June 7, 2023

Diagnostica Stago SAS
% Anthony Dennis
Director of US Market Access
Diagnostica Stago Inc.
5 Century Drive
Parsippany, New Jersey 07054

Re: K212183
Trade/Device Name: STA R Max 3, STA Compact Max 3
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose System For In Vitro Coagulation Studies
Regulatory Class: Class II
Product Code: JPA
Dated: September 30, 2022
Received: October 5, 2022

Dear Anthony Dennis:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Min Wu -S

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K212183

Device Name
STA R Max 3® and STA Compact Max 3®

Indications for Use *(Describe)*
The STA R Max 3® and STA Compact Max 3® are fully automatic clinical analyzers designed to be used by professional laboratory personnel and to perform tests on human venous plasmas (in 3.2% trisodium citrate tubes) the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.

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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# 510(k) SUMMARY

This 510(k) summary of safety and effectiveness is submitted in accordance with the requirements of 21 CFR 807.92 and follows FDA guidance 'The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]', issued July 28, 2014.

## 1. Submitter

Diagnostica Stago, Inc.
5 Century Drive
Parsippany, NJ 07054
Primary Contact: Anthony Dennis, RAC, CBA (ASQ), MBA
Director, US Market Access
Phone: 1 – (973) – 775-1200 x4162

On Behalf of: Diagnostica Stago SAS

Date: 12 July 2021; Revised 05 June 2023

## 2. Device

| | |
|---|---|
| Device Name: | STA R Max 3® / STA Compact Max 3® |
| Common Name: | Automated Coagulation Analyzer |
| Classification Name: | System, Multipurpose for In Vitro Coagulation Studies |
| Regulatory Class: | Class II |
| Panel: | Hematology |
| Product Code: | JPA |
| Regulation Number | 21 CFR 864.5424 |

Note that as a successor of earlier instruments in their respective families, reference to "STA R Max 3" or "Compact Max 3" is in reference to these families of analyzers with the aforementioned improvements. As such, elements in this submission, such as the intended use below are not version specific.

**Intended Use:**
The STA R Max 3® and STA Compact Max 3® are fully automatic clinical analyzers designed to be used by professional laboratory personnel and to perform tests on human venous plasmas (in 3.2% trisodium citrate tubes) the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.

## 3. Predicate Device

| | |
|---|---|
| Device Name: | STA R Max® (K151867) / STA Compact Max® (K130090) |
| Common Name: | Automated Coagulation Analyzer |
| Classification Name: | System, Multipurpose for In Vitro Coagulation Studies |
| Regulatory Class: | Class II |
| Panel: | Hematology |
| Product Code: | JPA |
| Regulation Number | 21 CFR 864.5424 |

The predicate has not been subject to design-related recalls for any of the applications associated with this premarket notification. No reference devices were used in this submission.

## 4. Device Description / Test Principle

### 4.1.1. STA R Max 3® and STA Compact Max 3® Test Principle

The technological characteristics are the same for all STA R Max® Family and STA Compact Max® family analyzers, including STA R Max 3® and STA Compact Max 3®, which is based on two measurement principles.

- Chronometric measurement principle:

The principle consists of measuring the variation of the metal ball oscillation amplitude through inductive sensors. The ball has a pendula movement due to an alternating electromagnetic field generated by two independent drive coils and two curved rail tracks in the bottom of the cuvettes. The oscillation amplitude is constant when the viscosity of the reaction volume in the cuvette remains constant.

The oscillation amplitude decreases when the viscosity of the reaction volume in the cuvette increases. The amplitude of the oscillation ball is analyzed to determine coagulation time in the cuvette.

- Photometry measurement principle:

The principles consists of measuring the variation of absorbance (optical density, O.D.) of monochromatic light (405 nm or 540 nm) passing through a cuvette as an enzymatic or immunological reaction takes place.

The variation of absorbance is analyzed to determine enzymatic activity or quantification (by immune aggregation) of factors related to coagulation.

### 4.1.2. STA R Max 3® Device Description

Diagnostica Stago's STA R Max 3® analyzers are modified versions of the STA R Max® analyzer, originally cleared for marketing by the FDA under K151867 as an in-vitro diagnostic device.

The STA-R family of analyzers is composed of:
- STAR® cleared in 1998: K983460
- STA-R Evolution® cleared in 2008: K082675
- STA-R Evolution® Expert Series cleared in 2009: K093001
- STA R Max® cleared in 2015: K151867

All these analyzers are fully automatic systems designed to perform tests on human plasmas and to study coagulation parameters.

Samples and test reagents are loaded into the instrument where sample handling, reagent delivery, analysis and reporting of results are performed automatically. A central processing unit controls the instrument such as, management of patient results, quality control, system supervision, support for instrument maintenance and workload optimization.

The analyzers use Diagnostica Stago reagents in addition to open adaptation of other available reagents. The instrument performs multiple test methodologies in random access, as selected by the user. These include clotting time or clot-based tests (i.e. chronometric measures) and photometric assays on plasma samples.
All the information on the analyzers, intended use and description, come from the instrument manual/labeling, which is the same for all STA R Max® family of analyzers (VOL_013, Labeling).

### 4.1.3. STA Compact Max 3® Device Description

Diagnostica Stago's STA Compact Max®3 analyzers are modified versions of the STA Compact Max® analyzer, originally cleared for marketing by the FDA under K130090 as an in-vitro diagnostic device.

The STA Compact® family of analyzers is composed of:
- STA Compact cleared in 1996: K961579, K093167
- STA Compact with Cap piercing Options cleared in 1996, with an add to file
- STA Compact Max cleared in 2013: K130090

All these analyzers are fully automatic systems designed to perform tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.

Once samples and test reagents are loaded onto the instrument, sample handling, reagent delivery, analysis and reporting of results are performed automatically. A central processing unit controls instrument functions, including management of patient's results, quality control, scheduling of instrument maintenance and workload organization.

The analyzers use Diagnostica Stago reagents in addition to open adaptation of other available reagents. The instrument performs multiple test methodologies in random access, as selected by the user. These include clotting time or clot-based tests (i.e. chronometric measures) and photometric assays on plasma samples.

All the information on the analyzers, intended use and description, come from the instrument manual/labeling, which is the same for all Compact Max® family of analyzers (VOL_013, Labeling).

### 4.1.4. Change to Control of Fluidic System and Addition of HIL Module

To facilitate in user maintenance and manufacturing process, the PSR module has been designed to replace the Hamilton syringes and Valcor pump of the fluidic circuit on all Diagnostica Stago analyzers.

The HIL module is a detection module developed to estimate interferences (Hemoglobin, Icterus, Lipemia) which may affect chromogenic and immune-turbidimetric tests. The analysis is performed before delivery in the cuvette and provides results of an index of interferences concentration to the biologist (display of the data on screen monitor). The plasma sample is not altered during HIL evaluation.

### 4.1.5. Reagent Applications in this 510(k) Notification

Five assays were used to demonstrate substantial equivalence, i.e. STA® - Neoplastine CI Plus ⑩, STA® - PTTA ⑤, STA® - Fibrinogen ⑤, STA® - Stachrom® ATIII ⑥ and STA® - Liatest DDi. These assays cover the three measuring principles, i.e. chronometric, chromogenic and immuno-turbidimetric, and the different reaction set-ups regarding sample dilution (undiluted or diluted) and reagents (use of only the third needle for reagent, or use of both second and third needles for reagent). The table below describes the configuration used for each assay.

**Table 1: Description of the test configurations for the assays used for validation**

| Assay | Measuring Principle | Sample Dilution Set-Up | Reagent Set-up | Prior regulatory clearance (K#) |
|---|---|---|---|---|
| STA® - Neoplastine CI Plus ⑩ | Chronometric | Undiluted | Only the third needle | K922040 |
| STA® - PTTA ⑤ | Chronometric | Undiluted | Second and third needles for reagent | K861190 |
| STA® - Fibrinogen ⑤ | Chronometric | Diluted | Only the third needle | K840211 |
| STA® - Stachrom ATIII ⑥ | Chromogenic | Diluted | Second and third needles for reagent | K832592 |
| STA® - Liatest DDi | Immuno-turbidimetric | Undiluted | Second and third needles for reagent | K162227 |

The intended Environment of Use is a clinical central/hospital laboratory.

## 5. Substantial Equivalence

**Table 2: STA R Max 3 Similarities Between Candidate and Predicate Devices**

| Attributes or Characteristics | Predicate Device STA R Max (K151867) | Candidate Device STA R Max 3 |
|---|---|---|
| **Regulatory Classification** | JPA, Class II<br>System, Multipurpose for in vitro coagulation studies | Same |
| **Indications for use** | The STA R Max is a fully automatic clinical instrument designed to perform tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy. | The STA R Max 3® and STA Compact Max 3® are fully automatic clinical analyzers designed to be used by professional laboratory personnel and to perform tests on human venous plasmas (in 3.2% trisodium citrate tubes) the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.. |
| **Anatomical Sites** | In vitro testing of human plasma | Same |
| **Sample Matrix** | Human plasma<br>3.2% sodium citrate | Same |
| **Where Used: hospital, home, ambulance, etc.** | Hospital Laboratory or other Health Care Laboratory. | Same |

| Attributes or Characteristics | Predicate Device<br>STA R Max (K151867) | Candidate Device<br>STA R Max 3 |
|---|---|---|
| **Measurement Principle** | Chronometric method (clotting time): mechanical measurement of the oscillation of the metal ball placed in the cuvette<br>Photometric method: light absorption technique provided by a filtered light source<br>(405nm, 540nm). | Same |
| **Cap Piercing** | Available as an option | Available as an option with HIL pre-analytical module.<br>New needle connector, new cap piercing foot and evolution of the lock system. |
| **Control of Fluidic System** | Valcor pump and Hamilton syringes | PSR (Pipettor Simple Resolution) in replacement of Valcor pump and Hamilton syringes |
| **Needles** | One sample, Two reagent | Same |
| **Operating Environment Temperature** | 59° - 89.5°F | Same |
| **User/Patient Data Input** | Touchscreen, keyboard, and/or barcode scanner | Same |
| **Specimen Processing** | Automatic pipetting and dilution | Same |
| **Random Access** | Yes | Same |
| **Liquid Level Sensing** | Yes | Same |
| **Stat Testing** | Yes | Same |
| **Parameters** | Prothrombin Time (PT) seconds, PT INR, Activated Partial Thromboplastin Time (APTT), Fibrinogen, Thrombin Time (TT), Reptilase, Extrinsic pathway factors, Intrinsic pathway factors, Anti-Xa (UFH, LMWH), Antithrombin (AT) activity, D-Dimer, Protein C activity, Protein S activity, Free Protein S antigen, Lupus anticoagulant, vWF antigen, Plasminogen | Same |

**Table 3: STA R Max 3 Differences Between Candidate and Predicate Devices**

| Attributes or Characteristics | Predicate Device<br>STA R Max (K151867) | Candidate Device<br>STA R Max 3 |
|---|---|---|
| **HIL Pre-analytical Module** | Not available | Avalable as an option: Semi quantitative determination of hemolysis, icterus and Lipemia (HIL) in patient plasma, reported as indices according to CLSI C56-A document. No predefined alerts are set-up in the analyzer; users are responsible for setting thresholds according to practices. Any evaluation of indices as potential interfering substances are left to the end users. |
| **Data Storage Capacity** | 160 GB | 320 GB |
| **Software** | Windows XP | Windows 10 |
| **Cybersecurity** | In 2019, Stago implemented a new PC-Gen with a new Windows 10 Operating System (OS), updated software, and the introduction of cybersecurity via internal documentation agreed with FDA during Q181507. | Introduced with user account management (reinforced passwords, restrictive access, log history…), firewall, antivirus, and data encryption. |

**Table 4: STA Compact Max 3 Similarities Between Candidate and Predicate Devices**

| Attributes or Characteristics | Predicate Device<br>STA Compact Max (K130090) | Candidate Device<br>STA Compact Max 3 |
|---|---|---|
| **Regulatory Classification** | JPA, Class II<br>System, Multipurpose for in vitro coagulation studies | Same |
| **Indications for use** | The STA Compact Max is a fully automatic clinical analyzer designed to perform tests on human plasmas, the results of which aid in the diagnosis~ of coagulation abnormalities or in monitoring anticoagulant therapy. | The STA R Max 3® and STA Compact Max 3® are fully automatic clinical analyzers designed to be used by professional laboratory personnel and to perform tests on human venous plasmas (in 3.2% trisodium citrate tubes) the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy. |
| **Anatomical Sites** | In vitro testing of human plasma | Same |
| **Sample Matrix** | Human plasma<br>3.2% sodium citrate | Same |
| **Where Used: hospital, home, ambulance, etc.** | Hospital Laboratory or other Health Care Laboratory. | Same |
| **Measurement Principle** | Chronometric method (clotting time): mechanical measurement of the oscillation of the metal ball placed in the cuvette<br>Photometric method: light absorption technique provided by a filtered light source | Same |

| Attributes or Characteristics | Predicate Device<br>STA Compact Max (K130090) | Candidate Device<br>STA Compact Max 3 |
|---|---|---|
| | (405nm, 540nm). | |
| **Cap Piercing** | Available as an option | Available as an option with HIL pre-analytical module.<br>New needle connector, new cap piercing foot and evolution of the lock system. |
| **Control of Fluidic System** | Valcor pump and Hamilton syringes | PSR (Pipettor Simple Resolution) in replacement of Valcor pump and Hamilton syringes |
| **Needles** | One sample, Two reagent | One sample, Two reagent |
| **Operating Environment Temperature** | 59° - 89.5°F | Same |
| **User/Patient Data Input** | Touchscreen, keyboard, and/or barcode scanner | Same |
| **Specimen Processing** | Automatic pipetting and dilution | Same |
| **Random Access** | Yes | Same |
| **Liquid Level Sensing** | Yes | Same |
| **Stat Testing** | Yes | Same |
| **Parameters** | Prothrombin Time (PT) seconds, PT INR, Activated Partial Thromboplastin Time (APTT), Fibrinogen, Thrombin Time (TT), Reptilase, Extrinsic pathway factors, Intrinsic pathway factors, Anti-Xa (UFH, LMWH), Antithrombin (AT) activity, D-Dimer, Protein C activity, Protein S activity, Free Protein S antigen, Lupus anticoagulant, vWF antigen, Plasminogen | Same |

**Table 5: STA Compact Max 3 Differences Between Candidate and Predicate Devices**

| Attributes or Characteristics | Predicate Device<br>STA Compact Max (K130090) | Candidate Device<br>STA Compact Max 3 |
|---|---|---|
| **HIL Pre-analytical Module** | Not available | Avalable as an option: Semi quantitative determination of hemolysis, icterus and Lipemia (HIL) in patient plasma, reported as indices according to CLSI C56-A document. No predefined alerts are set-up in the analyzer; users are responsible for setting thresholds according to practices. Any evaluation of indices as potential interfering substances are left to the end users. |
| **Data Storage Capacity** | 160 GB | 320 GB |
| **Software** | Windows XP | Windows 10 |
| **Cybersecurity** | In 2019, Stago implemented a new PC-Gen with a new Windows 10 Operating System (OS), updated software, and the introduction of cybersecurity via internal documentation agreed with FDA during Q181507. | Introduced with user account management (reinforced passwords, restrictive access, log history…), firewall, antivirus, and data encryption. |

## Standards/Guidance Documents Referenced:

- CLSI EP09c, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline
- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition.

## Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Method Comparison: STA R Max 3

Method comparison studies designed according to CLSI EP09c recommendations were conducted at three external sites.

Samples were selected in order to cover the entire measuring range of each assay and measured on both the predicate device (STA R Max) and subject device (STA R Max 3). Results were compared by either Passing & Bablok or Deming regression analysis based on the distribution. The following summary shows the results of this analysis without outliers across the analytical measuring range and targeted medical decision points per parameter.

**STA R Max 3: STA – Neoplastine CI Plus Passing-Bablok Regression Numerical Results**

| Site | Slope (95% CI) | Intercept (95% CI) | $r_{Spearman}$ (95% CI) |
|---|---|---|---|
| **All Sites** | 0.98 (0.97 to 0.98) | 0.20 sec (0.06 to 0.30) | 0.997 (0.996 to 0.998) |

**STA R Max 3: STA – PTTA Passing-Bablok Regression Numerical Results**

| Site | Slope (95% CI) | Intercept (95% CI) | $r_{Spearman}$ (95% CI) |
|---|---|---|---|
| **All Sites** | 1.00 (0.98 to 1.01) | -0.32 (-1.02 to 0.32) | 0.997 (0.996 to 0.998) |

**STA R Max 3: STA – Fibrinogen Passing-Bablok Regression Numerical Results**

| Site | Slope (95% CI) | Intercept (95% CI) | $r_{Spearman}$ (95% CI) |
|---|---|---|---|
| **All Sites** | 1.01 (0.99 to 1.03) | 4.26 mg/dL (-1.83 ; 10.14) | 0.996 (0.995 to 0.997) |

**STA R Max 3: STA – Stachrom ATIII Passing-Bablok Regression Numerical Results**

| Site | Slope (95% CI) | Intercept (95% CI) | $r_{Spearman}$ (95% CI) |
|---|---|---|---|
| **All Sites** | 1.03 (1.00 to 1.07) | -1.03% (-3.15 ; 2.00) | 0.980 (0.972 to 0.985) |

**STA R Max 3: STA – Liatest D-DI Passing-Bablok Regression Numerical Results**

| Site | Slope (95% CI) | Intercept (95% CI) | $r_{Spearman}$ (95% CI) |
|---|---|---|---|
| **All Sites** | 1.02 (1.01 to 1.03) | -0.02 µg/mL (-0.04 ; 0,01) | 0.998 (0.998 to 0.999) |

Method Comparison: STA Compact Max 3

Method comparison studies designed according to CLSI EP09c recommendations were conducted at three external sites.

Samples were selected in order to cover the entire measuring range of each assay and measured on both the predicate device (STA Compact Max) and subject device (STA Compact Max 3). Results were compared by either Passing & Bablok or Deming regression analysis based on the distribution. The following summary shows the results of this analysis without outliers across the analytical measuring range and targeted medical decision points per parameter.

**STA Compact Max 3: STA – Neoplastine CI Plus Passing-Bablok Regression Numerical Results**

| Site | Slope (95% CI) | Intercept (95% CI) | $r_{Spearman}$ (95% CI) |
|---|---|---|---|
| **All Sites** | 0.99 (0.98 to 1.00) | 0.20 sec (0.05 to 0.35) | 0.994 (0.993 to 0.996) |

**STA Compact Max 3: STA – PTTA Passing-Bablok Regression Numerical Results**

| Site | Slope (95% CI) | Intercept (95% CI) | $r_{Spearman}$ (95% CI) |
|---|---|---|---|
| **All Sites** | 0.99 (0.97 to 1.00) | 0.06 sec (-0.56 to 0.81) | 0.996 (0.995 to 0.997) |

**STA Compact Max 3: STA – Fibrinogen Passing-Bablok Regression Numerical Results**

| Site | Slope (95% CI) | Intercept (95% CI) | $r_{Spearman}$ (95% CI) |
|---|---|---|---|
| **All Sites** | 1.01 (1.00 to 1.03) | 4.94 mg/dL (0.67 to 11.25) | 0.995 (0.993 to 0.996) |

**STA Compact Max 3: STA – Stachrom ATIII Passing-Bablok Regression Numerical Results**

| Site | Slope (95% CI) | Intercept (95% CI) | $r_{Spearman}$ (95% CI) |
|---|---|---|---|
| **All Sites** | 1.00 (1.00 to 1.03) | 0.00% (-1.63 to 0.00) | 0.981 (0.975 to 0.986) |

**STA Compact Max 3: STA – Liatest D-DI Passing-Bablok Regression Numerical Results**

| Site | Slope (95% CI) | Intercept (95% CI) | $r_{Spearman}$ (95% CI) |
|---|---|---|---|
| **All Sites** | 1.02 (1.01 to 1.03) | -0.01 µg/mL (-0.04 to 0.01) | 0.997 (0.996 to 0.998) |

Method Comparison: HIL

The candidate instrument STA R Max 3 was compared to the reference methods, cobas® 8000 modular analyzer (Hemolyis, Icterus, and Lipemia) and spectrophotometer (Lipemia) in a method comparison study performed in accordance with CLSI EP09c guideline at one site.

**Hemolysis Passing-Bablok Regression**

| Analysis | Slope (95% CI) | Intercept (95% CI) | R Spearman (95% CI) |
|---|---|---|---|
| **Hemolysis With Outliers** | 1.12 (1.08 to 1.19) | -0.03 g/L (-0.06 to -0.01) | 0.954 (0.916 to 0.975) |
| **Hemolysis Without Outliers** | 1.11 (1.07 to 1.14) | -0.03 g/L (-0.05 to -0.01) | 0.948 (0.904 to 0.972) |

**Icterus Passing-Bablok Regression**

| Analysis | Slope (95% CI) | Intercept (95% CI) | R Spearman (95% CI) |
|---|---|---|---|
| **Icterus** | 0.99 (0.96 to 1.07) | 0.26 mg/dL (0.02 to 0.48) | 0.956 (0.920 to 0.976) |

**Lipemia Linear Regression versus Spectrophotometer**

| Analysis | Regression coefficient (r) |
|---|---|
| **Lipemia** | 0.91 ; P<0.001 |

**Lipemia Linear Regression versus cobas® 8000**

| Analysis | Regression coefficient (r) |
|---|---|
| **Lipemia** | 0.97 ; P<0.001 |

Precision/Reproducibility

Single-site precision testing was performed in accordance with CLSI EP05-A3 over 20 days at one external site. Three samples per parameter were tested across the applicable measuring ranges, with two runs per day and two replicates per day. Each run was at least two hours apart. The acceptance criteria were met for all samples in the studies.

**PT (STA-Neoplastine CI Plus ⑩ (sec))**

| STA-Neoplastine CI Plus (sec) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Analyzer | Sample | N | Mean | Within-Run | | Between-Run (= Between-Operator) | | Between-Day | | Between-Instrument | | Within-Site | |
| | | | sec | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) |
| **403** | 1 | 80 | 15.8 | 0.139 | **0.9** | 0.104 | **0.7** | 0.036 | **0.2** | | | 0.177 | **1.1** |
| | 2 | 80 | 39.7 | 0.243 | **0.6** | 0.417 | **1.1** | 0.000 | **0.0** | | | 0.483 | **1.2** |
| | 3 | 80 | 61.1 | 0.415 | **0.7** | 0.606 | **1.0** | 0.326 | **0.5** | | | 0.804 | **1.3** |
| | 4 | 80 | 14.0 | 0.092 | **0.7** | 0.034 | **0.2** | 0.044 | **0.3** | | | 0.108 | **0.8** |
| | 5 | 80 | 24.0 | 0.186 | **0.8** | 0.176 | **0.7** | 0.000 | **0.0** | | | 0.256 | **1.1** |
| **404** | 1 | 80 | 15.7 | 0.101 | **0.6** | 0.145 | **0.9** | 0.000 | **0.0** | | | 0.177 | **1.1** |
| | 2 | 80 | 39.5 | 0.188 | **0.5** | 0.309 | **0.8** | 0.170 | **0.4** | | | 0.400 | **1.0** |
| | 3 | 80 | 60.7 | 0.376 | **0.6** | 0.691 | **1.1** | 0.271 | **0.4** | | | 0.832 | **1.4** |
| | 4 | 80 | 13.8 | 0.096 | **0.7** | 0.158 | **1.1** | 0.000 | **0.0** | | | 0.185 | **1.3** |
| | 5 | 80 | 23.7 | 0.165 | **0.7** | 0.294 | **1.2** | 0.000 | **0.0** | | | 0.337 | **1.4** |
| **426** | 1 | 80 | 15.7 | 0.088 | **0.6** | 0.140 | **0.9** | 0.027 | **0.2** | | | 0.168 | **1.1** |
| | 2 | 80 | 39.5 | 0.306 | **0.8** | 0.326 | **0.8** | 0.181 | **0.5** | | | 0.483 | **1.2** |
| | 3 | 80 | 60.6 | 0.281 | **0.5** | 0.723 | **1.2** | 0.048 | **0.1** | | | 0.777 | **1.3** |
| | 4 | 80 | 13.8 | 0.075 | **0.5** | 0.079 | **0.6** | 0.000 | **0.0** | | | 0.109 | **0.8** |
| | 5 | 80 | 23.8 | 0.158 | **0.7** | 0.147 | **0.6** | 0.027 | **0.1** | | | 0.218 | **0.9** |
| All instruments combined | 1 | 240 | 15.7 | 0.112 | **0.7** | 0.131 | **0.8** | 0.000 | **0.0** | 0.065 | **0.4** | 0.184 | **1.2** |
| | 2 | 240 | 39.6 | 0.251 | **0.6** | 0.355 | **0.9** | 0.111 | **0.3** | 0.113 | **0.3** | 0.462 | **1.2** |
| | 3 | 240 | 60.8 | 0.363 | **0.6** | 0.672 | **1.1** | 0.253 | **0.4** | 0.186 | **0.3** | 0.826 | **1.4** |
| | 4 | 240 | 13.9 | 0.088 | **0.6** | 0.104 | **0.7** | 0.000 | **0.0** | 0.105 | **0.8** | 0.172 | **1.2** |
| | 5 | 240 | 23.8 | 0.169 | **0.7** | 0.218 | **0.9** | 0.000 | **0.0** | 0.151 | **0.6** | 0.314 | **1.3** |

**APTT (STA-PTTA ⑤ (sec))**

| STA-PTTA (sec) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Analyzer | Sample | N | Mean | Within-Run | | Between-Run (= Between-Operator) | | Between-Day | | Between-Instrument | | Within-Site | |
| | | | sec | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) |
| **403** | 1 | 80 | 31.5 | 0.195 | **0.6** | 0.238 | **0.8** | 0.000 | **0.0** | | | 0.308 | **1.0** |
| | 2 | 80 | 89.5 | 1.123 | **1.3** | 1.433 | **1.6** | 1.244 | **1.4** | | | 2.205 | **2.5** |
| | 3 | 80 | 133.2 | 2.237 | **1.7** | 2.239 | **1.7** | 1.792 | **1.3** | | | 3.637 | **2.7** |
| | 4 | 80 | 31.9 | 0.138 | **0.4** | 0.167 | **0.5** | 0.000 | **0.0** | | | 0.216 | **0.7** |
| | 5 | 80 | 55.5 | 0.504 | **0.9** | 0.716 | **1.3** | 0.393 | **0.7** | | | 0.960 | **1.7** |
| **404** | 1 | 80 | 31.5 | 0.185 | **0.6** | 0.253 | **0.8** | 0.000 | **0.0** | | | 0.313 | **1.0** |
| | 2 | 80 | 88.6 | 0.772 | **0.9** | 1.238 | **1.4** | 0.694 | **0.8** | | | 1.616 | **1.8** |
| | 3 | 80 | 131.5 | 1.057 | **0.8** | 2.378 | **1.8** | 1.184 | **0.9** | | | 2.859 | **2.2** |
| | 4 | 80 | 31.9 | 0.116 | **0.4** | 0.167 | **0.5** | 0.000 | **0.0** | | | 0.203 | **0.6** |
| | 5 | 80 | 55.0 | 0.236 | **0.4** | 0.563 | **1.0** | 0.425 | **0.8** | | | 0.744 | **1.4** |
| **426** | 1 | 80 | 31.2 | 0.165 | **0.5** | 0.244 | **0.8** | 0.000 | **0.0** | | | 0.294 | **0.9** |
| | 2 | 80 | 88.6 | 0.486 | **0.5** | 1.653 | **1.9** | 0.662 | **0.7** | | | 1.846 | **2.1** |
| | 3 | 80 | 129.0 | 2.241 | **1.7** | 1.322 | **1.0** | 2.124 | **1.6** | | | 3.359 | **2.6** |
| | 4 | 80 | 31.6 | 0.165 | **0.5** | 0.189 | **0.6** | 0.000 | **0.0** | | | 0.251 | **0.8** |
| | 5 | 80 | 54.8 | 0.370 | **0.7** | 0.796 | **1.5** | 0.283 | **0.5** | | | 0.922 | **1.7** |
| All instruments combined | 1 | 240 | 31.4 | 0.181 | **0.6** | 0.244 | **0.8** | 0.000 | **0.0** | 0.152 | **0.5** | 0.340 | **1.1** |
| | 2 | 240 | 88.9 | 0.837 | **0.9** | 1.456 | **1.6** | 0.897 | **1.0** | 0.441 | **0.5** | 1.955 | **2.2** |
| | 3 | 240 | 131.2 | 1.935 | **1.5** | 2.035 | **1.6** | 1.734 | **1.3** | 2.003 | **1.5** | 3.861 | **2.9** |
| | 4 | 240 | 31.8 | 0.141 | **0.4** | 0.175 | **0.6** | 0.000 | **0.0** | 0.200 | **0.6** | 0.301 | **0.9** |
| | 5 | 240 | 55.1 | 0.388 | **0.7** | 0.700 | **1.3** | 0.367 | **0.7** | 0.330 | **0.6** | 0.940 | **1.7** |

## FIB (STA-Fibrinogen ⑤ (mg/dL))

**STA-Fibrinogen (mg/dL)**

| Analyzer | Sample | N | Mean | Within-Run | | Between-Run (= Between-Operator) | | Between-Day | | Between-Instrument | | Within-Site | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | mg/dL | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) |
| **403** | 1 | 80 | 553 | 8.042 | **1.5** | 5.749 | **1.0** | 0.000 | **0.0** | | | 9.886 | **1.8** |
| | 2 | 80 | 736 | 10.434 | **1.4** | 8.252 | **1.1** | 0.000 | **0.0** | | | 13.303 | **1.8** |
| | 3 | 80 | 992 | 20.287 | **2.0** | 0.000 | **0.0** | 8.186 | **0.8** | | | 21.876 | **2.2** |
| | 4 | 80 | 252 | 4.970 | **2.0** | 2.966 | **1.2** | 1.099 | **0.4** | | | 5.891 | **2.3** |
| | 5 | 80 | 110 | 1.761 | **1.6** | 1.204 | **1.1** | 0.000 | **0.0** | | | 2.133 | **1.9** |
| **404** | 1 | 80 | 562 | 9.145 | **1.6** | 6.271 | **1.1** | 3.673 | **0.7** | | | 11.681 | **2.1** |
| | 2 | 80 | 747 | 12.298 | **1.6** | 7.388 | **1.0** | 5.236 | **0.7** | | | 15.272 | **2.0** |
| | 3 | 80 | 1021 | 16.929 | **1.7** | 7.893 | **0.8** | 3.941 | **0.4** | | | 19.090 | **1.9** |
| | 4 | 80 | 254 | 3.362 | **1.3** | 5.261 | **2.1** | 0.000 | **0.0** | | | 6.243 | **2.5** |
| | 5 | 80 | 110 | 1.419 | **1.3** | 0.935 | **0.9** | 0.222 | **0.2** | | | 1.714 | **1.6** |
| **426** | 1 | 80 | 565 | 7.305 | **1.3** | 3.298 | **0.6** | 6.510 | **1.2** | | | 10.326 | **1.8** |
| | 2 | 80 | 752 | 12.748 | **1.7** | 6.718 | **0.9** | 3.415 | **0.5** | | | 14.808 | **2.0** |
| | 3 | 80 | 1025 | 18.465 | **1.8** | 12.045 | **1.2** | 0.000 | **0.0** | | | 22.046 | **2.2** |
| | 4 | 80 | 262 | 5.527 | **2.1** | 0.000 | **0.0** | 2.157 | **0.8** | | | 5.933 | **2.3** |
| | 5 | 80 | 113 | 1.265 | **1.1** | 1.378 | **1.2** | 0.000 | **0.0** | | | 1.871 | **1.7** |
| All instruments combined | 1 | 240 | 560 | 8.221 | **1.5** | 5.282 | **0.9** | 4.104 | **0.7** | 6.208 | **1.1** | 12.283 | **2.2** |
| | 2 | 240 | 745 | 11.893 | **1.6** | 7.442 | **1.0** | 3.140 | **0.4** | 8.405 | **1.1** | 16.653 | **2.2** |
| | 3 | 240 | 1013 | 18.689 | **1.8** | 7.642 | **0.8** | 1.630 | **0.2** | 17.832 | **1.8** | 26.987 | **2.7** |
| | 4 | 240 | 256 | 4.719 | **1.8** | 3.237 | **1.3** | 0.521 | **0.2** | 2.167 | **0.8** | 7.728 | **3.0** |
| | 5 | 240 | 111 | 1.501 | **1.4** | 1.189 | **1.1** | 0.000 | **0.0** | 1.556 | **1.4** | 2.467 | **2.2** |

## AT (STA-Stachrom ATIII ⑥ (%))

**STA-Stachrom ATIII (%)**

| Analyzer | Sample | N | Mean | Within-Run | | Between-Run (= Between-Operator) | | Between-Day | | Between-Instrument | | Within-Site | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | % | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) |
| **403** | 1 | 80 | 31 | **1.251** | 4.0 | **1.332** | 4.3 | **0.000** | 0.0 | | | **1.828** | 5.9 |
| | 2 | 80 | 71 | 1.043 | **1.5** | 2.234 | **3.1** | 0.000 | **0.0** | | | 2.466 | **3.5** |
| | 3 | 80 | 113 | 1.347 | **1.2** | 2.461 | **2.2** | 0.000 | **0.0** | | | 2.806 | **2.5** |
| | 4 | 80 | 99 | 1.265 | **1.3** | 1.479 | **1.5** | 0.000 | **0.0** | | | 1.947 | **2.0** |
| | 5 | 80 | 46 | 0.873 | **1.9** | 1.364 | **3.0** | 0.000 | **0.0** | | | 1.619 | **3.5** |
| **404** | 1 | 80 | 31 | **1.045** | 3.4 | **1.989** | 6.4 | **0.000** | 0.0 | | | **2.247** | 7.2 |
| | 2 | 80 | 70 | 1.172 | **1.7** | 1.755 | **2.5** | 0.000 | **0.0** | | | 2.111 | **3.0** |
| | 3 | 80 | 111 | 1.574 | **1.4** | 1.362 | **1.2** | 0.000 | **0.0** | | | 2.081 | **1.9** |
| | 4 | 80 | 98 | 1.277 | **1.3** | 2.143 | **2.2** | 0.000 | **0.0** | | | 2.494 | **2.5** |
| | 5 | 80 | 46 | 0.665 | **1.4** | 1.924 | **4.2** | 0.000 | **0.0** | | | 2.036 | **4.4** |
| **426** | 1 | 80 | 31 | **1.160** | 3.7 | **1.962** | 6.3 | **0.000** | 0.0 | | | **2.280** | 7.4 |
| | 2 | 80 | 72 | 0.998 | **1.4** | 1.854 | **2.6** | 0.891 | **1.2** | | | 2.286 | **3.2** |
| | 3 | 80 | 114 | 1.324 | **1.2** | 1.259 | **1.1** | 0.807 | **0.7** | | | 1.997 | **1.8** |
| | 4 | 80 | 101 | 1.226 | **1.2** | 1.670 | **1.7** | 0.440 | **0.4** | | | 2.118 | **2.1** |
| | 5 | 80 | 46 | 0.802 | **1.7** | 2.036 | **4.4** | 0.000 | **0.0** | | | 2.188 | **4.8** |
| All instruments combined | 1 | 240 | 31 | **1.159** | 3.7 | **1.791** | 5.8 | **0.000** | 0.0 | **0.000** | 0.0 | **2.133** | 6.9 |
| | 2 | 240 | 71 | 1.064 | **1.5** | 1.962 | **2.8** | 0.177 | **0.2** | 0.827 | **1.2** | 2.387 | **3.4** |
| | 3 | 240 | 113 | 1.425 | **1.3** | 1.781 | **1.6** | 0.000 | **0.0** | 1.723 | **1.5** | 2.858 | **2.5** |
| | 4 | 240 | 99 | 1.260 | **1.3** | 1.790 | **1.8** | 0.000 | **0.0** | 1.480 | **1.5** | 2.643 | **2.7** |
| | 5 | 240 | 46 | 0.788 | **1.7** | 1.802 | **3.9** | 0.000 | **0.0** | 0.197 | **0.4** | 1.976 | **4.3** |

## D-Dimer (STA-Liatest D-DI (µg/mL))

**STA-Liatest D-DI (µg/mL)**

| Analyzer | Sample | N | Mean | Within-Run | | Between-Run (= Between-Operator) | | Between-Day | | Between-Instrument | | Within-Site | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | µg/mL | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) |
| **403** | 1 | 80 | 0.53 | **0.036** | 6.8 | **0.021** | 4.0 | **0.000** | 0.0 | | | **0.042** | 7.9 |
| | 2 | 80 | 7.16 | 0.242 | **3.4** | 0.106 | **1.5** | 0.048 | **0.7** | | | 0.268 | **3.7** |
| | 3 | 80 | 16.04 | 0.369 | **2.3** | 0.143 | **0.9** | 0.000 | **0.0** | | | 0.396 | **2.5** |
| | 4 | 80 | 0.27 | **0.011** | 4.1 | **0.000** | 0.0 | **0.000** | 0.0 | | | **0.011** | 4.1 |
| | 5 | 80 | 2.21 | 0.055 | **2.5** | 0.000 | **0.0** | 0.000 | **0.0** | | | 0.055 | **2.5** |
| **404** | 1 | 80 | 0.59 | **0.043** | 7.3 | **0.020** | 3.4 | **0.022** | 3.7 | | | **0.052** | 8.8 |
| | 2 | 80 | 7.45 | 0.231 | **3.1** | 0.138 | **1.9** | 0.000 | **0.0** | | | 0.269 | **3.6** |
| | 3 | 80 | 16.61 | 0.337 | **2.0** | 0.214 | **1.3** | 0.000 | **0.0** | | | 0.399 | **2.4** |
| | 4 | 80 | 0.28 | **0.025** | 8.9 | **0.009** | 3.2 | **0.000** | 0.0 | | | **0.026** | 9.3 |
| | 5 | 80 | 2.25 | 0.044 | **2.0** | 0.018 | **0.8** | 0.000 | **0.0** | | | 0.047 | **2.1** |
| **426** | 1 | 80 | 0.56 | **0.034** | 6.1 | **0.024** | 4.3 | **0.000** | 0.0 | | | **0.041** | 7.3 |
| | 2 | 80 | 7.38 | 0.157 | **2.1** | 0.079 | **1.1** | 0.093 | **1.3** | | | 0.199 | **2.7** |
| | 3 | 80 | 16.14 | 0.272 | **1.7** | 0.165 | **1.0** | 0.075 | **0.5** | | | 0.327 | **2.0** |
| | 4 | 80 | 0.28 | **0.013** | 4.6 | **0.011** | 3.9 | **0.000** | 0.0 | | | **0.017** | 6.1 |
| | 5 | 80 | 2.23 | 0.034 | **1.5** | 0.02 | **0.9** | 0.019 | **0.9** | | | 0.043 | **1.9** |
| All instruments combined | 1 | 240 | 0.56 | **0.038** | 6.8 | **0.020** | 3.6 | **0.009** | 1.6 | **0.033** | 5.9 | **0.055** | 9.8 |
| | 2 | 240 | 7.33 | 0.212 | **2.9** | 0.108 | **1.5** | 0.029 | **0.4** | 0.145 | **2.0** | 0.280 | **3.8** |
| | 3 | 240 | 16.26 | 0.328 | **2.0** | 0.174 | **1.1** | 0.000 | **0.0** | 0.298 | **1.8** | 0.477 | **2.9** |
| | 4 | 240 | 0.28 | **0.017** | 6.1 | **0.008** | 2.9 | **0.000** | 0.0 | **0.006** | 2.1 | **0.020** | 7.1 |
| | 5 | 240 | 2.23 | 0.045 | **2.0** | 0.007 | **0.3** | 0.000 | **0.0** | 0.021 | **0.9** | 0.050 | **2.2** |

*STA Compact Max 3*

**PT (STA-Neoplastine CI Plus ⑩ (sec))**

| STA-Neoplastine CI Plus (sec) | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Analyzer | Sample | N | Mean | Within-Run | | Between-Run (= Between-Operator) | | Between-Day | | Between-Instrument | | Within-Site | |
| | | | sec | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) |
| **3522** | 1 | 80 | 13.0 | 0.173 | **1.3** | 0.019 | **0.1** | 0.036 | **0.3** | | | 0.178 | **1.4** |
| | 2 | 80 | 38.2 | 0.232 | **0.6** | 0.477 | **1.2** | 0.315 | **0.8** | | | 0.617 | **1.6** |
| | 3 | 80 | 60.3 | 0.623 | **1.0** | 1.041 | **1.7** | 0.000 | **0.0** | | | 1.213 | **2.0** |
| | 4 | 80 | 14.0 | 0.089 | **0.6** | 0.096 | **0.7** | 0.000 | **0.0** | | | 0.131 | **0.9** |
| | 5 | 80 | 23.1 | 0.203 | **0.9** | 0.256 | **1.1** | 0.043 | **0.2** | | | 0.33 | **1.4** |
| **3524** | 1 | 80 | 12.8 | 0.152 | **1.2** | 0.065 | **0.5** | 0.065 | **0.5** | | | 0.178 | **1.4** |
| | 2 | 80 | 38.1 | 0.241 | **0.6** | 0.355 | **0.9** | 0.182 | **0.5** | | | 0.466 | **1.2** |
| | 3 | 80 | 59.2 | 0.521 | **0.9** | 0.795 | **1.3** | 0.000 | **0.0** | | | 0.95 | **1.6** |
| | 4 | 80 | 13.9 | 0.117 | **0.8** | 0.119 | **0.9** | 0.000 | **0.0** | | | 0.167 | **1.2** |
| | 5 | 80 | 23.0 | 0.254 | **1.1** | 0.239 | **1.0** | 0.142 | **0.6** | | | 0.376 | **1.6** |
| **3525** | 1 | 80 | 12.8 | 0.184 | **1.4** | 0.000 | **0.0** | 0.006 | **0.0** | | | 0.184 | **1.4** |
| | 2 | 80 | 38.0 | 0.297 | **0.8** | 0.471 | **1.2** | 0.276 | **0.7** | | | 0.621 | **1.6** |
| | 3 | 80 | 60.1 | 0.509 | **0.8** | 0.767 | **1.3** | 0.350 | **0.6** | | | 0.985 | **1.6** |
| | 4 | 80 | 14.0 | 0.084 | **0.6** | 0.104 | **0.7** | 0.000 | **0.0** | | | 0.133 | **1.0** |
| | 5 | 80 | 23.1 | 0.178 | **0.8** | 0.263 | **1.1** | 0.000 | **0.0** | | | 0.318 | **1.4** |
| All instruments combined | 1 | 240 | 12.9 | 0.171 | **1.3** | 0.000 | **0.0** | 0.041 | **0.3** | 0.068 | **0.5** | 0.188 | **1.5** |
| | 2 | 240 | 38.1 | 0.259 | **0.7** | 0.439 | **1.2** | 0.261 | **0.7** | 0.079 | **0.2** | 0.578 | **1.5** |
| | 3 | 240 | 59.8 | 0.553 | **0.9** | 0.880 | **1.5** | 0.000 | **0.0** | 0.568 | **0.9** | 1.185 | **2.0** |
| | 4 | 240 | 14.0 | 0.097 | **0.7** | 0.107 | **0.8** | 0.000 | **0.0** | 0.058 | **0.4** | 0.156 | **1.1** |
| | 5 | 240 | 23.1 | 0.213 | **0.9** | 0.254 | **1.1** | 0.061 | **0.3** | 0.081 | **0.4** | 0.347 | **1.5** |

**APTT (STA-PTTA ⑤ (sec))**

| STA-PTTA (sec) | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Analyzer | Sample | N | Mean | Within-Run | | Between-Run (= Between-Operator) | | Between-Day | | Between-Instrument | | Within-Site | |
| | | | sec | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) |
| **3522** | 1 | 80 | 31.9 | 0.328 | **1.0** | 0.230 | **0.7** | 0.199 | **0.6** | | | 0.447 | **1.4** |
| | 2 | 80 | 102.2 | 1.114 | **1.1** | 1.972 | **1.9** | 2.174 | **2.1** | | | 3.140 | **3.1** |
| | 3 | 80 | 118.9 | 1.060 | **0.9** | 1.746 | **1.5** | 0.771 | **0.6** | | | 2.183 | **1.8** |
| | 4 | 80 | 32.8 | 0.409 | **1.2** | 0.011 | **0.0** | 0.105 | **0.3** | | | 0.422 | **1.3** |
| | 5 | 80 | 53.8 | 0.327 | **0.6** | 0.716 | **1.3** | 0.000 | **0.0** | | | 0.788 | **1.5** |
| **3524** | 1 | 80 | 31.7 | 0.199 | **0.6** | 0.372 | **1.2** | 0.173 | **0.5** | | | 0.456 | **1.4** |
| | 2 | 80 | 100.8 | 0.944 | **0.9** | 1.697 | **1.7** | 1.448 | **1.4** | | | 2.422 | **2.4** |
| | 3 | 80 | 121.3 | 1.010 | **0.8** | 1.950 | **1.6** | 1.202 | **1.0** | | | 2.503 | **2.1** |
| | 4 | 80 | 32.5 | 0.307 | **0.9** | 0.196 | **0.6** | 0.123 | **0.4** | | | 0.384 | **1.2** |
| | 5 | 80 | 53.9 | 0.338 | **0.6** | 0.695 | **1.3** | 0.353 | **0.7** | | | 0.850 | **1.6** |
| **3525** | 1 | 80 | 31.8 | 0.400 | **1.3** | 0.292 | **0.9** | 0.000 | **0.0** | | | 0.495 | **1.6** |
| | 2 | 80 | 100.9 | 1.036 | **1.0** | 1.158 | **1.1** | 1.327 | **1.3** | | | 2.043 | **2.0** |
| | 3 | 80 | 120.8 | 0.942 | **0.8** | 1.802 | **1.5** | 0.942 | **0.8** | | | 2.052 | **1.7** |
| | 4 | 80 | 32.7 | 0.355 | **1.1** | 0.202 | **0.6** | 0.147 | **0.4** | | | 0.435 | **1.3** |
| | 5 | 80 | 54.2 | 0.306 | **0.6** | 0.785 | **1.4** | 0.000 | **0.0** | | | 0.843 | **1.6** |
| All instruments combined | 1 | 240 | 31.8 | 0.321 | **1.0** | 0.302 | **0.9** | 0.152 | **0.5** | 0.104 | **0.3** | 0.478 | **1.5** |
| | 2 | 240 | 101.3 | 1.037 | **1.0** | 1.648 | **1.6** | 1.685 | **1.7** | 0.591 | **0.6** | 2.642 | **2.6** |
| | 3 | 240 | 120.4 | 1.009 | **0.8** | 1.820 | **1.5** | 0.866 | **0.7** | 1.217 | **1.0** | 2.562 | **2.1** |
| | 4 | 240 | 32.7 | 0.360 | **1.1** | 0.161 | **0.5** | 0.126 | **0.4** | 0.188 | **0.6** | 0.455 | **1.4** |
| | 5 | 240 | 54.0 | 0.318 | **0.6** | 0.727 | **1.3** | 0.135 | **0.3** | 0.146 | **0.3** | 0.818 | **1.5** |

## FIB (STA-Fibrinogen ⑤ (mg/dL))

| STA-Fibrinogen (mg/dL) | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Analyzer | Sample | N | Mean | Within-Run | | Between-Run (= Between-Operator) | | Between-Day | | Between-Instrument | | Within-Site | |
| | | | mg/dL | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) |
| **3522** | 1 | 80 | 555 | 14.551 | **2.6** | 15.116 | **2.7** | 8.198 | **1.5** | | | 22.526 | **4.1** |
| | 2 | 80 | 772 | 9.317 | **1.2** | 17.028 | **2.2** | 12.600 | **1.6** | | | 23.142 | **3.0** |
| | 3 | 80 | 1046 | 18.238 | **1.7** | 25.567 | **2.4** | 26.377 | **2.5** | | | 41.013 | **3.9** |
| | 4 | 80 | 270 | 5.106 | **1.9** | 5.780 | **2.1** | 0.000 | **0.0** | | | 7.713 | **2.9** |
| | 5 | 80 | 114 | 1.383 | **1.2** | 2.704 | **2.4** | 0.000 | **0.0** | | | 3.037 | **2.7** |
| **3524** | 1 | 80 | 551 | 15.199 | **2.8** | 5.415 | **1.0** | 16.011 | **2.9** | | | 22.731 | **4.1** |
| | 2 | 80 | 764 | 13.896 | **1.8** | 13.301 | **1.7** | 16.895 | **2.2** | | | 25.601 | **3.4** |
| | 3 | 80 | 1044 | 24.405 | **2.3** | 22.802 | **2.2** | 24.648 | **2.4** | | | 41.510 | **4.0** |
| | 4 | 80 | 269 | 5.835 | **2.2** | 4.141 | **1.5** | 3.700 | **1.4** | | | 8.055 | **3.0** |
| | 5 | 80 | 112 | 1.792 | **1.6** | 2.764 | **2.5** | 0.000 | **0.0** | | | 3.294 | **2.9** |
| **3525** | 1 | 80 | 557 | 11.584 | **2.1** | 7.269 | **1.3** | 10.763 | **1.9** | | | 17.404 | **3.1** |
| | 2 | 80 | 767 | 13.374 | **1.7** | 14.352 | **1.9** | 13.520 | **1.8** | | | 23.825 | **3.1** |
| | 3 | 80 | 1027 | 18.555 | **1.8** | 12.260 | **1.2** | 19.363 | **1.9** | | | 29.488 | **2.9** |
| | 4 | 80 | 270 | 4.503 | **1.7** | 3.834 | **1.4** | 4.965 | **1.8** | | | 7.722 | **2.9** |
| | 5 | 80 | 114 | 1.673 | **1.5** | 1.684 | **1.5** | 0.424 | **0.4** | | | 2.412 | **2.1** |
| All instruments combined | 1 | 240 | 554 | 13.892 | **2.5** | 10.152 | **1.8** | 12.092 | **2.2** | 0.000 | **0.0** | 21.030 | **3.8** |
| | 2 | 240 | 768 | 12.404 | **1.6** | 15.003 | **2.0** | 14.391 | **1.9** | 0.343 | **0.0** | 24.211 | **3.2** |
| | 3 | 240 | 1039 | 20.659 | **2.0** | 21.019 | **2.0** | 23.579 | **2.3** | 8.053 | **0.8** | 38.593 | **3.7** |
| | 4 | 240 | 270 | 5.094 | **1.9** | 4.666 | **1.7** | 3.654 | **1.4** | 0.000 | **0.0** | 7.815 | **2.9** |
| | 5 | 240 | 113 | 1.611 | **1.4** | 2.436 | **2.2** | 0.000 | **0.0** | 0.510 | **0.5** | 2.965 | **2.6** |

## AT (STA-Stachrom ATIII ⑥ (%))

| STA-Stachrom ATIII (%) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Analyzer | Sample | N | Mean | Within-Run | | Between-Run (= Between-Operator) | | Between-Day | | Between-Instrument | | Within-Site | |
| | | | % | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) |
| **3522** | 1 | 80 | 22 | **1.064** | 4.8 | **0.969** | 4.4 | **0.000** | 0.0 | | | **1.439** | 6.5 |
| | 2 | 80 | 58 | 1.236 | **2.1** | 0.981 | **1.7** | 0.000 | **0.0** | | | 1.578 | **2.7** |
| | 3 | 80 | 109 | 0.975 | **0.9** | 1.027 | **0.9** | 0.000 | **0.0** | | | 1.416 | **1.3** |
| | 4 | 80 | 98 | 0.936 | **1.0** | 1.042 | **1.1** | 0.000 | **0.0** | | | 1.400 | **1.4** |
| | 5 | 80 | 41 | 2.049 | **5.0** | 0.000 | **0.0** | 0.304 | **0.7** | | | 2.071 | **5.1** |
| **3524** | 1 | 80 | 23 | **1.006** | 4.4 | **0.533** | 2.3 | **0.596** | 2.6 | | | **1.285** | 5.6 |
| | 2 | 80 | 58 | 0.924 | **1.6** | 0.875 | **1.5** | 0.000 | **0.0** | | | 1.273 | **2.2** |
| | 3 | 80 | 108 | 1.200 | **1.1** | 0.579 | **0.5** | 0.575 | **0.5** | | | 1.451 | **1.3** |
| | 4 | 80 | 97 | 1.047 | **1.1** | 0.705 | **0.7** | 0.731 | **0.8** | | | 1.459 | **1.5** |
| | 5 | 80 | 42 | 2.058 | **4.9** | 0.000 | **0.0** | 0.572 | **1.4** | | | 2.136 | **5.1** |
| **3525** | 1 | 80 | 24 | **0.802** | 3.3 | **1.111** | 4.6 | **0.000** | 0.0 | | | **1.370** | 5.7 |
| | 2 | 80 | 60 | 0.798 | **1.3** | 1.573 | **2.6** | 0.000 | **0.0** | | | 1.764 | **2.9** |
| | 3 | 80 | 110 | 0.859 | **0.8** | 0.998 | **0.9** | 0.000 | **0.0** | | | 1.317 | **1.2** |
| | 4 | 80 | 98 | 0.912 | **0.9** | 1.520 | **1.6** | 0.000 | **0.0** | | | 1.772 | **1.8** |
| | 5 | 80 | 44 | 1.598 | **3.6** | 0.810 | **1.8** | 0.542 | **1.2** | | | 1.872 | **4.3** |
| All instruments combined | 1 | 240 | 23 | **0.967** | 4.2 | **0.902** | 3.9 | **0.000** | 0.0 | **1.105** | 4.8 | **1.723** | 7.5 |
| | 2 | 240 | 59 | 0.999 | **1.7** | 1.187 | **2.0** | 0.000 | **0.0** | 0.821 | **1.4** | 1.755 | **3.0** |
| | 3 | 240 | 109 | 0.971 | **0.9** | 0.956 | **0.9** | 0.000 | **0.0** | 0.855 | **0.8** | 1.609 | **1.5** |
| | 4 | 240 | 98 | 0.959 | **1.0** | 1.152 | **1.2** | 0.000 | **0.0** | 0.916 | **0.9** | 1.757 | **1.8** |
| | 5 | 240 | 42 | 1.913 | **4.6** | 0.000 | **0.0** | 0.462 | **1.1** | 1.376 | **3.3** | 2.401 | **5.7** |

**D-Dimer (STA-Liatest D-DI (µg/mL))**

| STA-Liatest D-DI (µg/mL) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Analyzer | Sample | N | Mean | Within-Run | | Between-Run (= Between-Operator) | | Between-Day | | Between-Instrument | | Within-Site | |
| | | | µg/mL | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) |
| **3522** | 1 | 80 | 0.68 | **0.035** | 5.1 | **0.013** | 1.9 | **0.000** | 0.0 | | | **0.037** | 5.4 |
| | 2 | 80 | 7.88 | 0.158 | **2.0** | 0.045 | **0.6** | 0.000 | **0.0** | | | 0.165 | **2.1** |
| | 3 | 80 | 16.49 | 0.317 | **1.9** | 0.000 | **0.0** | 0.038 | **0.2** | | | 0.320 | **1.9** |
| | 4 | 80 | 0.33 | **0.036** | 10.9 | **0.000** | 0.0 | **0.000** | 0.0 | | | **0.036** | 10.9 |
| | 5 | 80 | 2.39 | 0.035 | **1.5** | 0.000 | **0.0** | 0.000 | **0.0** | | | 0.035 | **1.5** |
| **3524** | 1 | 80 | 0.66 | **0.038** | 5.8 | **0.010** | 1.5 | **0.000** | 0.0 | | | **0.040** | 6.1 |
| | 2 | 80 | 7.75 | 0.176 | **2.3** | 0.048 | **0.6** | 0.000 | **0.0** | | | 0.182 | **2.3** |
| | 3 | 80 | 15.72 | 0.275 | **1.7** | 0.142 | **0.9** | 0.000 | **0.0** | | | 0.309 | **2.0** |
| | 4 | 80 | 0.34 | **0.041** | 12.1 | **0.000** | 0.0 | **0.010** | 2.9 | | | **0.042** | 12.4 |
| | 5 | 80 | 2.30 | 0.036 | **1.6** | 0.014 | **0.6** | 0.005 | **0.2** | | | 0.039 | **1.7** |
| **3525** | 1 | 80 | 0.66 | **0.031** | 4.7 | **0.000** | 0.0 | **0.000** | 0.0 | | | **0.031** | 4.7 |
| | 2 | 80 | 7.56 | 0.173 | **2.3** | 0.000 | **0.0** | 0.000 | **0.0** | | | 0.173 | **2.3** |
| | 3 | 80 | 15.35 | 0.279 | **1.8** | 0.000 | **0.0** | 0.000 | **0.0** | | | 0.279 | **1.8** |
| | 4 | 80 | 0.33 | **0.026** | 7.9 | **0.000** | 0.0 | **0.011** | 3.3 | | | **0.029** | 8.8 |
| | 5 | 80 | 2.27 | 0.04 | **1.8** | 0.000 | **0.0** | 0.014 | **0.6** | | | 0.042 | **1.9** |
| All instruments combined | 1 | 240 | 0.66 | **0.035** | 5.3 | **0.009** | 1.4 | **0.000** | 0.0 | **0.012** | 1.8 | **0.038** | 5.8 |
| | 2 | 240 | 7.73 | 0.169 | **2.2** | 0.038 | **0.5** | 0.000 | **0.0** | 0.162 | **2.1** | 0.238 | **3.1** |
| | 3 | 240 | 15.85 | 0.291 | **1.8** | 0.063 | **0.4** | 0.000 | **0.0** | 0.581 | **3.7** | 0.653 | **4.1** |
| | 4 | 240 | 0.33 | **0.035** | 10.6 | **0.000** | 0.0 | **0.007** | 2.1 | **0.002** | 0.6 | **0.036** | 10.9 |
| | 5 | 240 | 2.32 | 0.037 | **1.6** | 0.000 | **0.0** | 0.005 | **0.2** | 0.065 | **2.8** | 0.075 | **3.2** |

Multi-site precision testing was performed in accordance with CLSI EP05-A3 over 5 days at three external sites. Three samples per parameter were tested across the applicable measuring ranges, with two runs per day and two replicates per day. Each run was at least two hours apart. The acceptance criteria were met for all samples in the studies. A summary of the within-run, between run, between day between site, and total precision is provided below.

*STA R Max 3*

| | Assay | Sample | N | Mean | Within-Run | | Between-Run (=Between-Operator) | | Between-Day | | Between-Site (= Between-Instrument) | | Total Precision | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) |
| **All 3 sites combined** | **PT** *(sec)* | CCN | 90 | 13.8 | 0.116 | **0.8** | 0.000 | **0.0** | 0.080 | **0.6** | 0.067 | **0.5** | 0.156 | **1.1** |
| | | CCP | 90 | 22.8 | 0.227 | **1.0** | 0.221 | **1.0** | 0.000 | **0.0** | 0.149 | **0.7** | 0.350 | **1.5** |
| | **APTT** *(sec)* | CCN | 90 | 28.7 | 0.210 | **0.7** | 0.146 | **0.5** | 0.120 | **0.4** | 0.143 | **0.5** | 0.317 | **1.1** |
| | | CCP | 90 | 48.7 | 0.368 | **0.8** | 0.560 | **1.1** | 0.502 | **1.0** | 0.321 | **0.7** | 0.897 | **1.8** |
| | **FIB** *(mg/dL)* | CCN | 90 | 304.0 | 8.413 | **2.8** | 2.472 | **0.8** | 0.000 | **0.0** | 5.272 | **1.7** | 10.231 | **3.4** |
| | | CCP | 90 | 113 | 2.438 | **2.2** | 1.020 | **0.9** | 0.000 | **0.0** | 1.597 | **1.4** | 3.088 | **2.7** |
| | **AT** *(%)* | CCN | 90 | 94.0 | 1.932 | **2.1** | 1.631 | **1.7** | 0.000 | **0.0** | 1.095 | **1.2** | 2.755 | **2.9** |
| | | CCP | 90 | 45 | 0.960 | **2.1** | 1.604 | **3.6** | 0.000 | **0.0** | 0.689 | **1.5** | 1.993 | **4.4** |
| | **D-Dimer** *(µg/mL)* | LCN | 90 | 0.31 | **0.027** | 8.7 | **0.008** | 2.6 | **0.008** | 2.6 | **0.014** | 4.5 | **0.033** | 10.6 |
| | | LCP | 90 | 2.22 | 0.044 | **2.0** | 0.040 | **1.8** | 0.016 | **0.7** | 0.007 | **0.3** | 0.062 | **2.8** |

*STA Compact Max 3*

| | Assay | Sample | N | Mean | Within-Run | | Between-Run (=Between-Operator) | | Between-Day | | Between-Site (= Between-Instrument) | | Total Precision | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) | SD | CV(%) |
| **All 3 sites combined** | **PT** *(sec)* | CCN | 90 | 14.0 | 0.148 | **1.1** | 0.138 | **1.0** | 0.000 | **0.0** | 0.000 | **0.0** | 0.203 | **1.5** |
| | | CCP | 90 | 23.9 | 0.304 | **1.3** | 0.338 | **1.4** | 0.000 | **0.0** | 0.254 | **1.1** | 0.521 | **2.2** |
| | **APTT** *(sec)* | CCN | 90 | 28.3 | 0.224 | **0.8** | 0.235 | **0.8** | 0.123 | **0.4** | 0.333 | **1.2** | 0.481 | **1.7** |
| | | CCP | 90 | 47.0 | 0.330 | **0.7** | 1.316 | **2.8** | 0.000 | **0.0** | 0.439 | **0.9** | 1.426 | **3.0** |
| | **FIB** *(mg/dL)* | CCN | 90 | 277 | 5.361 | **1.9** | 3.291 | **1.2** | 0.000 | **0.0** | 0.952 | **0.3** | 6.362 | **2.3** |
| | | CCP | 90 | 115 | 1.745 | **1.5** | 2.331 | **2.0** | 0.000 | **0.0** | 0.000 | **0.0** | 2.912 | **2.5** |
| | **AT** *(%)* | CCN | 90 | 98 | 1.130 | **1.2** | 2.106 | **2.1** | 0.938 | **1.0** | 1.068 | **1.1** | 2.781 | **2.8** |
| | | CCP | 90 | 42 | 1.160 | **2.8** | 2.443 | **5.8** | 0.592 | **1.4** | 2.681 | **6.4** | 3.854 | **9.2** |
| | **D-Dimer** *(µg/mL)* | LCN | 90 | 0.31 | **0.021** | 6.8 | **0.010** | 3.2 | **0.002** | 0.6 | **0.008** | 2.6 | **0.025** | 8.1 |
| | | LCP | 90 | 2.30 | 0.056 | **2.4** | 0.031 | **1.3** | 0.022 | **1.0** | 0.042 | **1.8** | 0.08 | **3.5** |

*HIL Interferences*
Cross-interferences were assessed by spiking plasma with hemoglobin, bilirubin and lipids (Intralipid®) at various concentrations in order to provide combinations of HIL concentrations to assess HIL measurement sensitivity for each interfering substance in the presence of other interfering substances at various concentrations. Spiked plasmas were prepared and each interfering substance was represented by various concentrations distributed across the designated indices. Each spiked plasmas concentration was assayed in triplicate on two subject devices. All results obtained matched the index determination for the subject devices and the theoretical index.

Detection Limit
Not applicable

Assay Cut-off
Not applicable

**Clinical Studies**
Clinical Sensitivity
Not applicable

Clinical Specificity
Not applicable

Clinical Cut-off
Not applicable

Reference Interval
Not applicable

**CONCLUSION**
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.