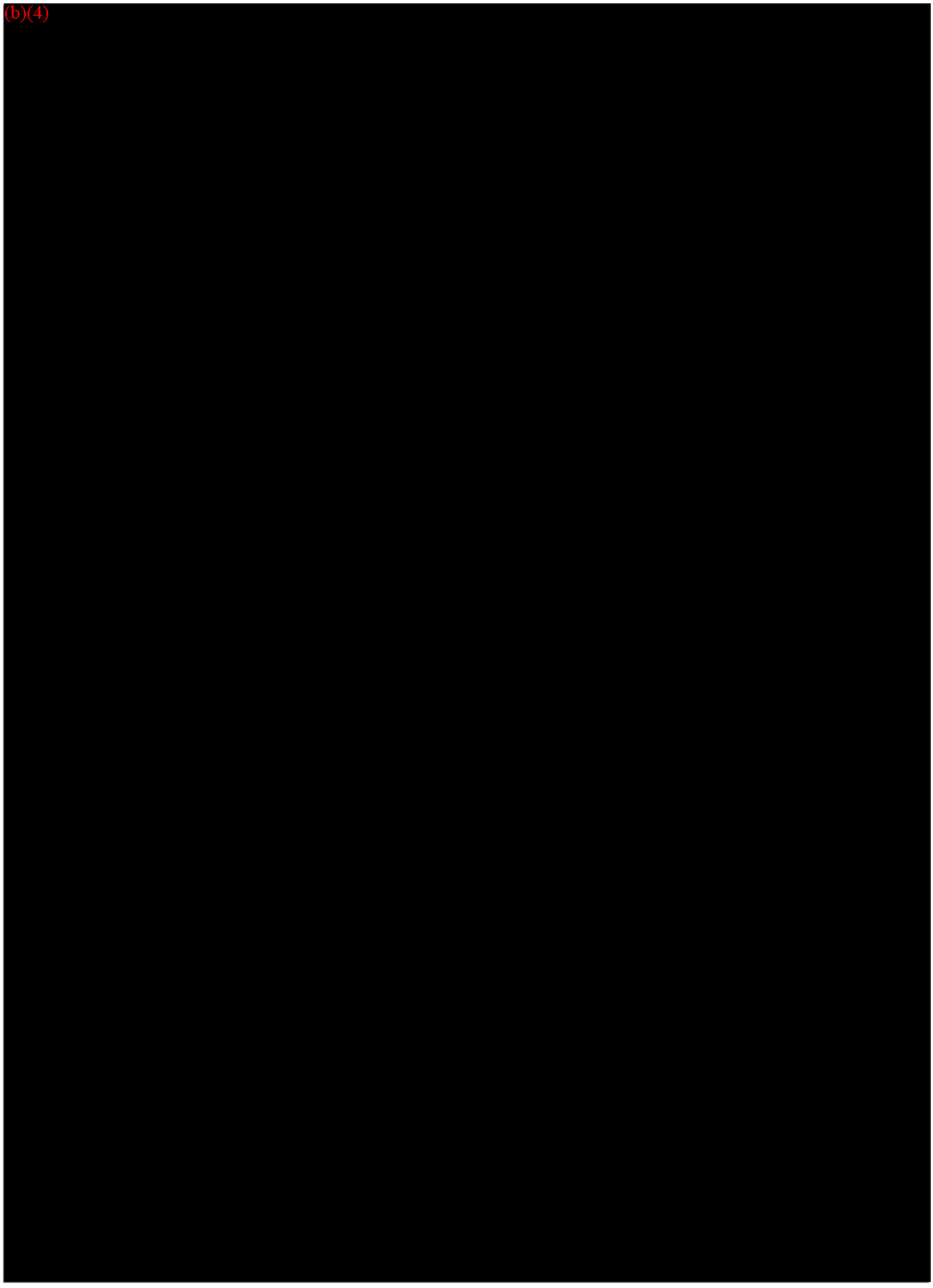
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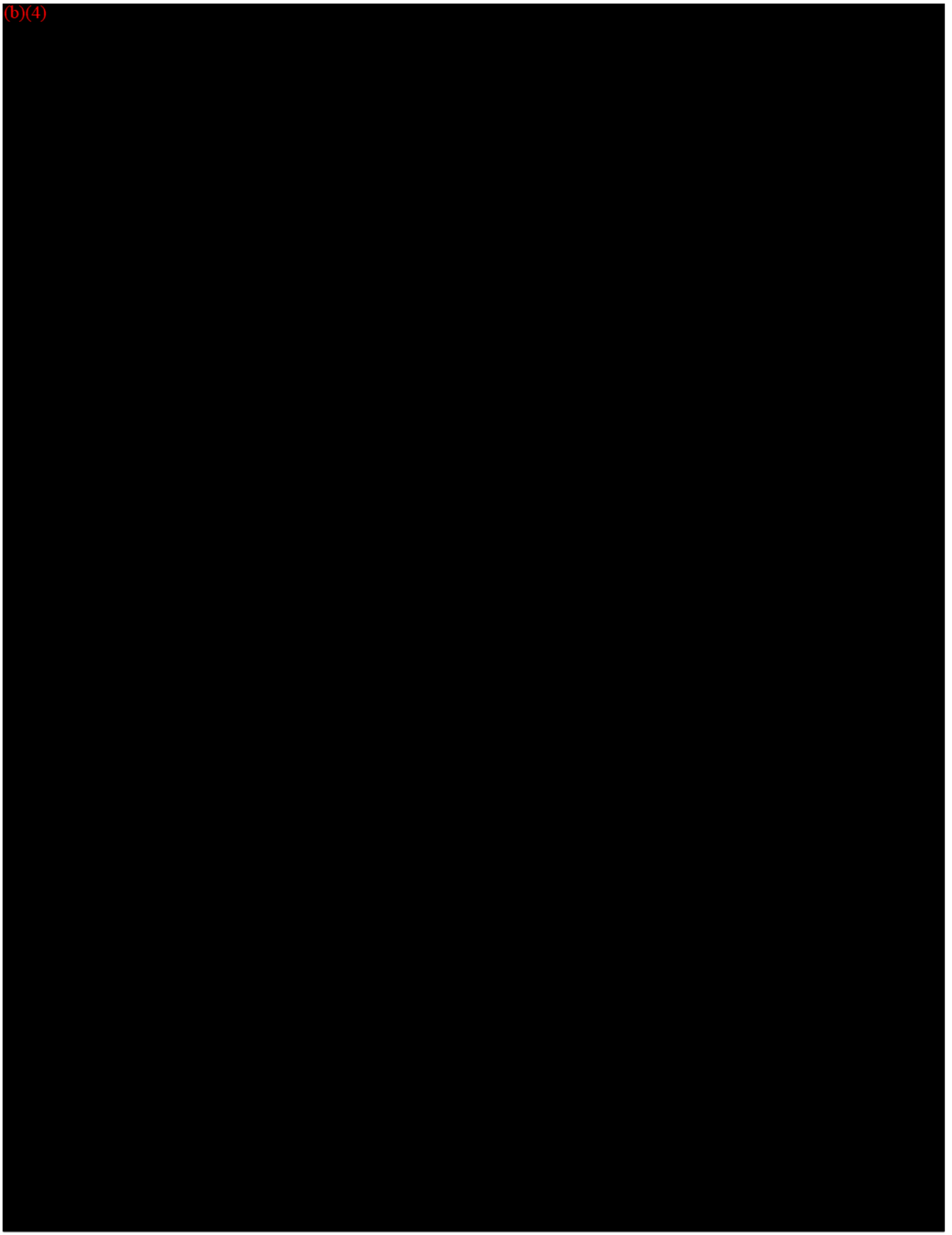
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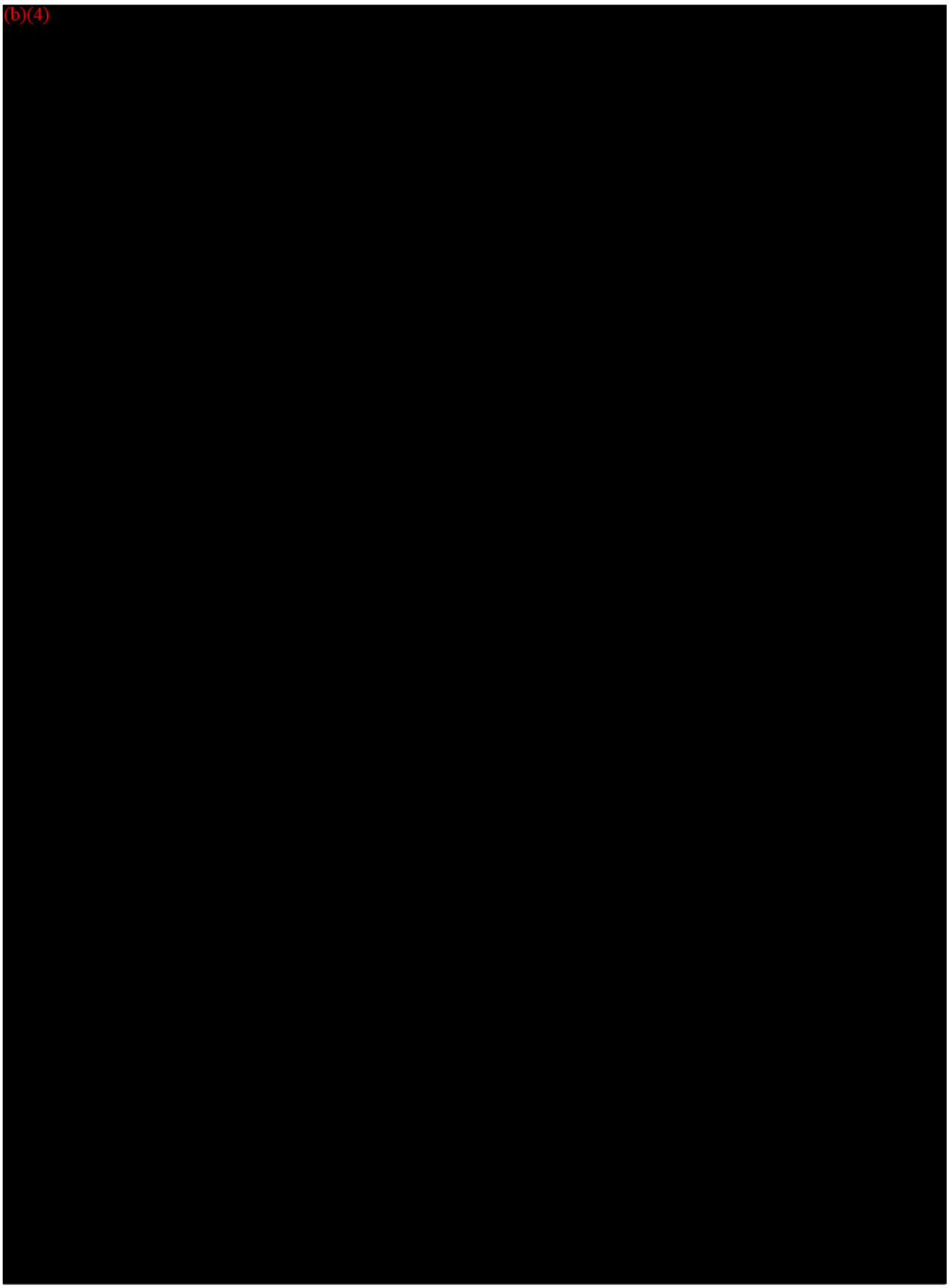
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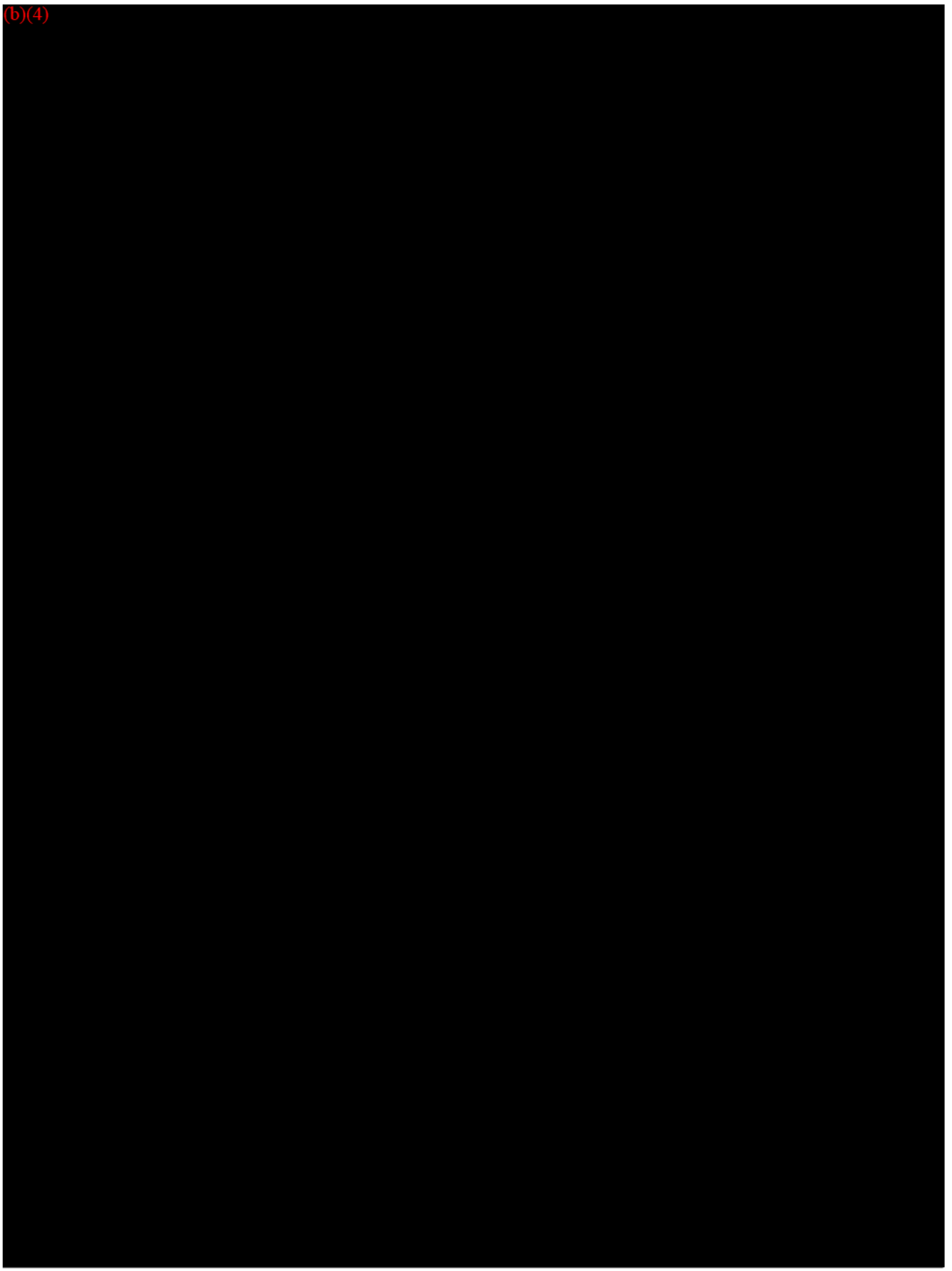
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You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

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Sincerely yours,

Leonthena R. Carrington -A

Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director (Acting)
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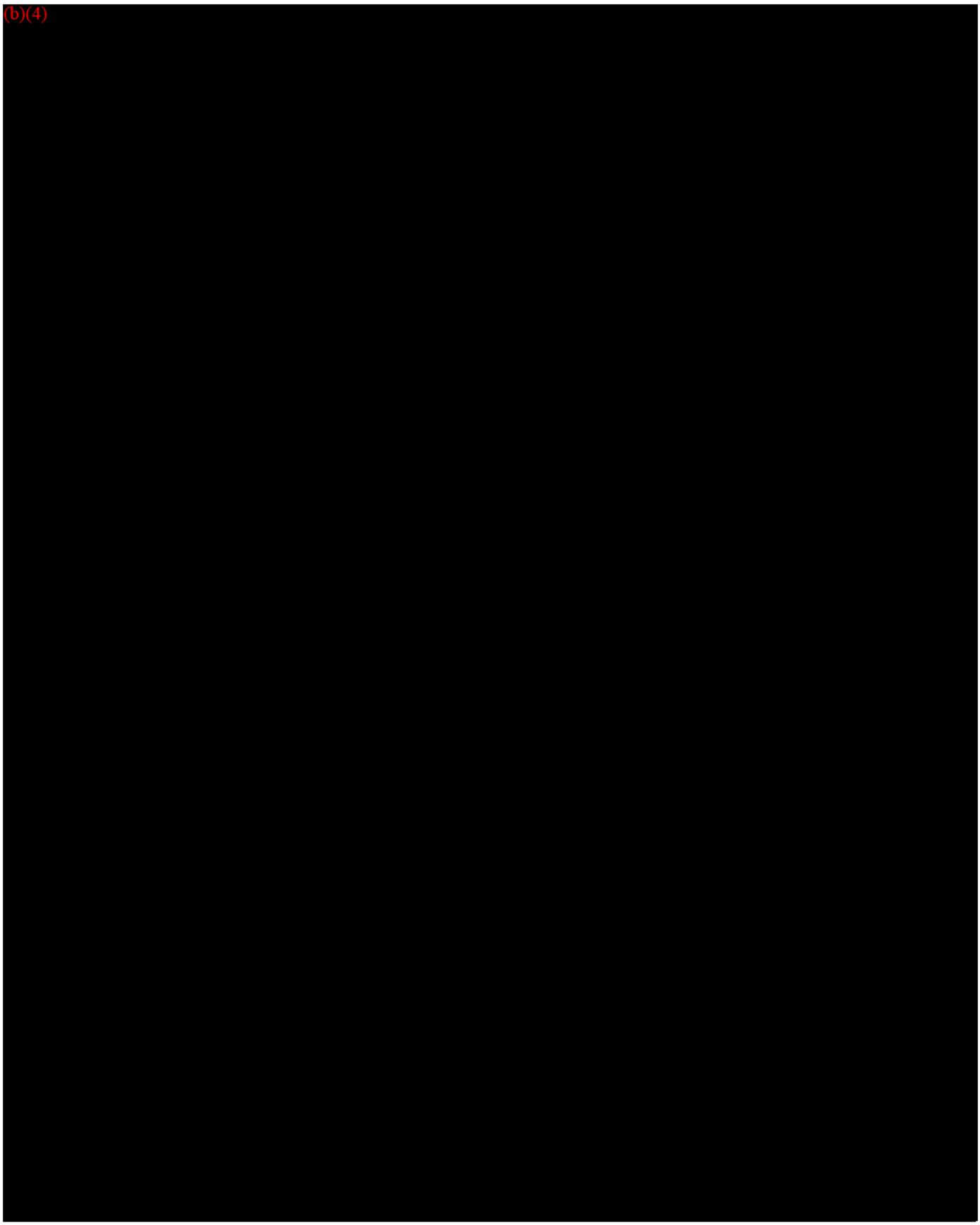
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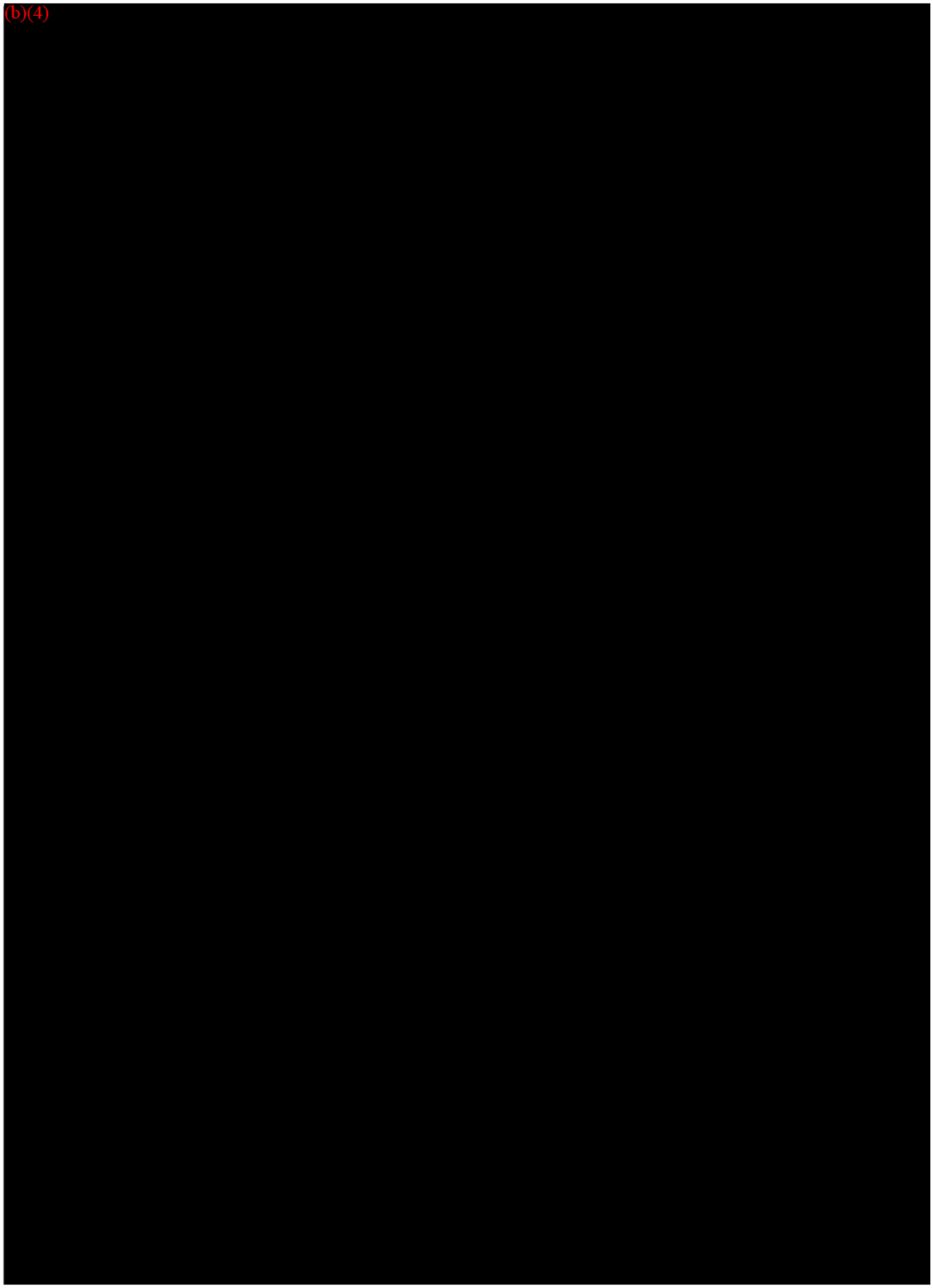
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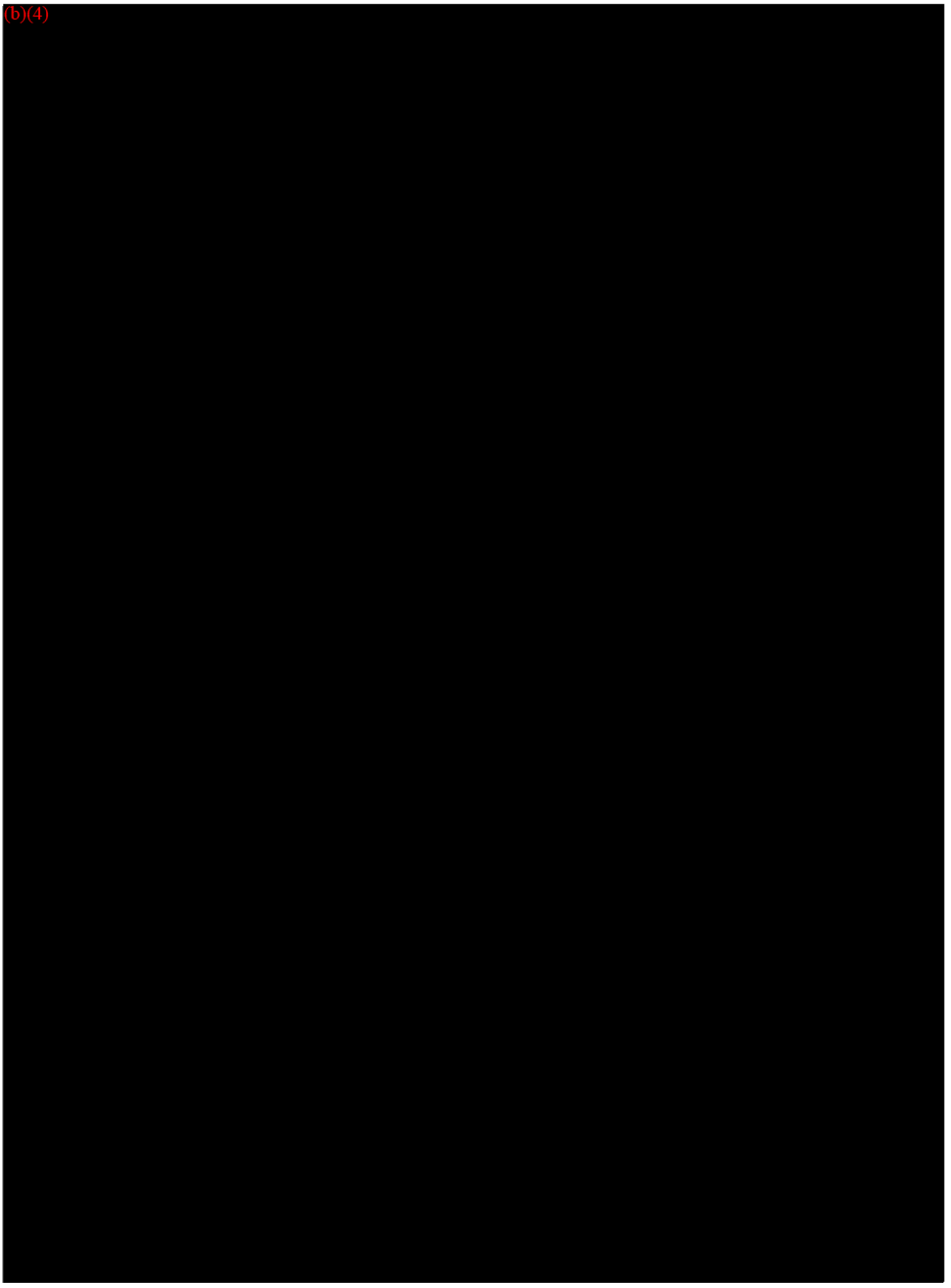
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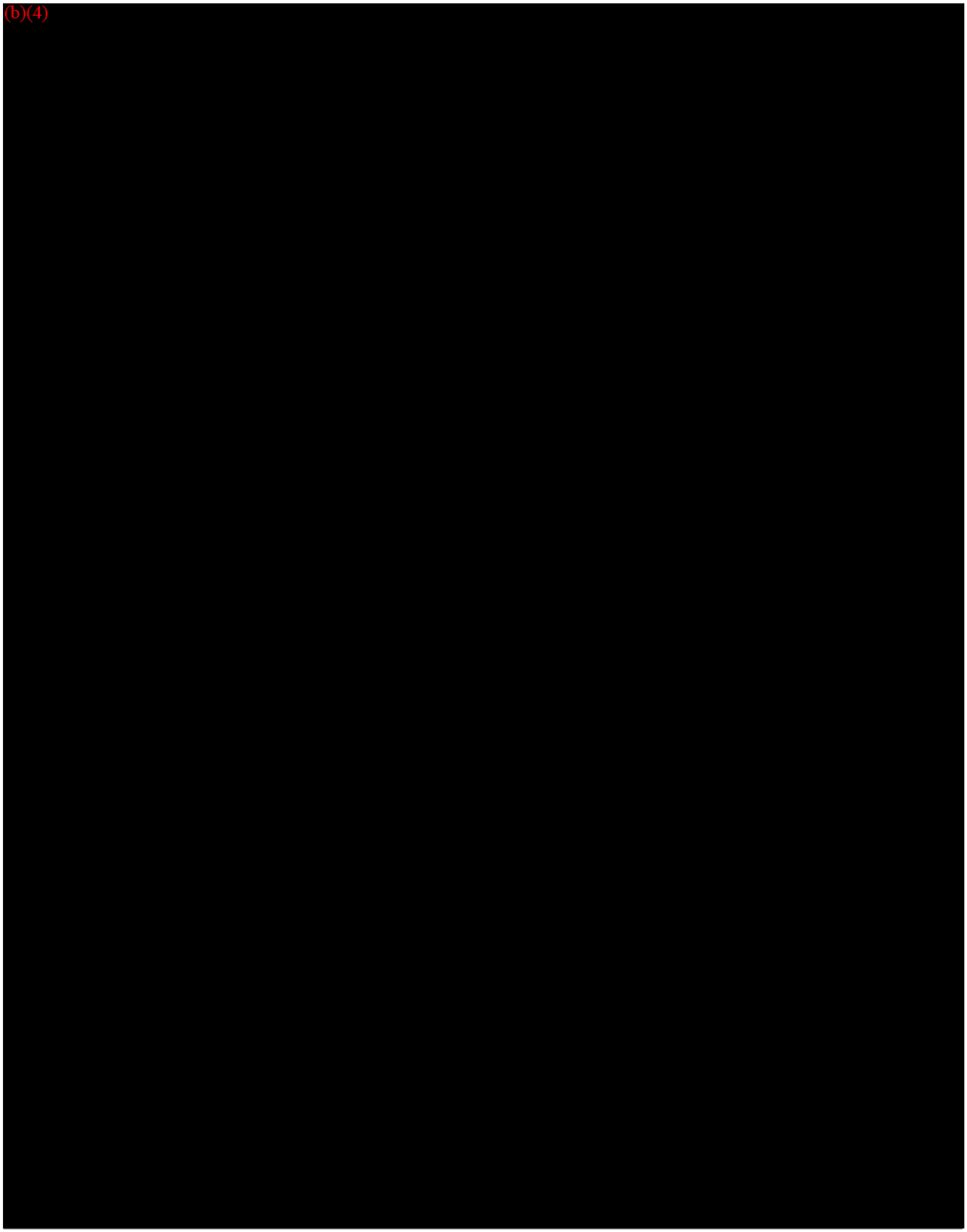
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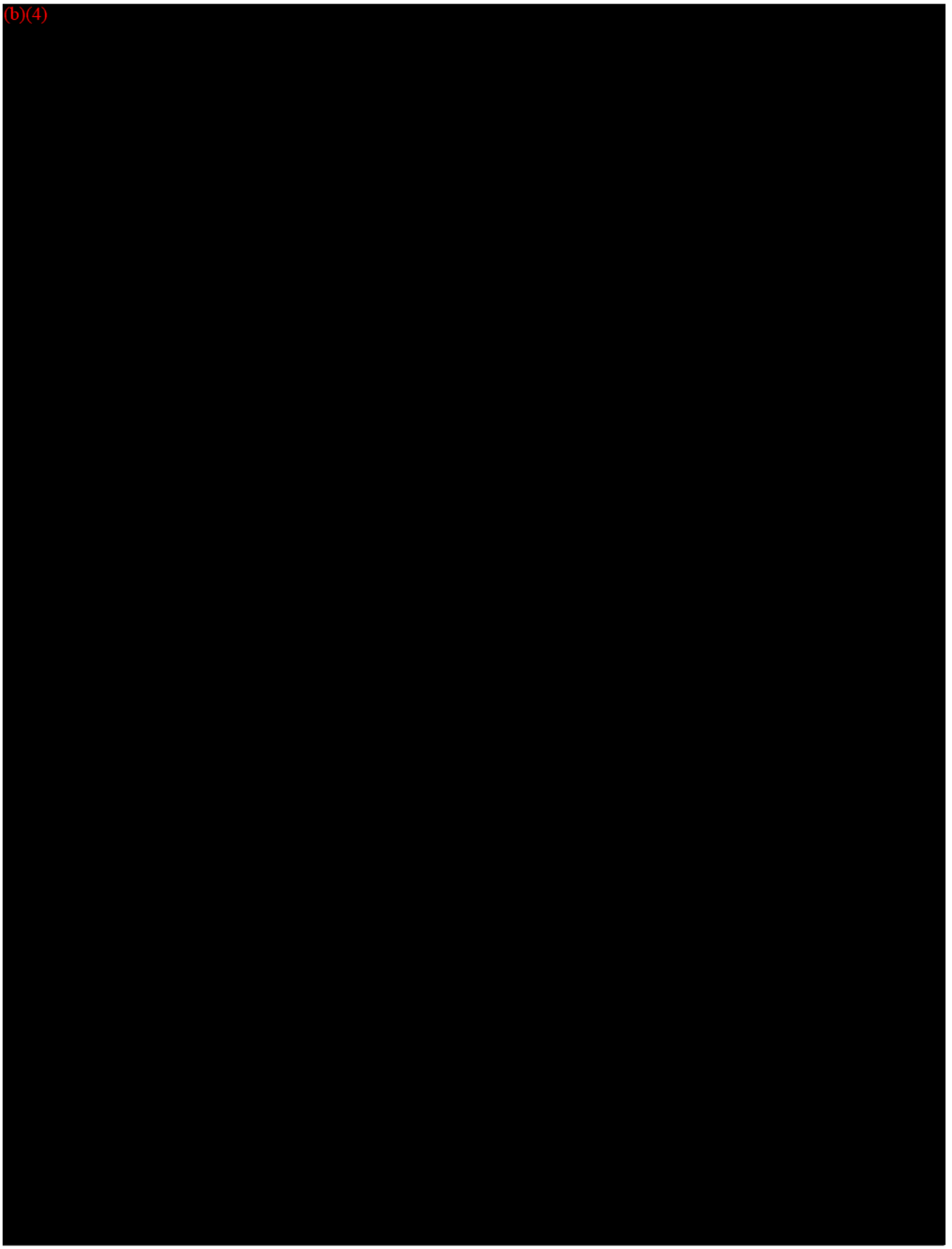
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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM

A. 510(k) Number:

K150041

B. Purpose for Submission:

Clearance of a new device

C. Measurand:

Coagulation factors (intrinsic and extrinsic pathway) and platelet aggregation

D. Type of Test:

Whole blood hemostasis

E. Applicant:

Coramed Technologies, LLC

F. Proprietary and Established Names:

CORA® (Coagulation Resonance Analysis) System

The system includes the CORA instrument and the following reagents: CK (Citrated Kaolin), CRT (Citrated RapidTEG), CKH (Citrated Kaolin with Heparinase), and CFF (Citrated Functional Fibrinogen).

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.5425, Multipurpose system for in vitro coagulation studies

   21 CFR 864.5700, Automated platelet aggregation system

2. Classification:

   Class II

3. Product code:

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JPA, System, Multipurpose For In Vitro Coagulation Control

GGN, Plasma, Coagulation Control

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use(s):

CORA Hemostasis System:

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The CORA System records the kinetic changes in a venous sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV. The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

Citrated Multichannel Cartridge:

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The citrated Multichannel Cartridge, to be used with the CORA System instrument, contains four independent assays (CK, CRT, CKH and CFF), described below.

The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).

The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CKH assay monitors the effects of heparin in 3.2% citrated whole blood specimens on the CORA System. CKH is used in conjunction with CK, and heparin influence is

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determined by comparing Clotting Times (R) between the two tests.

The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contribution to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

Abnormal Wet Quality Control (WQC) Material:

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The Abnormal Wet Quality Control Material is to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

2. Indication(s) for use:

   The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

3. Special conditions for use statement(s):

   Prescription Use Only

4. Special instrument requirements:

   For use with the CORA® (Coagulation Resonance Analysis) Instrument

I. Device Description:

The CORA System consists of a four-channel diagnostic analyzer with integrated computer module, system reagents, and Abnormal Quality Control material and microfluidic test cartridges. The reagents included in the cartridge consist of: 1) Citrated Kaolin (CK); where the hemostasis process via the intrinsic pathway is measured, and clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle), and Maximum Clot Strength (MA), 2) Citrated RapidTEG (CRT); where the hemostasis process via both the intrinsic and extrinsic pathway is measured, and clotting

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characteristics are described by the functional parameter Maximum Clot Strength (MA), 3) Citrated Functional Fibrinogen (CFF); where the hemostasis process, in conjunction with the CK reagent, is monitored after blocking platelet contributions to clot strength, and clotting characteristics are described by the functional parameter Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV), 4) Citrated Kaolin Heparinase (CKH); where the effects of heparin in the blood stream, in conjunction with the CKH reagent, and heparin influence is determined by comparing Clotting Times (R) between the two tests. Reagents are dried-in-place within the cartridges during manufacturing.

Abnormal Quality Control material is lyophilized and can be reconstituted with water as needed for WQC testing with reagent cartridges.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Thromboelastograph® Coagualtion Analyzer (TEG)-5000 Series, Haemoscope Corporation

2. Predicate 510(k) number(s):

   K002177

3. Comparison with predicate:

Similarities		
Item	CORA System	TEG 5000 Predicate
Intended Use	The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The CORA System records the kinetic changes in a venous sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV. The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges. Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture	The TEG 5000 Series Analyzer is intended to be used to provide a quantitative and qualitative indication of the coagulation state of a blood sample by monitoring, measuring, analyzing and reporting coagulation parameter information. The Thrombelastograph (TEG) Coagulation Analyzer TEG-5000 Series records the kinetic changes in a sample of whole blood, plasma or platelet-rich-plasma as the sample clots, retracts and./or lyses (breaks apart). Results from the TEG Analyzer should not be the sole basis for a patient diagnosis; TEG results should be considered along with a clinical assessment on the patient's

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Similarities		
Item	CORA System	TEG 5000 Predicate
	and, if necessary, further hemostasis tests. The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The citrated Multichannel Cartridge, to be used with the CORA System instrument, contains four independent assays (CK, CRT, CKH and CFF), described below. The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA). The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay. The CKH assay monitors the effects of heparin in 3.2% citrated whole blood specimens on the CORA System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests. The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contribution to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the	condition and other coagulation laboratory tests. For professional use only.

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Similarities		
Item	CORA System	TEG 5000 Predicate
	Estimated Functional Fibrinogen Level (FLEV). The Abnormal Wet Quality Control Material is to be used for monitoring the accuracy and precision of tests carried out on the CORA System.	
Matrix	Citrated Whole Blood	Whole blood, plasma or platelet rich-plasma
Measurand	Changes in clot elasticity over time.	Same
Reagents	• Intrinsic Contact Activation Reagent (CK): Kaolin and CaCl2 • Intrinsic Contact Activation Reagent with Heparinase for heparin reversal (CKH) • Citrated Rapid TEG (CRT): Tissue Factor, Kaolin and CaCl2 • Citrated Functional Fibrinogen (CFF)/Platelet-Blocked (Tissue Factor Activated) • Calcium Chloride Reagent (CC) (for re-calcification)	Same
Quality Control	CORA Wet Quality Control (abnormal)	TEG coagulation control – Level 1 (normal) and Level 2 (abnormal)

Differences		
Item	CORA System	TEG 5000 Predicate
Operating Principle	Non-contact measurement of shear elasticity of a coagulating sample: Clotting process causes an increase in the modulus of elasticity, which increases stiffness and increases the force of the clot within the ring walls when moving up and down in the ring tube against the sample's own weight. This increases the resonant frequency, which increases the CORA clot strength amplitude.	Direct-contact measurement of shear elasticity of a coagulating sample: Clotting process causes an increase in the modulus of elasticity, which increases stiffness and increases the force binding the cup and pin when the cup rotates. This increases the rotation of the pin, causing increased angular force on the torsion wire, which increases the TEG clot strength amplitude. During clot dissolution (lysis), the TEG angular force decreases, corresponding to decreasing clot strength amplitude.
Testing Configuration	Vertically-oriented cylindrical container (ring or tube) containing sample with meniscus formed at bottom; non-contact measurement of meniscus amplitude of	Rotating cylindrical container (cup) with pin suspended inside cup; non-contact measurement of pin rotation

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Differences		
Item	CORA System	TEG 5000 Predicate
	vibration	
Measuring Channels	4	2
Signal Generation	Multi-frequency harmonic oscillation of a small open-ended cylinder containing the sample	Single-frequency harmonic oscillation of a cylindrical cuvette containing the sample around a suspended pin
Signal Transduction	Optical detection (silicon photodiode) of the motion of a free surface of the sample	Electromechanical detection (rotary variable inductive transformer) of rotary motion of a pin suspended in the sample
Sample Volume (per channel)	63µL	360-380µL
Reaction Volume	20 µL	360-380µL
Sample Preparation	Performed under instrument control within the disposable cartridge	Performed by the operator using pipettes to reconstitute reagents and mix reagents with the sample
Sample Application	Unmetered transfer pipette or syringe; blood sample is added until it fills to a level above the line marked on the blood intake well of the cartridge	Manual accurate pipettes
Consumables	Carrier (acrylic plastic) with microfluidics laminate and test rings (acrylic plastic)	Cups & Pins (acrylic plastic)

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP05-A2, Vol.19, No. 2 *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline*

CLSI EP6-A, Vol. 23, No. 16 *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*

CLSI EP07-A2, *Interference Testing in Clinical Chemistry; Approved Guideline*

CLSI EP09-A3, Vol. 33, No. 11 *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline*

CLSI EP25-A, Vol. 29, No. 20 *Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline*

CLSI C28-A3c, Vol. 28, No. 30 *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline*

IEC 61010-1 *Safety Requirements for Electrical Laboratory Equipment-Part 1: Edition 2*

IEC 61010-1-2:2007 Ed 3: *Medical Electrical Equipment Part 1-2: Electromagnetic Compatibility-Requirements and Tests*

L. Test Principle:

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The CORA technology is based on a disposable containing up to four independent measurement cells. Each cell consists of a short vertically-oriented injection molded tube (ring) with a diameter of 2.5mm and a length of 4.5mm. Clot detection on the CORA System is performed optically. Under control of the analyzer, approximately 20μL of prepared sample is delivered to the tube, where a meniscus naturally forms at each end of the tube. The tube is positioned so that the lower meniscus partially blocks light traveling from a collimated source toward a photodiode.

To perform a test, a disposable CORA Cartridge is inserted into the analyzer. Blood or WQC material is added to an entry port on the cartridge and drawn into the cartridge under analyzer control. The amount of the sample drawn into the cartridge is automatically determined by the volume of the blood chambers in the cartridge. Once in the disposable, the sample is metered into as many as four separate analysis channels, depending upon the assays being performed. Reconstitution of reagents dried within the cartridge is accomplished by moving the sample back and forth through reagent chambers, under the control of microfluidic valves and bellows (pumps) within the cartridge. After each sample has been mixed with reagent, it is delivered to a test cell where it is monitored for visco-elastic changes due to coagulation. Excess sample material is moved under microfluidic control into an enclosed waste chamber within the cartridge.

During testing, a piezoelectric actuator drives the measurement cell(s) through a motion profile composed of summed sinusoids at different frequencies. Some of the measurement cell motion will induce motion in the sample meniscus, which will be detected by the photodiode. The resulting motion of the meniscus is monitored optically and recorded by the analyzer to calculate the resonant frequency and modulus of elasticity (stiffness) of the sample. By performing a Fast Fourier Transform (FFT) on meniscus motion data, it is possible to determine the frequencies of input motion that caused the greatest deflection of the sample (these are called the resonant frequencies).

Resonance is the tendency of a material or structure to oscillate with greater amplitude at some frequencies than others. The exact frequencies at which resonance occurs will depend on the stiffness and mass of the sample. Stiffness, in turn, is a function of a material's modulus of elasticity and the boundary conditions to which the material is exposed, such as the geometry and materials of a test cell. By holding these boundary conditions and sample mass constant from run to run, the CORA System allows direct comparison of elasticity between samples.

In a typical test, blood that has been delivered to the measurement cell will not clot for several minutes. During this time the sample has no inherent stiffness except that provided by surface tension, and since this remains constant the measured resonant frequencies will not change. Once clotting begins, however, the elastic modulus and thus the resonant frequencies increase rapidly. During fibrinolysis, the process is reversed, with elastic modulus and resonant frequencies decreasing. In tests where clotting does not occur, the resonant frequency of the sample will not change. During coagulation, however, a clot will bind to the test tube (ring) and the resonant frequency will rise with increasing firmness of the clot. The

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CORA Analyzer collects meniscus motion data, tracks changing resonant frequencies and analyzes the frequency data to provide semi-quantitative parameters describing the clot.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision testing was performed in the Coramed laboratory according to CLSI EP5-A2. Acceptance criteria for all reagents are: %CV ≤ 15% for the R parameter, %CV ≤ 25% for the K parameter, and %CV ≤ 10% for the Alpha and MA parameters. Two precision studies were conducted. In the initial precision study, testing was performed with blood draws from three donors (one Hypocoagulable, one Normal, and one Hypercoagulable patient) on each of five non-consecutive days. Testing was performed by two operators using three reagent lots, 120 cartridges per lot, and 12 analyzers.

The precision test estimates for the initial precision study by test, parameter and donor sample test level are summarized in the table below:

Test	Parameter	Level	Mean	Reagent Lot		Operator*		Instrument (within Operator, Reagent Lot)		Day (within Instrument, Operator, Reagent Lot)		Repeatability		Total		Total without Day (Within Day)	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
CFF	FLEV	Hypo	269.8	2.36	0.9	0	0.0	0	0.0	5.32	2.0	5.87	2.2	8.27	3.1	6.33	2.3
		Normal	376.8	0	0.0	2.25	0.6	0	0.0	5.49	1.5	3.98	1.1	7.15	1.9	4.57	1.2
		Hyper	597.4	0	0.0	0	0.0	0	0.0	49.38	8.3	9.62	1.6	50.31	8.4	9.62	1.6
	MA	Hypo	14.8	0.11	0.8	0	0.0	0	0.0	0.29	2.0	0.33	2.2	0.45	3.0	0.35	2.3
		Normal	20.6	0	0.0	0.13	0.6	0	0.0	0.3	1.5	0.22	1.1	0.39	1.9	0.25	1.2
		Hyper	32.7	0	0.0	0	0.0	0	0.0	2.71	8.3	0.53	1.6	2.76	8.4	0.53	1.6
CKH	R	Hypo	8.2	0	0.0	0	0.0	0.18	2.2	0.36	4.3	0.76	9.2	0.86	10.0	0.78	9.5
		Normal	6.0	0	0.0	0.05	0.9	0.09	1.6	0.14	2.3	0.42	7.1	0.46	7.7	0.44	7.3
		Hyper	4.9	0	0.0	0.05	1.1	0	0.0	0.28	5.7	0.5	10.0	0.58	12.0	0.5	10.0
CK	Angle	Hypo	68.7	0	0.0	1.09	1.6	0	0.0	1.61	2.3	3.01	4.4	3.59	5.2	3.2	4.7
		Normal	72.1	0	0.0	0	0.0	0	0.0	1.14	1.6	1.73	2.4	2.07	2.9	1.73	2.4
		Hyper	76.7	0	0.0	0	0.0	0	0.0	1.84	2.4	1.77	2.3	2.56	3.3	1.77	2.3
	K	Hypo	1.8	0.03	1.9	0.06	3.6	0	0.0	0.13	7.2	0.18	10.0	0.23	13.0	0.19	11.0
		Normal	1.4	0	0.0	0	0.0	0	0.0	0.09	6.7	0.16	12.0	0.19	13.0	0.16	12.0
		Hyper	0.9	0	0.0	0	0.0	0	0.0	0.12	12.0	0.18	20.0	0.22	23.0	0.18	20.0
	MA	Hypo	52.4	0.33	0.6	0.55	1.0	0.26	0.5	0.83	1.6	0.77	1.5	1.33	2.5	1.03	2.0
		Normal	59.4	0	0.0	0.5	0.8	0.48	0.8	0.57	1.0	0.86	1.4	1.24	2.1	1.1	1.9
		Hyper	68.0	0	0.0	0.2	0.3	0	0.0	0.9	1.3	0.52	0.8	1.06	1.6	0.56	0.8
	R	Hypo	8.9	0	0.0	0.29	3.3	0	0.0	0.64	7.1	0.85	9.5	1.1	12.0	0.9	10.0
		Normal	6.5	0	0.0	0	0.0	0	0.0	0.28	4.3	0.49	7.6	0.56	8.7	0.49	7.6
		Hyper	5.2	0.13	2.5	0	0.0	0	0.0	0.31	5.8	0.66	13.0	0.74	14.0	0.67	13.0
CRT	MA	Hypo	52.4	0.39	0.7	0.22	0.4	0	0.0	0.92	1.8	0.59	1.1	1.18	2.3	0.74	1.4
		Normal	62.7	0	0.0	0.15	0.2	0.14	0.2	0.37	0.6	0.31	0.5	0.52	0.8	0.37	0.6

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Test	Parameter	Level	Mean	Reagent Lot		Operator*		Instrument (within Operator, Reagent Lot)		Day (within Instrument, Operator, Reagent Lot)		Repeatability		Total		Total without Day (Within Day)	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
		Hyper	69.4	0	0.0	0	0.0	0	0.0	0.91	1.3	0.2	0.3	0.93	1.3	0.2	0.3

*Operator = Operator + operator-by-reagent lot interaction

Additional precision studies were conducted to supplement the initial precision study. Testing was performed with patient derived samples on anticoagulation therapy and contrived samples in order to adequately evaluate performance at the upper and lower limits of the analytical measurement range (AMR). Three different sample types were utilized:

- Hypocoagulable patient derived (blood from six (6) clinical patients being treated with therapeutic levels of anticoagulants (dabigatran or warfarin / Coumadin).
- Hypocoagulable samples consisting of spiked blood from normal donors with natural coagulation levels of R and MA parameters near the center of the reference ranges. Samples were spiked with high concentrations of dabigatran to increase the R parameter and Cytochalasin D and ReoPro® to reduce the MA parameter.
- Hypercoagulable samples consisting of spiked blood from normal donors with natural coagulation levels of R and MA parameters near the center of the reference ranges. Samples were spiked with Kaolin solution to reduce the R parameter and RiaStap® (fibrinogen) to increase the MA parameter.

With few appropriately justified exceptions, the total Precision %CV values of the additional precision studies fell within pre-established acceptance criteria limits of %CV $\leq$ 15% for the R parameter, %CV $\leq$ 25% for the K parameter, and %CV $\leq$ 10% for the Alpha and MA parameters.

Abnormal Wet Quality Control Material:
Repeatability:
The abnormal wet quality control material (WQC) was tested in duplicate over a period of 20 working days. The two (2) runs were be separated by at least two (2) hours. Data analysis calculated estimates of between-day, between-run and within-device precision. Operator-to-operator variability was established with five (5) different operators each using a different CORA instrument to analyze the WQC on one working day, using two different channels per test/sample. Results met the precision criteria outlined in the table below:

Test	R %CV	K %CV	Alpha%CV	MA%CV
Within-run (channel-to-channel)	< 15	< 15	< 10	< 10
Between-day	< 15	< 15	< 10	< 10
Between-run	< 15	< 15	< 10	< 10
Within-device	< 15	< 15	< 10	< 10

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Test	R %CV	K %CV	Alpha%CV	MA%CV
Between-operator	< 15	< 15	< 10	< 10
Between-lot	< 15	< 15	< 10	< 10

WQC Repeatability Summary				
Reagent	Parameter	Mean	SD	%CV
Kaolin (CK)	R (min)	1.085	0.025	2.30
	K (min)	0.823	0.051	6.20
	Angle (deg)	78.54	0.433	0.55
	MA (mm)	33.33	0.759	2.28
RapidTEG CRT)	MA (mm)	35.55	1.458	4.10
Kaolin with Heparinase (CKH)	R (min)	0.951	0.003	0.32
Functional Fibrinogen (CFF)	MA (mm)	36.25	0.096	0.26
	FLEV (mg/dl)	662	1.8	0.27

Reproducibility:
Reproducibility was assessed at three sites, with the same cartridge lot across all sites, and two different CORA instruments per site. At each site, one or more operators performed one run of each of the three lots of WQC in quadruplicate for each reagent. Results met the acceptance criteria summarized in the table below:

Test	R % CV	K %CV	Alpha %CV	MA %CV
Reproducibility Precision	≤ 15	≤ 15	≤ 10	≤ 10

WQC Reproducibility Summary				
Reagent	Parameter	Mean	SD	%CV
Kaolin (CK)	R (min)	1.1	0.15	13.64
	K (min)	0.62	0.05	8.06
	Angle (deg)	81.67	0.83	1.02
	MA (mm)	41.25	3.19	7.73
RapidTEG CRT)	MA (mm)	40.95	2.4	5.86
Kaolin with Heparinase (CKH)	R (min)	1.05	0.08	7.62
Functional Fibrinogen (CFF)	MA (mm)	38.77	2.73	7.04

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WQC Reproducibility Summary				
Reagent	Parameter	Mean	SD	%CV
	FLEV (mg/dl)	707	50	7.07

b. *Linearity/assay reportable range:*

Reference Range for the CORA Reagents:
A normal range for a reference population was established according to CLSI C28-A3c for the CORA Functional Fibrinogen test. The following table contains the reference range data for each parameter. Customers are advised to validate reference ranges based on their local population.

Reagent	N	R (min)	N	K (min)	N	Angle (deg)	N	MA (mm)	N	FLEV (mg/dl)
CK	157	4.6–9.1	157	0.8–2.1	155	63–78	151	52–69		
CRT							152	52–70		
CKH	155	4.3–8.3								
CFF							151	15–32	152	278–581

The assay reportable range is based on the data presented in the method comparison study and summarized in the table below:

Reagent	Parameter	Low	High
CK	R (min)	0.4	17
	K (min)	0.5	5
	Angle (degrees)	39	81
	MA (mm)	40	75
CRT	MA(mm)	40	75
CKH	R (min)	0.3	17
CFF	MA (mm)	4	52
	FLEV (mg/dL)	130	950

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Shelf-life: Real time and accelerated stability studies were performed in support of an 18-month stability claim for CORA System reagents, CK, CKH, CRT, and CFF. Three months of accelerated stability testing was performed with three lots of each reagent stored at 35ºC for the duration of the study. Whole blood from a single donor was tested across all three lots for every time point tested. The reagent stability claim is limited to the available real time stability data available at time of clearance.

Real time stability studies included three (3) lots of each reagent stored at 2–8ºC for the duration of the study. A whole blood sample from the same donor was tested across all cartridges for every time point tested. An isochronous study design was

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utilized, where the 6 and 12-month time points were compared to a newly manufactured lot of cartridges. Similarly, lots stored for 18 or 24 months were compared to another newly manufactured lot of cartridges. The allowable 10% degradation from the initial value was not exceeded in the indicated testing timeframe, thereby supporting an 18-month shelf life claim for storage at 2–8 °C.
In-use stability: For each reagent type, two cartridges from each of three (3) lots were removed from their foil pouches at each of multiple time points and stored at ambient temperature. Cartridges were stored up to three hours under in-use conditions prior to testing. Each cartridge was tested with donor blood in quadruplicate, and compared to results of freshly opened pouches. No significant difference in performance was observed after the claimed two hours of storage under in-use conditions following removal from the foil pouch.

Transport simulation studies: For each reagent type, three (3) lots of reagents were tested for transport stability using a study design based on International Safe Transit Association (ISTA) Procedure 7D "Summer Profile" for 72-hour expedited international airfreight transport. An extended hold at 30°C was added to simulate a total of seven (7) days instead of three (3). The study design is summarized in the table below.

1	Temperature Preconditioning	2–8° C for 24 hours
2	Shock - Drop test	Height of drop based on weight of package
3	Temperature Cycle period 1	22° C for 4 hours
4	Vibration	Overall G_{rms} level of 1.15
5	Temperature cycle period 2	35°C for 6 hours
6	Shock - Drop test	Height of drop based on weight of package
7	Temperature cycle period 3	30°C for 152 hours
8	Temperature cycle period 4	35°C for 6 hours

Compared to one lot of reagent stored at the recommended storage conditions of 2–8°C, stability of the reagent lots is not impacted by the exposure to the simulated shipping conditions outlined in the table above.

Sample stability: In order to assess sample stability, five consecutive runs of each of three patient samples (normal, hypo- and hypercoagulable) were tested. Blood samples were tested in quadruplicate at each time point demonstrating no significant sample deterioration within 2 hours after sample collection.

d. Detection limit:

Not applicable

e. Analytical specificity:

The Kaolin with Heparinase assay was tested to validate that 6 IU of Heparinase per 1 mL of blood (the amount of Heparinase in the CKH assay) will effectively neutralize

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the effects of both Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) on Kaolin-activated citrated whole blood samples.

The capacity to neutralize UFH levels of 5.0 IU/mL blood and LMWH levels of 0.013 mg/mL blood was evaluated by testing spiked whole blood samples tested with the Kaolin Heparinase reagent compared to unspiked matched samples with the Kaolin cartridges. The heparin neutralization results for the R parameters were ≥ 15.2% deviation from unspiked control, where tests reported R parameter values were within the normal range, confirming the neutralization effectiveness of the assay.

The following potential interferents were evaluated in accordance with CLSI EP07-A2:

Reagent	Interferents	Result
CK	Absence of discard tube	No
	Epsilon-animocapoic acid (EACA)	No
	Hemodilution	MA >20%, others ≥50%
	Hemolysis	Yes
	Short draw	No
CKH	Protamine	≥0.062mg/mL
CRT	Absence of discard tube	No
	Epsilon-animocapoic acid (EACA)	No
	Hemodilution	>20%
	Hemolysis	Yes
	Short draw	Yes
CFF	Heparin	>1 IU/mL
	Hemodilution	>30%

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison testing with the predicate device, TEG5000, was conducted at (b)(4) (b)(4) Enrolled subjects were patients undergoing heart surgery or percutaneous coronary intervention (PCI) procedures, with blood samples drawn pre-and post-surgery and in the Intensive Care Unit. Approximately 100 patients were enrolled at each site. In order to broaden the range of comparison for selected parameters, up to 10% contrived samples were added. A summary of the statistical analysis are presented below:

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Method Comparison Statistics Summary – All Clinical Sites					
Parameter	R	Intercept	95% CI	Slope	95% CI
CK – R (min)	0.868	-0.325	-0.425– (-0.225)	1.069	1.034–1.103
CK – K (min)	0.740	-0.097	-0.292–0.098	0.906	0.769–1.042
CK – Alpha (deg)	0.680	7.305	-13.160–27.769	0.940	0.640–1.240
CK – MA (mm)	0.924	2.351	0.166–4.536	0.948	0.912–0.983
CKH – R (min)	0.812	-0.329	-0.393– (-0.265)	1.057	1.026–1.089
CRT|CK – M (mm)	0.929	-0.126	-1.909–1.656	0.978	0.948–1.007
CFF – MA (mm)	0.938	-0.774	-1.836–0.289	1.126	1.072–1.180
CFF – FLEV (mg/dl)	0.928	-12.495	-36.810–11.819	1.127	1.059–1.194

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

For the CORA reagents, normal ranges for a reference population were established according to CLSI C28-A3 with a total of 151–157 measurements in healthy individuals

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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for each parameter. Please refer to the table below for the resulting reference ranges for each parameter.

Reagent	Parameter	Minimum	Maximum	Number of Observations
Kaolin	R (min)	4.6	9.1	157
	K (min)	0.8	2.1	157
	Alpha (degrees)	63.1	77.6	155
	MA (mm)	51.6	68.7	151
Kaolin Heparinase	R (min)	4.3	8.3	155
RAPID TEG	MA (mm)	52.4	69.7	152
Functional Fibrinogen	MA (mm)	15.2	31.9	151
	FLEV (mg/dL)	278.2	580.6	152

N. Instrument Name

CORA Instrument

O. System Descriptions:

1. Modes of Operation:

   Automatic

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ____x____ or No _____

3. Specimen Identification:

   Manual patient identification entry

4. Specimen Sampling and Handling:

   Samples are collected in 3.2% sodium citrate. No further additives or preservatives are necessary to maintain the integrity of the sample, but samples must be used within two hours of draw to maintain in-use stability. The blood is applied to the sample port and is pulled into the four staging areas, mixed with dried reagents before transfer to the test cells.

5. Calibration:

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The CORA instrument is factory calibrated and does not require routine calibration.

6. Quality Control:

Expected value Range for the Abnormal Wet Quality Control (WQC):
Expected value ranges for the WQC material when used with CORA Multichannel Citrated cartridges were estimated, according to CLSI C28-A3c. Using three lots of WQC and three Multichannel Citrated cartridge lots, a total of over 135 test results were obtained.

Reagent & Abnormal WQC (WQC)	R (min)	K (min)	Angle (degrees)	MA (mm)	FLEV (mg/dl)
CK - WQC	0.8–1.5	0.6–0.8	75–83	32–47	
CRT – WQC				32–46	
CKH – WQC	0.8–1.5				
CFF – WQC				30–60	563–873

Citrated whole blood from a healthy individual should be tested in conjunction with the WQC. Laboratories should establish their own normal donor control for reagents and may consider the following:

1) Establish a normal donor control group for normal values using blood drawn from healthy adults, not exposed to medication affecting blood coagulation or platelet function.
2) If the results of donor control assays do not fall within the expected range, a second normal donor should be tested. If the second donor control assay results are also outside the expected range, the assay should be considered out of control and no further testing should be performed.

Coramed recommends that, as a minimum, a normal donor control and the abnormal quality control material check be performed for each new lot of assay cartridges. Additional quality control checks on a monthly, weekly, daily or shift basis may be utilized based on the laboratory's quality control policies. The end user should follow the recommendations of the applicable local and state regulatory guidelines and is advised to call technical support for assistance.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not applicable.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

-------- REMOVE SECTIONS BELOW THIS LINE FOR WEB-POSTING ---------

S. Other Supportive Device and Instrument Information:
Summary of completed validation studies:

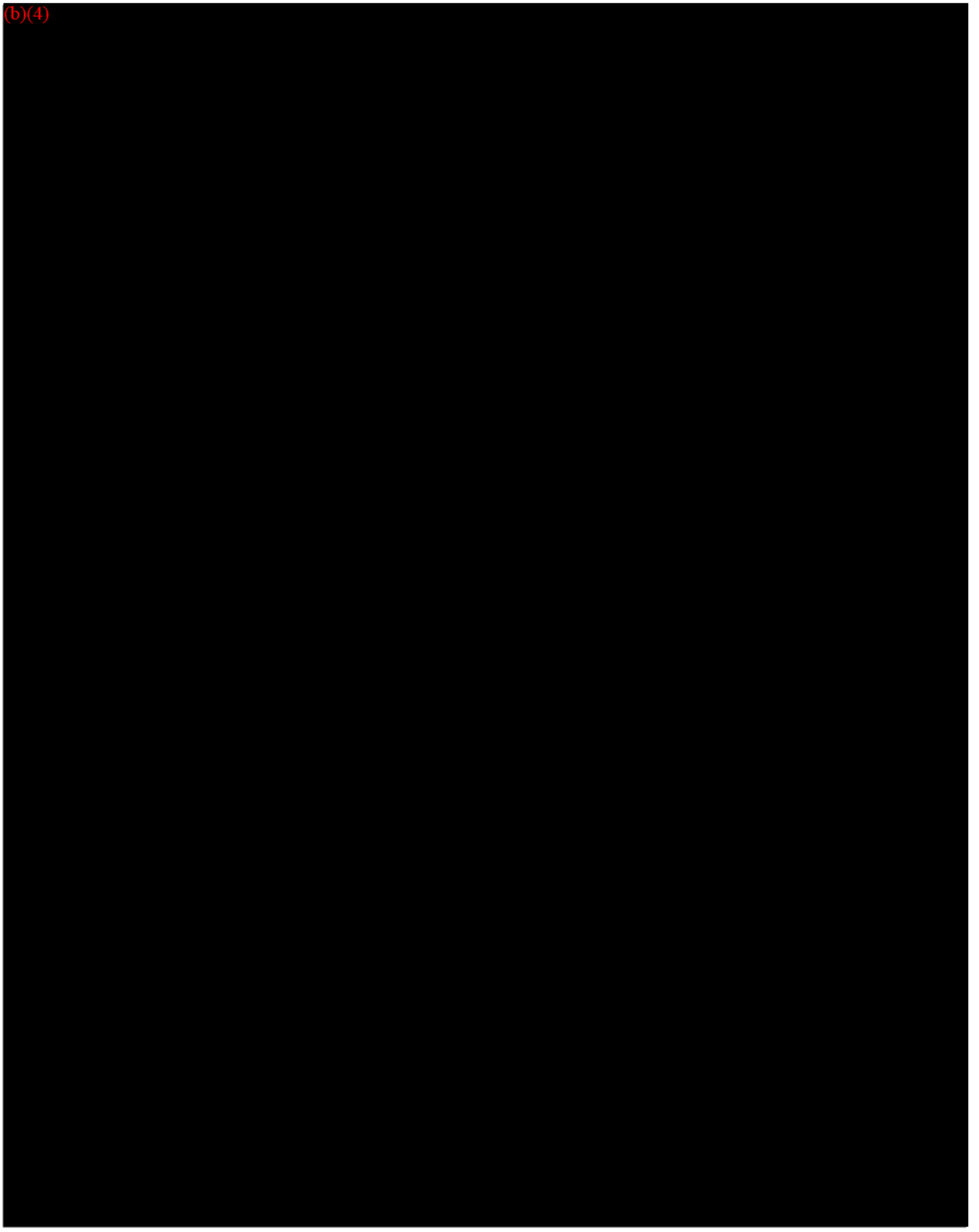
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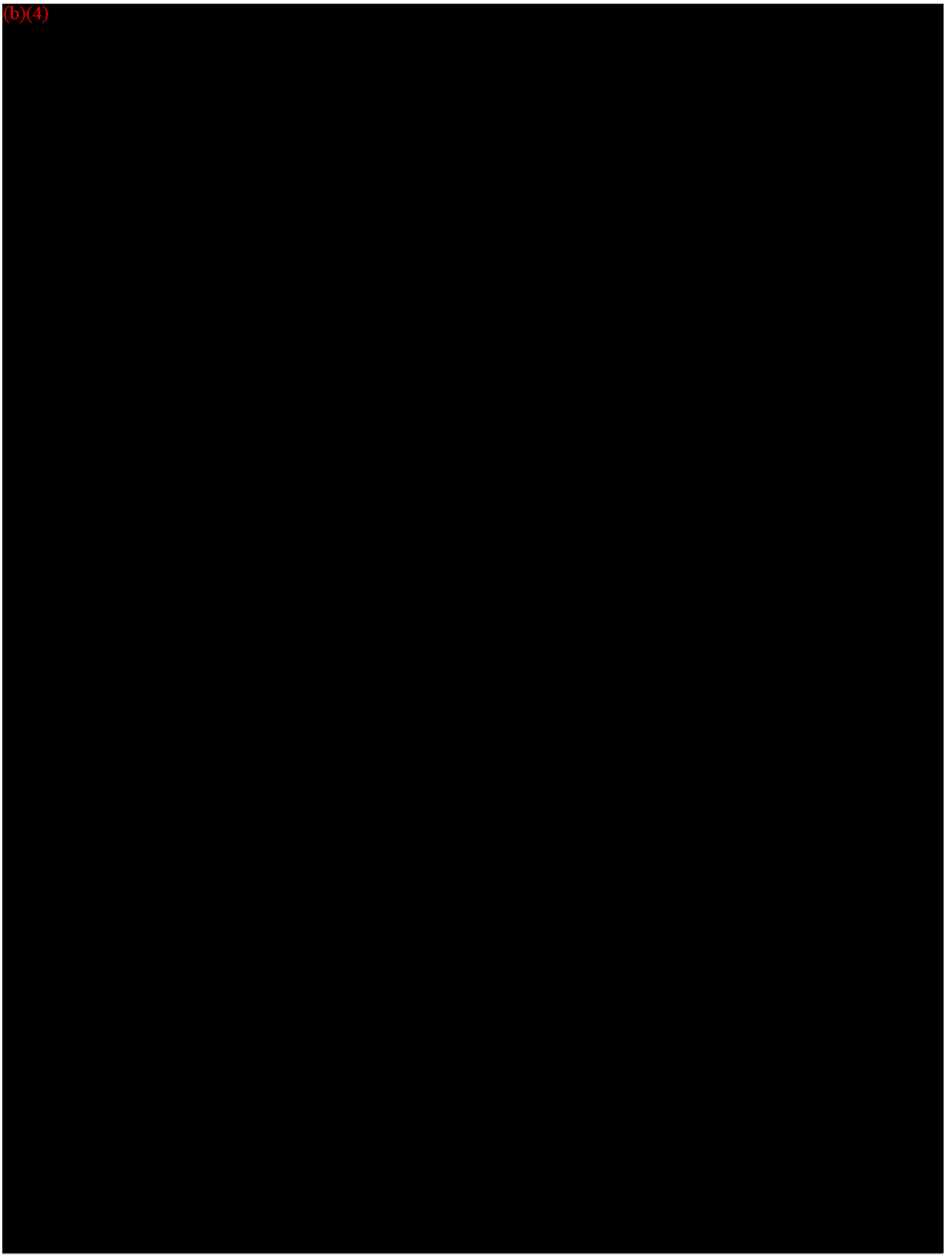
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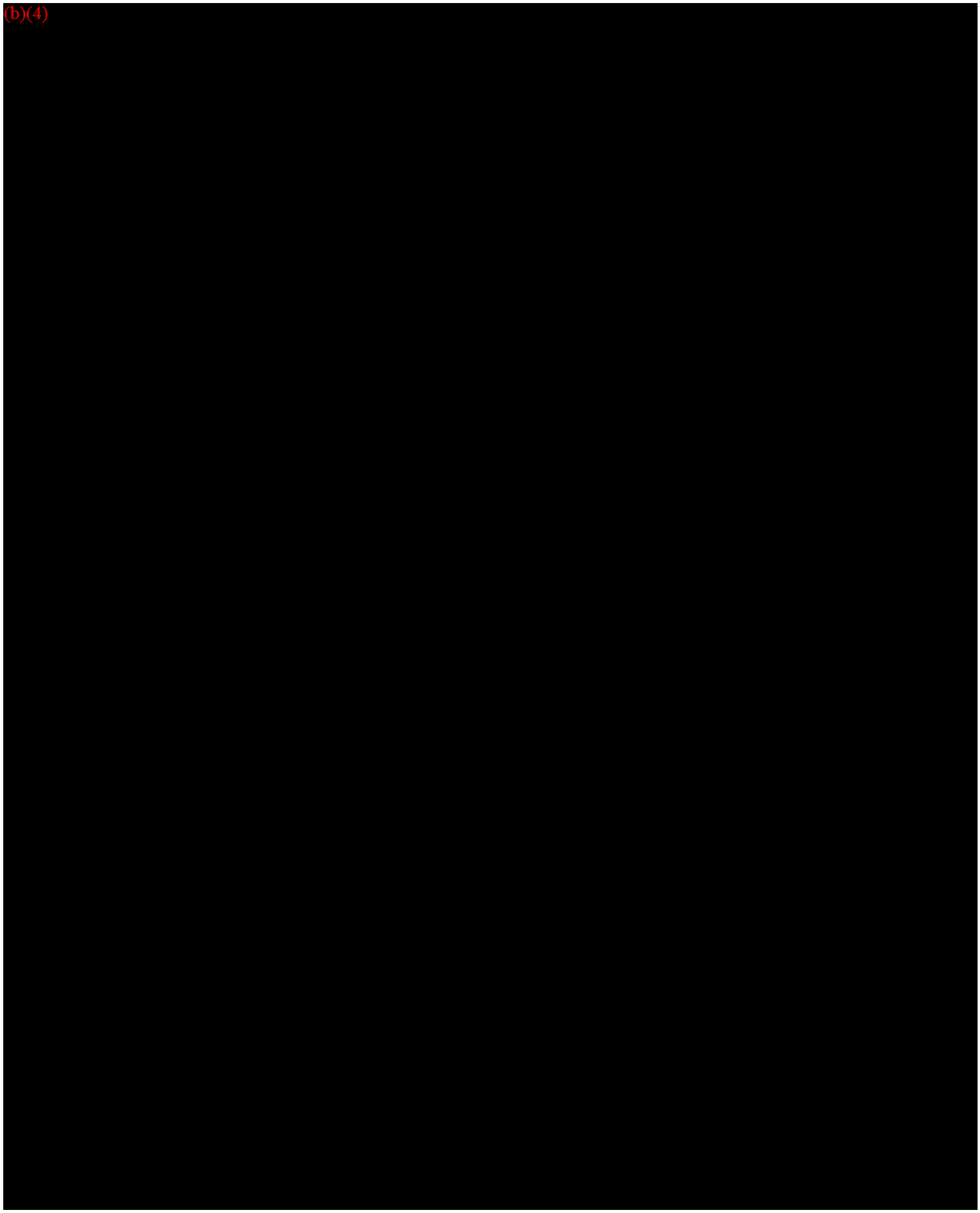
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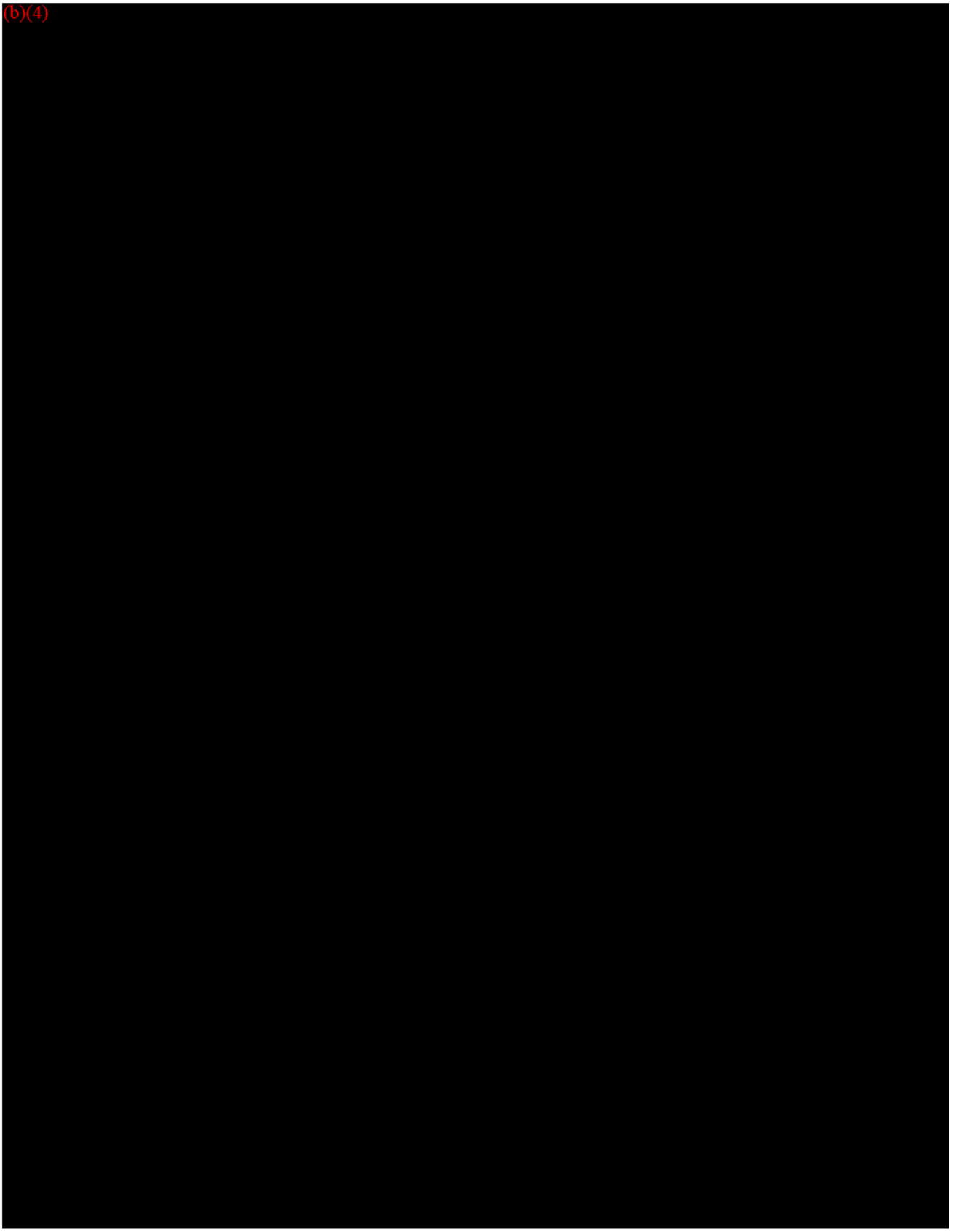
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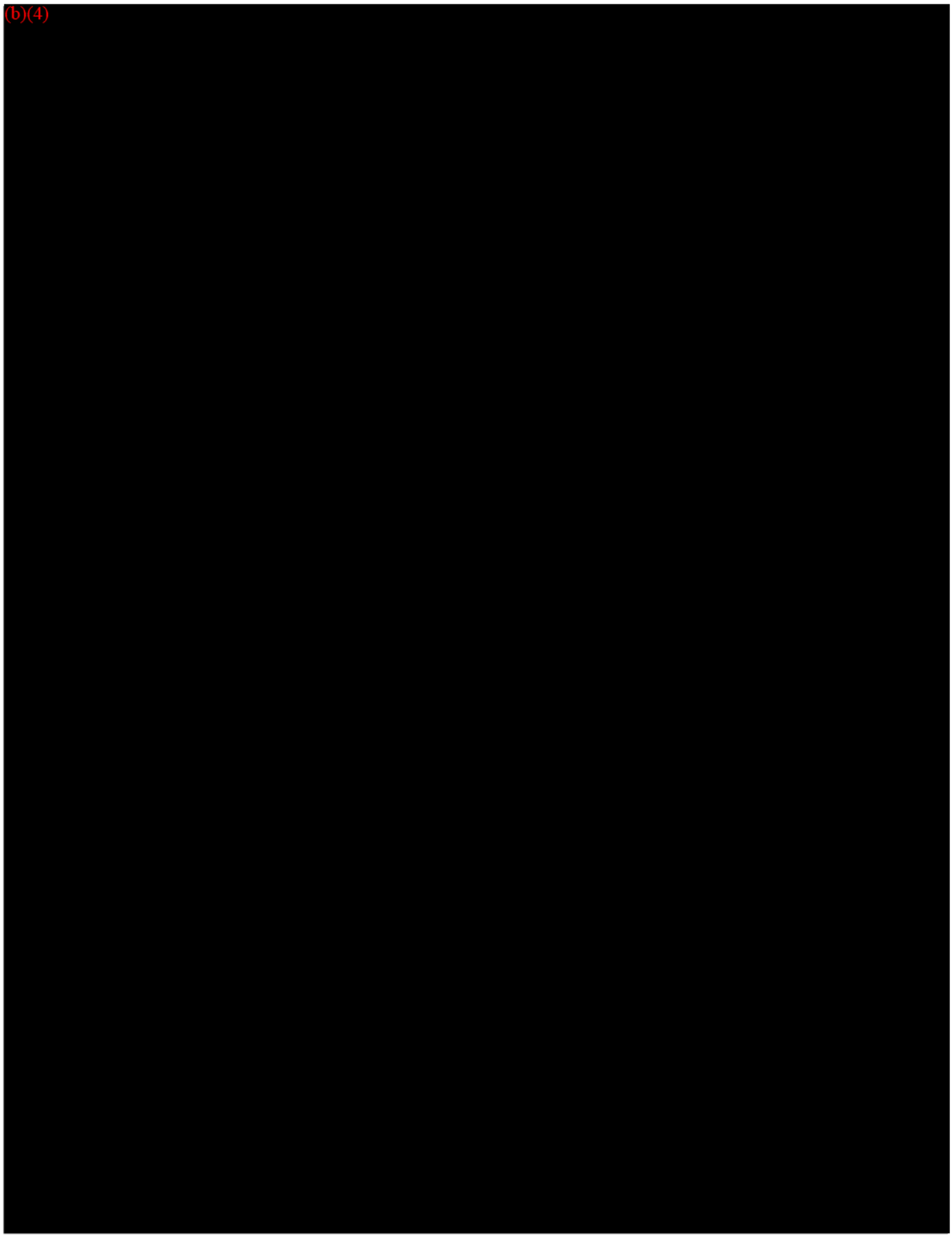
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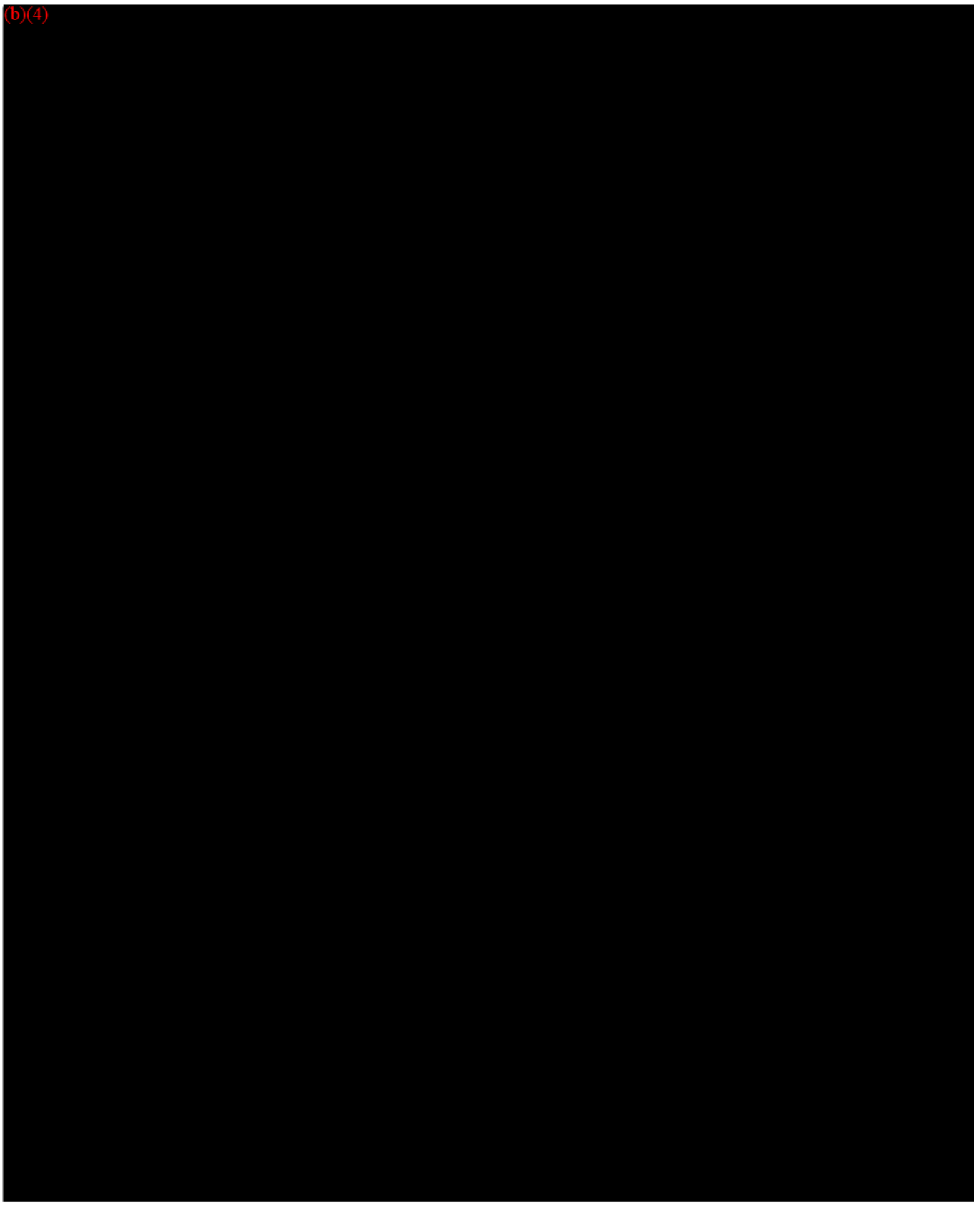
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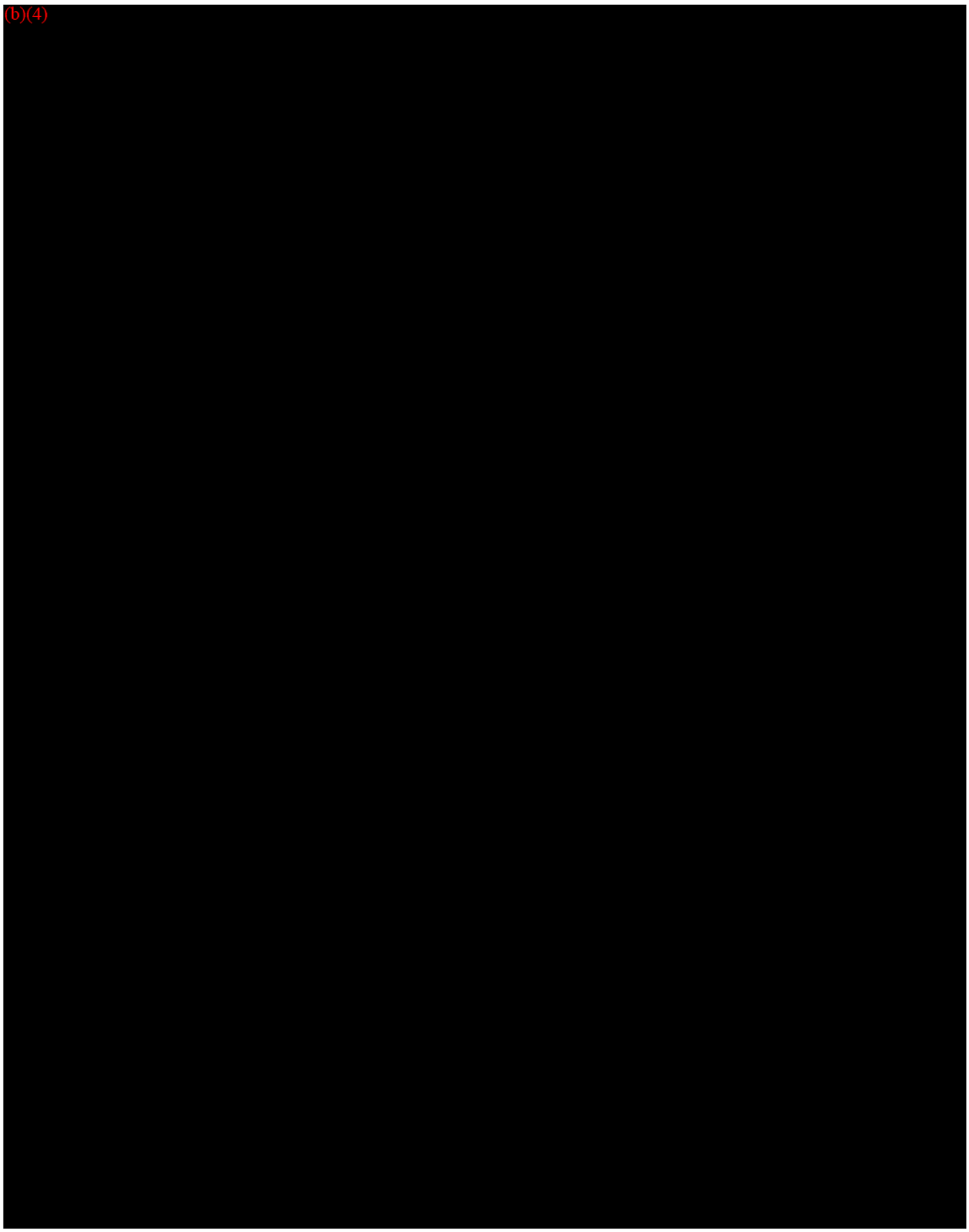
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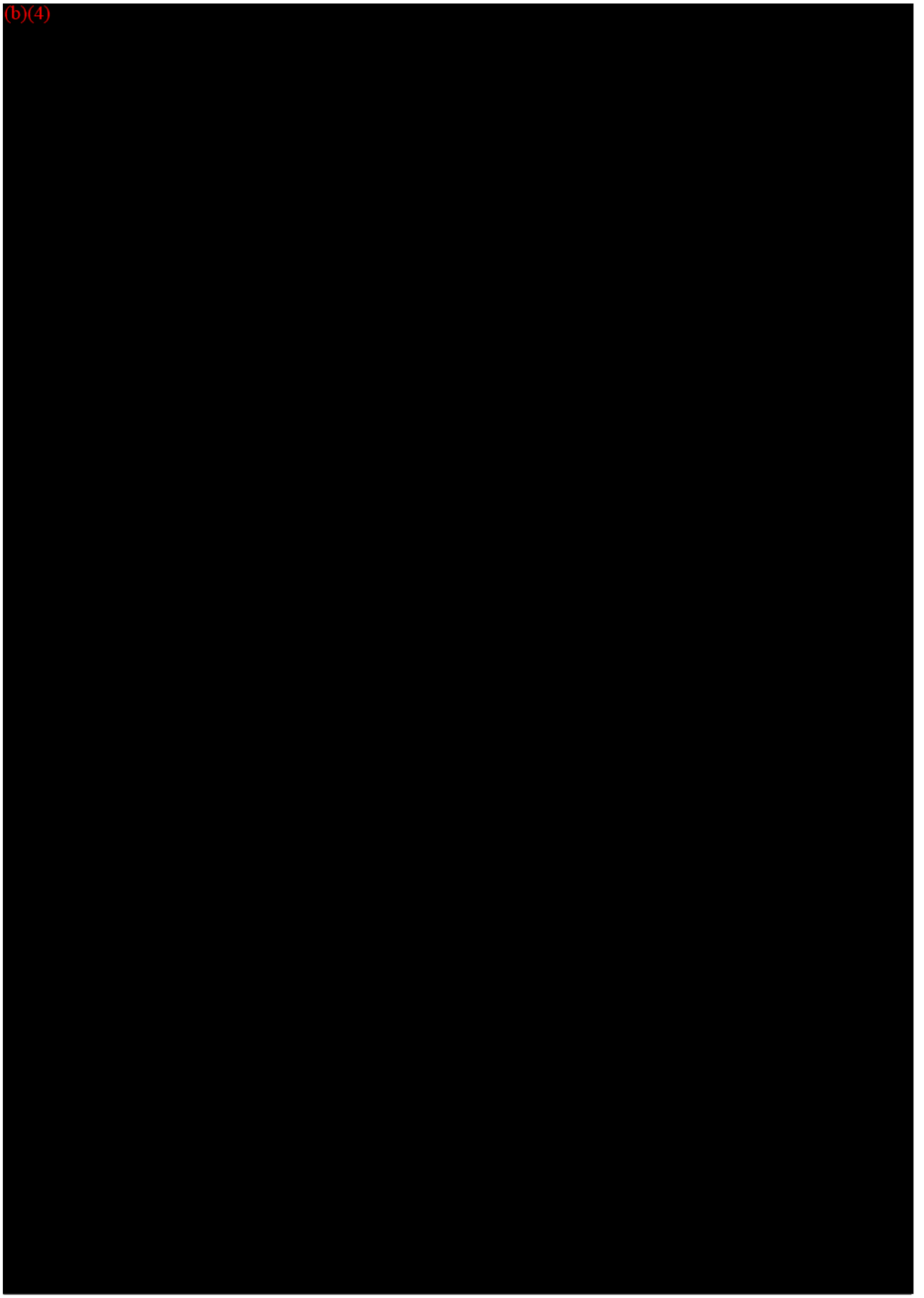
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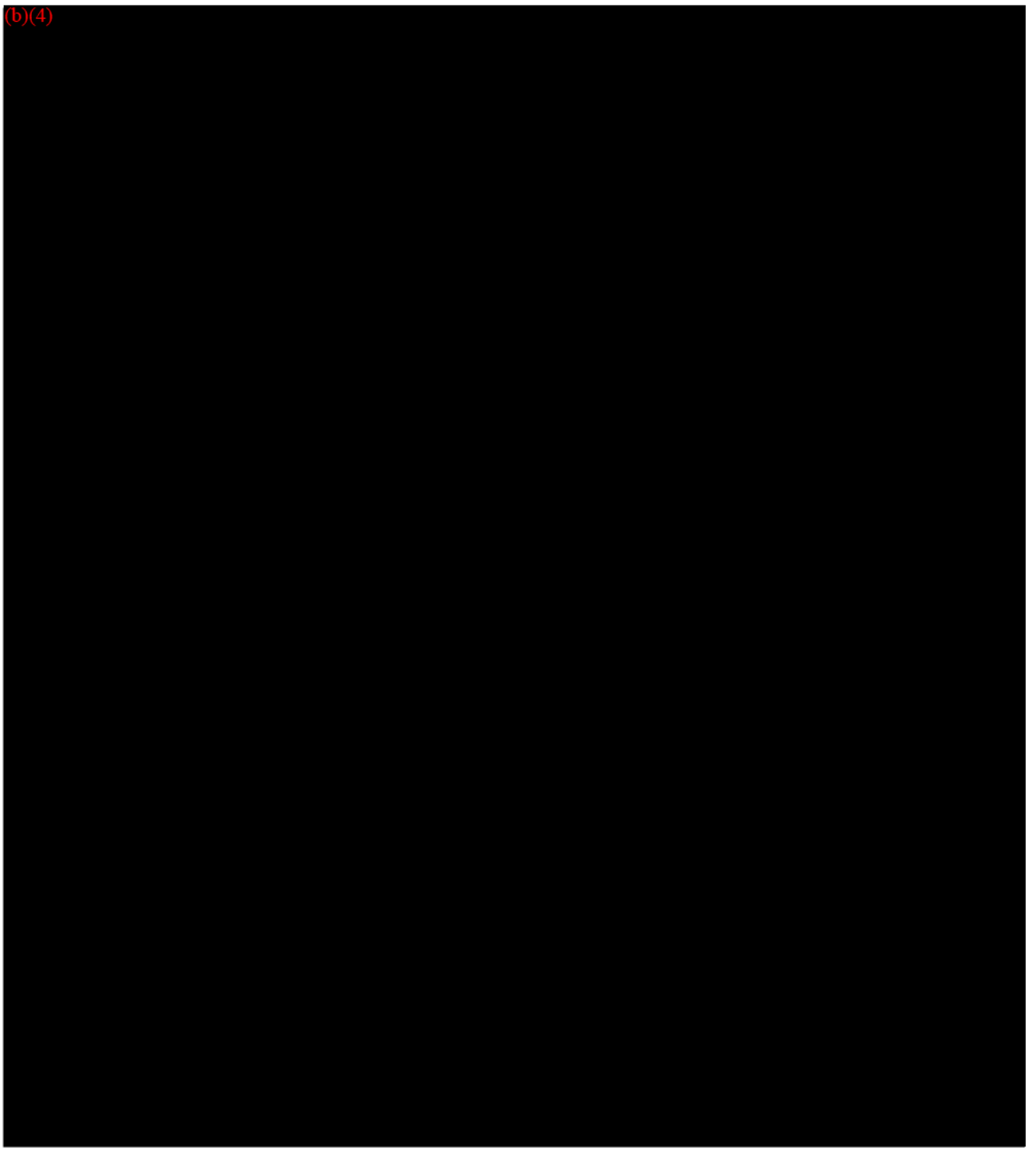
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	Yes	No	
(Identify the new device and the predicate device) 1. Is the predicate device legally marketed?	X		If **YES** = Go To 2 If **NO** = Stop **NSE**
(Review all labeling and assure that it is consistent with IFU statements) 2. Do the devices have the same intended use?	X		If **YES** = Go to 3, Respond to "A." below If **NO** = Stop **NSE**, Respond to "A." below
(Review design, materials, energy source and other features of the devices) 3. Do the devices have the same technological characteristics?		X	If **YES** = Stop **SE** If **NO** = Go to 4, Respond to "B." below
(Determine what questions of safety and effectiveness the different technological characteristics raise) 4. Do the different technological characteristics of the devices raise different questions of safety and effectiveness?		X	If **YES** = Stop **NSE**, Respond to "C." below If **NO** = Go to 5
(Review the proposed scientific methods for evaluating new/ different characteristics' effects on safety and effectiveness) 5a. Are the methods acceptable?	X		If **YES** = Go to 5b If **NO** = Stop **NSE**, Respond to "D." below
(Evaluate performance data) 5b. Do the data demonstrate substantial equivalence?	X		If **YES** = Stop **SE**, Respond to "E." below If **NO** = Stop **NSE**, Respond to "E." below

Final Decision: SE

Note: Please complete the following table and answer the corresponding questions.

A. Please explain how the intended use of the subject device is similar to or different from the predicate device.

The subject device records the kinetic changes in a sample of citrated whole blood as the sample clots, and retracts in real time, whereas the predicate device records the kinetic changes in a sample of citrated whole blood as the sample clots, and retracts in real time.

B. Please describe the different technological characteristics.

Both the subject device and the predicate device monitor the elastic modulus of clots.

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The subject device is based on non-contact measurement of shear elasticity of a coagulating sample, and it measures the changes of the resonant frequency of the clot over time. Briefly, the clotting process causes an increase in the modulus of elasticity, which increases stiffness and increases the force of the clot within the ring walls when moving up and down in the ring tube against the sample's own weight. This increases the resonant frequency, which increases the subject device's clot strength amplitude.

The predicate device measures shear elasticity of a coagulating sample by direct contact, and it measures the changes of the linkage forces of the clot between the cup and pin over time. Briefly, the clotting process causes an increase in the modulus of elasticity, which increases stiffness and increases the force binding the cup and pin when the cup rotates. This increases the rotation of the pin, causing increased angular force on the torsion wire, which increases the predicate device's clot strength amplitude.

C. Please explain how the technological characteristics raise different questions of safety and effectiveness.

Not applicable

D. Please explain why the proposed scientific method for evaluating new/ different characteristics' effects on safety and effectiveness are not acceptable.

Not applicable

E. Please explain how the data do or do not demonstrate substantial equivalence.

The performance data provided for precision, stability, interference, linearity, sensitivity and specificity, heparin neutralization, reference range and method comparison demonstrate that device performance was not affected by changes in the technology.

U. Reviewer Name and Signature:

Digital Signature Concurrence Table	
Reviewer Sign-Off	Seameen J. Dehdashti -S (Affiliate) 2015.06.26 10:24:36 -04'00'
Branch Chief Sign-Off (optional)	
Division Sign-Off (optional)	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 26, 2015

Coramed Technologies, LLC
Mr. Norman Brunner
Director of RA/QA
6225 W. Howard Street
Niles, IL 60714

Re: K150041
Trade/Device Name: CORA® (Coagulation Resonance Analysis) System
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: II
Product Code: JPA
Dated: May 21, 2015
Received: May 22, 2015

Dear Mr. Brunner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 26, 2015

Coramed Technologies, LLC
Mr. Norman Brunner
Director of RA/QA
6225 W. Howard Street
Niles, IL 60714

Re: K150041
Trade/Device Name: CORA® (Coagulation Resonance Analysis) System
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: II
Product Code: JPA
Dated: May 21, 2015
Received: May 22, 2015

Dear Mr. Brunner:

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Sincerely yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K150041 Date Received by DCC: 01/09/2015

Lead Reviewer: Claudia Dollins, PhD RAC

Branch: HEMB Division: DIHD Center/Office: CDRH/OIR

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions **Answers in the shaded blocks indicate consultations with Center advisor is needed**	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		X
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

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Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

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A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*	X			
b) Statement contains all elements per 21 CFR 807.93				
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content.			X	
7) Submission contains clinical data	X			
a) Submission includes completed Financial Certification (Form 3454) or Disclosure (Form 3455) information for each covered clinical study included in the submission.	X			
b) Submission includes completed Certification of Compliance with the requirements of ClinicalTrials.gov Data Bank (Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission.			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.	X			

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B. Device Description				
10)				
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system			X	
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			

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16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			
D. Proposed Labeling (see also 21 CFR part 801)				
X If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.	X			
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	X			
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.			X	
F. Shelf Life				
26) Proposed shelf life/expiration date stated	X			
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.			X	
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.			X	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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H. Software				
Submission states that the device: (one of the below must be checked)				
× does contain software/firmware.				
does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
32) Submission includes a statement of software level of concern and rationale for the software level of concern.	×			
33) All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submitter has provided an alternative approach with a rationale.	×			
I. EMC and Electrical Safety				
Submission states that the device: (one of the below must be checked)				
× does require EMC and Electrical Safety evaluation.				
does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
34) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	×			
35) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	×			
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				

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36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	X			
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
38) If literature is referenced in the submission, submission includes:			X	
39) For each completed nonclinical (i.e., animal) study conducted			X	
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				
Submission states that the device: (one of the below must be checked)				
X is an in vitro diagnostic device.				
is not an in vitro diagnostic device.				
40) Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:				
a) Precision/reproducibility	X			
b) Accuracy(includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.			X	
c) Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).			X	
d) Analytical specificity	X			
41)				

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a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
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Decision: (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Claudia M. Dollins -S 2015.01.22 21:01:27 -05'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

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