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

November 25, 2014

ROCHE DIAGNOSTICS OPERATIONS
NOEL MENCIAS
REGULATORY AFFAIRS PRINCIPAL
9115 HAGUE ROAD
INDIANAPOLIS IN 46250

Re: K141928
Trade/Device Name: cobas c Acetaminophen Gen.2 Assay
ACET2 Calibrator
Regulation Number: 21 CFR 862.3030
Regulation Name: Acetaminophen test system
Regulatory Class: II
Product Code: LDP, DKB
Dated: October 10, 2014
Received: October 14, 2014

Dear Mr. Noel Mencias:

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.

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,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k141928

Device Name
cobas c Acetaminophen Gen.2 assay
ACET2 Calibrator

Indications for Use *(Describe)*

cobas c Acetaminophen Gen.2 assay:
The cobas c Acetaminophen Gen.2 assay is an in vitro diagnostic test for the quantitative determination of acetaminophen in serum and plasma for use in the diagnosis of acetaminophen overdose in serum and plasma on Roche/Hitachi cobas c systems.

ACET2 calibrator:
The ACET2 calibrator is for use in the calibration of the Acetaminophen Gen.2 Roche assay.

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 for cobas c Acetaminophen Gen.2 Test System

Date prepared: November 18, 2014

Purpose of submission

In accordance with 21 CFR 807.87, Roche Diagnostics hereby submits official notification as required by Section 510(k) of the Federal Food, Drug and Cosmetics Act of our intention to market the device described in this Premarket Notification [510(k)].

The purpose of this premarket notification is to obtain FDA review and clearance for the **cobas c** Acetaminophen Gen.2 assay and Acetaminophen calibrator.

Measurand Acetaminophen

Type of test Quantitative homogeneous enzyme immunoassay method

Applicant

Noel Mencias, Regulatory Affairs Consultant
Roche Diagnostics
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Candidate device names

Proprietary name: **cobas c** Acetaminophen Gen.2 assay
Common name: Acetaminophen Gen.2 assay
Short name: ACET2

Proprietary name: ACET2 calibrator
Common name: Acetaminophen calibrator
Short name: ACETC

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510(k) Summary for cobas c Acetaminophen Gen.2 Test System, Continued

Regulatory information

Product Code	Classification	Regulation	Panel
LDP	Class II	21 CFR 862.3030 (Acetaminophen test system)	Toxicology
DKB	Class II	21 CFR 862.3200 (Clinical toxicology calibrator)	Toxicology

Intended use

The **cobas c** Acetaminophen assay is intended for use as an vitro diagnostic test for the quantitative determination of acetaminophen overdose in serum and plasma on Roche/Hitachi **cobas c** systems.

The ACET2 calibrator is intended for use in the calibration of the Acetaminophen Gen.2 Roche assay.

Indications for use

The **cobas c** Acetaminophen Gen.2 assay is intended for use as an in vitro test for the quantitative determination of acetaminophen overdose in serum and plasma on Roche/Hitachi **cobas c** systems. Acetaminophen is a widely used analgesic and antipyretic found in a number of over-the-counter and prescription products. When consumed in overdose quantities, acetaminophen may cause severe liver and kidney damage, or death. The patient may have few or no symptoms early after acute overdose of acetaminophen. The only reliable early diagnostic indicator is provided by a quantitative measurement of the serum acetaminophen level.

The ACET2 calibrator is intended for use in the calibration of the Acetaminophen Gen.2 Roche assay. The calibrator is prepared to contain a known quantity of acetaminophen in buffer. The calibrator is used to establish a standard curve from which the quantity of acetaminophen in unknown specimens can be determined.

Special conditions for use

For prescription use only

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510(k) Summary for cobas c Acetaminophen Gen.2 Test System, Continued

Special instrument requirements

For use on the Roche/Hitachi **cobas c** clinical chemistry analyzer

Candidate device description

The **cobas c** Acetaminophen Gen.2 assay is based on a homogeneous enzyme immunoassay technique used for the quantitative analysis of acetaminophen in human serum and plasma.

Reagents are packaged in a cassette labeled with their instrument positioning R1 (Reagent 1) and R2 (Reagent 2).

- R1 contains anti-acetaminophen antibody (sheep polyclonal), G6P, NAD, bovine serum albumin, preservatives and stabilizers.
- R2 contains acetaminophen labeled with bacterial G6PDH, Tris buffer, preservatives, bovine serum albumin, and stabilizers.

The ACET2 calibrator contains a known quantity of acetaminophen. The **cobas c** 501 analyzer dilutes the ACET2 calibrator on-board the analyzer with NaCl diluent, in order to create five concentration levels, and level 1 is water. This results in a six-level calibrator set, and the calibrator set is then used to establish a standard curve. The ACET2 calibrator contains acetaminophen, phosphate buffer, and preservatives.

Predicate device

Roche Diagnostics claims substantial equivalence to the Siemens Emit ® tox™ Acetaminophen Assay and the Siemens Emit ® tox™ Acetaminophen Calibrators which were both cleared in k002974.

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510(k) Summary for cobas c Acetaminophen Gen.2 Test System, Continued

Substantial Equivalence – Assay Similarities

The following table compares the similar features of the candidate device to the predicate device that was cleared in 510(k) k002974.

Assay Comparison Similarities		
Feature	**Predicate Device: Emit® tox™ Acetaminophen Assay**	**Candidate Device: Acetaminophen Gen.2 Assay**
Intended Use	The Emit® tox™ Acetaminophen Assay is a homogeneous enzyme immunoassay intended for in vitro diagnostic use in the quantitative analysis of acetaminophen in human serum or plasma.	The **cobas c** Acetaminophen Gen.2 assay is intended for use as an in vitro test for the quantitative determination of toxic levels of acetaminophen in serum and plasma on Roche/Hitachi **cobas c** systems.
Reagent Composition	R1: sheep antibodies reactive to acetaminophen, G6P NAD, bovine serum albumin, preservatives, and stabilizers R2: acetaminophen labeled with bacterial G6PDH, Tris buffer, preservatives, bovine serum albumin, and stabilizers	Same
Reagent Shelf Life Stability	2-8 ºC until expiration date	Same
Test Principle	Homogeneous enzyme immunoassay	Same
Measuring Range	Up to 200 µg/mL (1324 µmol/L)	5-200 µg/mL (33.1-1324 µmol/L)
Traceability	This method has been standardized against USP reference standards.	Same
Expected Values	Normal therapeutic doses of acetaminophen result in serum concentrations of 10–30 µg/mL (66–199 µmol/L) in healthy adults.	Same

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510(k) Summary for cobas c Acetaminophen Gen.2 Test System, Continued

Substantial Equivalence – Assay Differences

The following table compares the differences of the candidate device to the predicate device that was cleared in 510(k) k002974.

Assay Comparison Differences		
Feature	**Predicate Device: Emit® tox™ Acetaminophen Assay**	**Candidate Device: Acetaminophen Gen.2 Assay**
Reagent On-Board Stability	Analyzer specific	on-board in use and refrigerated on the analyzer: 12 weeks
Sample Types	EDTA, heparin, citrate and oxalate/fluoride	K_2- or K_3-EDTA, or lithium heparinized plasma
Controls	Commercially available controls	TDM Control Set Level I TDM Control Set Level II TDM Control Set Level III
Instrument Platform	Several analyzers	Roche/Hitachi **cobas c** 501
Lower Limits of Measurement	The sensitivity level of the Emit® tox™ Acetaminophen Assay is less than 0.25 µg/mL acetaminophen. This level represents the lowest concentration of acetaminophen that can be distinguished from 0 µg/mL with a confidence level of 95%.	LoB = 1.5 µg/mL LoD = 3 µg/mL LoQ = 5 µg/mL

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510(k) Summary for cobas c Acetaminophen Gen.2 Test System, Continued

Substantial equivalence – calibrator similarities

The following table compares the similar features of the candidate device to the predicate device that was cleared in 510(k) k002974.

Calibrator Comparison Similarities		
Feature	**Predicate Device: Emit® tox™ Acetaminophen Calibrators**	**Candidate Device: ACET2 Calibrator**
Intended Use	The Emit® tox™ Acetaminophen Calibrators are intended for use with the Emit® tox™ Acetaminophen Assay.	ACET2 calibrator is for use in the calibration of the Acetaminophen Gen.2 Roche assay.
Format	Liquid ready-to-use	Same
Analyte	Acetaminophen	Same
Storage Conditions	2-8°C	Same
Storage and Stability	When stored refrigerated at 2–8°C, the Emit® tox™ Acetaminophen Calibrators are stable until the expiration date printed on the dropper vial label.	Store at 2-8 °C. Do not freeze. The calibrator may be used until the expiration date when stored at 2-8°C.

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510(k) Summary for cobas c Acetaminophen Gen.2 Test System, Continued

Substantial equivalence – calibrator difference

The following table compares the difference of the candidate device to the predicate device that was cleared in 510(k) k002974.

Calibrator Comparison Difference		
Feature	**Predicate Device: Emit® tox™ Acetaminophen Calibrators**	**Candidate Device: ACET2 Calibrator**
Quantity	Emit® tox™ Acetaminophen Calibrators are a six-level set that contain the following acetaminophen concentrations: 0, 10, 25, 50, 100, 200 µg/mL.	The ACET2 calibrator has a nominal value of 200 µg/mL of acetaminophen. The analyzer dilutes the ACET2 calibrator on-board with NaCl diluent, in order to create five concentration levels, and level 1 is water. This results in a six-level calibrator set: 0.0, 10.0, 30.2, 75.0, 100, 200 µg/mL.

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510(k) Summary for cobas c Acetaminophen Gen.2 Test System, Continued

Test principle

The assay is based on a homogeneous enzyme immunoassay technique used for the quantitative analysis of acetaminophen in human serum or plasma. The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, so the drug concentration in the sample can be measured in terms of enzyme activity. Active enzyme converts oxidized nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that is measured spectrophotometrically. Endogenous serum G6PDH does not interfere because the coenzyme functions only with the bacterial (Leuconostoc mesenteroides) enzyme employed in the assay**.**

Precision

Precision was determined using human samples and controls in accordance with the CLSI EP5-A2 requirements with repeatability (n = 84) and intermediate precision (2 aliquots per run, 2 runs per day, 21 days). The following results were obtained on the Roche/Hitachi **cobas c** 501.

Repeatability Summary

Specimen	Mean (µg/mL)	SD (µg/mL)	CV (%)
Control 1	15.3	0.4	2.5
Control 2	34.9	0.9	2.5
Control 3	106	2	2.2
Human Serum 1	7.7	0.2	2.9
Human Serum 2	73.2	1.7	2.3
Human Serum 3	130	4	2.7
Human Serum 4	168	4	2.5
Human Serum 5	184	4	2.3

Intermediate Precision Summary

Specimen	Mean (µg/mL)	SD (µg/mL)	CV (%)
Control 1	15.3	0.5	3.2
Control 2	34.9	1.0	2.8
Control 3	106	3	3.0
Human Serum 1	7.4	0.3	3.5
Human Serum 2	73.2	1.9	2.7
Human Serum 3	130	4	3.2
Human Serum 4	168	5	3.2
Human Serum 5	185	6	3.0

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510(k) Summary for cobas c Acetaminophen Gen.2 Test System, Continued

Method Comparison to Predicate Device

Acetaminophen values for human serum samples obtained on Roche/Hitachi **cobas c** 501 analyzer (y) were compared to those determined with the Emit® tox™ Acetaminophen assay reagent on Olympus AU5400 analyzer (x). The sample concentrations were between 5.2 and 198 µg/mL, and they were tested in singlicate.
Sample size (n) = 105

Deming Regression Weighted
y = 1.02x - 0.699 µg/mL
r = 0.997

Linearity

Linearity was assessed according to CLSI EP6-A with one batch of reagent, in one run, and with samples measured in triplicate. Two separate dilution series differing by sample type (serum and Li-Heparin plasma) were prepared with thirteen levels.

The diluted samples span the measuring range including a non-zero sample below the measuring range and a sample above the measuring range.

The linearity results support the measuring range of 5.0-200 µg/mL.

Linear Regression Equation for Serum:
y = 1.014x – 0.248 Pearson correlation coefficient (R) = 0.998963

Linear Regression Equation for Plasma:
y = 1.011x – 0.193 Pearson correlation coefficient (R) = 0.999010

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510(k) Summary for cobas c Acetaminophen Gen.2 Test System, Continued

Linearity (continued)

Calculation to spiked concentration levels:
Linearity Statistics with Serum

Linearity Sample	Spiked conc. (µg/mL)	c 501 mean (µg/mL)	Absolute deviation (µg/mL)	% recovery
1	0	0	0	-
2	3	2.4	-0.6	-
3	6	5.4	-0.6	-
4	24	23.1	-	96
5	48	45.7	-	95
6	72	68.4	-	95
7	96	92.1	-	96
8	120	113	-	94
9	144	139	-	97
10	168	160	-	95
11	192	188	-	98
12	216	206	-	95
13	240	232	-	97

Linearity Statistics with Plasma

Linearity Sample	Spiked conc. (µg/mL)	c 501 mean (µg/mL)	Absolute deviation (µg/mL)	% recovery
1	0	0	0	-
2	3	2.4	-0.6	-
3	6	5.1	-0.9	-
4	24	21.7	-	90
5	48	44.3	-	92
6	72	65.4	-	91
7	96	89.0	-	93
8	120	110	-	92
9	144	132	-	92
10	168	155	-	92
11	192	180	-	94
12	216	194	-	90
13	240	228	-	95

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510(k) Summary for cobas c Acetaminophen Gen.2 Test System, Continued

Detection limit

LoB, LoD, and LoQ studies were performed based upon CLSI EP17-A2.

LoB Protocol: One analyte-free sample was tested in n=5 with two analyzers with three reagent batches for six runs per day across three days.

LoD Protocol: Five low-analyte samples spiked with acetaminophen were measured in singlicate on two analyzers with three reagent batches for six runs per day across three days.

LoQ Protocol: A low-level sample set of six was measured in two aliquots using three reagent batches on one analyzer over at least six days. The LoQ is determined based on a total error of 20%.

The LoB, LoD, and LoQ claims represent the specifications for each.
LoB claim = 1.5 µg/mL
LoD claim = 3 µg/mL
LoQ claim = 5 µg/mL

Analytical specificity-cross reactivity

Two sample pools at two target concentrations of acetaminophen, one at a low concentration of ~5.0 µg/mL and the second one at a high concentration of ~ 30.0 µg/mL are used.

- The absolute bias is calculated as follows:

Total Bias = Mean concentration of test sample – Mean concentration of control sample

- The cross reactivity is calculated as follows:

% cross reactivity =((Total Bias) / (concentration of test substance)) x 100

Compound	Compound Concentration (µg/mL)	Acetaminophen (µg/mL)	% cross reactivity
Acetaminophen cysteine	100	6.1	0.5
Acetaminophen glucuronide	1000	5.2	n.d.*
Acetaminophen mercapturate	300	5.4	0.2
Acetaminophen sulfate	200	6.1	n.d.*
Cysteine	1300	5.8	n.d.*
N-Acetylcysteine	1663	6.3	n.d.*
Phenacitin	500	6.7	0.5

*n.d. = not detectable

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510(k) Summary for cobas c Acetaminophen Gen.2 Test System, Continued

Analytical specificity-cross reactivity, continued

Compound	Compound Concentration (µg/mL)	Acetaminophen (µg/mL)	% cross reactivity
Acetaminophen cysteine	100	29.2	-0.3
Acetaminophen glucuronide	1000	25.4	-0.1
Acetaminophen mercapturate	300	25.9	0.2
Acetaminophen sulfate	200	27.8	0.1
Cysteine	1300	29.0	n.d.*
N-Acetylcysteine	1663	28.5	n.d.*
Phenacitin	500	29.3	1.3

*n.d. = not detectable

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510(k) Summary for cobas c Acetaminophen Gen.2 Test System, Continued

Analytical specificity – interference from endogenous substances

The reagent was evaluated with three endogenous substances, hemoglobin, lipids, and bilirubin for potential interference with the measurement of acetaminophen.

Data Summary

	Approximate Acetaminophen Concentration (µg/mL)	no interference up to	Triglyceride theoretical value (mg/dL)	Claim as it appears in the labeling.
Lipemia Level 1	5	672 L index	1100	**No significant interference up to an L index of 400.**
Lipemia Level 2	30	608 L index	997	
Lipemia Level 3	50	492 L index	810	
Lipemia Level 4	100	418 L index	698	
Lipemia Level 5	150	413 L index	682	
Lipemia Level 6	180	411 L index	678	
Hemolysis Level 1	5	926 H index	N/A	**No significant interference up to an H index of 800.**
Hemolysis Level 2	30	936 H index	N/A	
Hemolysis Level 3	50	1009 H index	N/A	
Hemolysis Level 4	90	1008 H index	N/A	
Hemolysis Level 5	140	1016 H index	N/A	
Hemolysis Level 6	180	1025 H index	N/A	
Unconjugated Bilirubin Level 1	5	47 I index	N/A	**No significant interference up to an I index of 30 for conjugated and unconjugated bilirubin.**
Unconjugated Bilirubin Level 2	30	45 I index	N/A	
Unconjugated Bilirubin Level 3	50	63 I index	N/A	
Unconjugated Bilirubin Level 4	100	63 I index	N/A	
Unconjugated Bilirubin Level 5	150	63 I index	N/A	
Unconjugated Bilirubin Level 6	180	63 I index	N/A	
Conjugated Bilirubin Level 1	5	45 I index	N/A	
Conjugated Bilirubin Level 2	30	46 I index	N/A	
Conjugated Bilirubin Level 3	50	44 I index	N/A	
Conjugated Bilirubin Level 4	100	47 I index	N/A	
Conjugated Bilirubin Level 5	150	50 I index	N/A	
Conjugated Bilirubin Level 6	180	42 I index	N/A	

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510(k) Summary for cobas c Acetaminophen Gen.2 Test System, Continued

Analytical specificity – interference from endogenous substances (continued)

The I Index value corresponds approximately to mg/dL bilirubin.
The H Index value corresponds approximately to mg/dL hemoglobin.
The Triglyceride theoretical value is the calculated correlation of L index to triglyceride concentration.

All data passed the following acceptance criteria:
Recovery within ± 1 µg/mL of initial value at an acetaminophen level of approximately 5 µg/mL and recovery within ± 10% of initial value at an acetaminophen level of approximately 30 µg/mL.

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510(k) Summary for cobas c Acetaminophen Gen.2 Test System, Continued

Analytical specificity—interference from common drugs

Twenty four commonly used drugs were examined for potential interference on measurement with **cobas c** Acetaminophen Gen.2 assay.
Drug interference testing was performed with serum sample pools at two target concentrations of acetaminophen (~ 5 and ~ 30 µg/mL). Acetaminophen concentration in all aliquots is measured in triplicate. The mean value among the triplicates for each aliquot is determined, and the percent recovery to the initial value (no drug in sample) is calculated.

The table below summarizes the common drug interferences data:

	Drug	Highest Concentration Shown Not to Interfere with ACET2
1	Acetylcystein	150 mg/L
2	Acetylsalycilic acid	1000 mg/L
3	Ampicillin-sodium	1000 mg/L
4	Ascorbic acid	300 mg/L
5	Cefoxitin	2500 mg/L
6	Cyclosporine	5 mg/L
7	Doxycycline	50 mg/L
8	Phenylbutazone	400 mg/L
9	Rifampicin	64 mg/L
10	Theophylline	100 mg/L
11	Amitriptylline	277 µg/mL
12	Caffeine	1000 µg/mL
13	Codeine	1.6 µg/mL
14	Diazepam	5.1 µg/mL
15	Heparin	5000 U
16	Ibuprofen	500 mg/L
17	Levodopa	20 mg/L
18	Methyldopa + 1.5 H_2O	20 mg/L
19	Metronidazole	200 mg/L
20	Methionine	1000 µg/mL
21	Phenylephrine	20 µg/mL
22	Propoxyphene	20 µg/mL
23	Salicylate	1000 µg/mL
24	Secobarbital	22 µg/mL

All data passed the following acceptance criteria:
Difference in recovery of acetaminophen:
≤ 10 µg/mL: ≤ ± 1µg/mL and > 10 µg/mL: 100 ± 10 %

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510(k) Summary for cobas c Acetaminophen Gen.2 Test System, Continued

Matrix comparison

Lithium-heparin, K_2-EDTA, and K3-EDTA are permissible anticoagulants for use with this reagent because they do not interfere with recovery of acetaminophen. In an internal study, 60 tubes were collected per anticoagulant. Plasma results were compared to serum results and percent recovery was determined. In terms of % recovery to serum, all data passed the following criteria:
For sample concentrations ≤ 10 µg/mL, the deviation must be ≤ ± 1 µg/mL.
For sample concentrations > 10 µg/mL, the deviation must be ≤ ± 10%.

anticoagulants	Sample concentration range tested (µg/mL)	Claimed Measuring Range (µg/mL)
Li-Heparin	2.6 - 187	5 – 200
K_2-EDTA	2.6 - 187	
K_3-EDTA	2.6 - 187	

In addition, method comparisons with plasma vs serum were calculated with the following results (Passing/Bablok):

Serum vs. Li-heparin y = 0.989x + 0.089, r = 0.998
Serum vs. K_2-EDTA y = 1.000x – 0.000, r = 0.998
Serum vs. K_3-EDTA y = 0.992x – 0.163, r = 0.998

Conclusion

The submitted information in this premarket notification supports a substantial equivalence decision.