July 24, 2026

Siemens Healthcare Diagnostics, Inc.
Kelly Maher
Sr. Regulatory Affairs Professional
511 Benedict Ave.
Tarrytown, New York 10591

Re: K261364
Trade/Device Name: Atellica CH Acetaminophen 2 (ACTM)
Regulation Number: 21 CFR 862.3030
Regulation Name: Acetaminophen test system
Regulatory Class: Class II
Product Code: LDP
Dated: April 24, 2026
Received: April 27, 2026

Dear Kelly Maher:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JOSEPH A. KOTAREK -S
Digitally signed by JOSEPH A. KOTAREK -S
Date: 2026.07.24 15:49:29 -04'00'

Joseph Kotarek, Ph.D.
Toxicology Branch Chief
Division of Chemistry and
Toxicology 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261364

Device Name
Atellica CH Acetaminophen 2 (ACTM)

Indications for Use *(Describe)*
The Atellica CH Acetaminophen 2 (ACTM) assay is for in vitro diagnostic use in the quantitative determination of acetaminophen in human serum and plasma (K2 EDTA, lithium heparin, sodium heparin) using the Atellica CH Analyzer. Measurements obtained by this device are used in the diagnosis and treatment of acetaminophen overdose.

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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This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K261364

1. Submitter's Information

Date of Preparation: April 27, 2026

Submitted By:
Siemens Healthcare Diagnostics, Inc.
511 Benedict Ave
Tarrytown, NY 10591, USA
(914) 631-8000

Primary Contact Person:
Kelly Maher
Sr. Regulatory Affairs Specialist
Siemens Healthcare Diagnostics, Inc.
511 Benedict Ave
Tarrytown, NY 10591, USA

2. Purpose of Submission

To obtain a substantial equivalence determination for the Atellica CH Acetaminophen 2 (ACTM) assay

3. Measurand

Acetaminophen

4. Type of Test

Quantitative, colorimetric assay

5. Proprietary and Established Names

Atellica CH Acetaminophen 2 (ACTM)

Common Name: Atellica CH ACTM

6. Regulatory Information

Review Panel	Product Code	Submission Type	Regulation Number	Device Class
Toxicology	LDP	Traditional 510(k)	21 CFR § 862.3030	II

7. Intended Use

The Atellica CH Acetaminophen 2 (ACTM) assay is for *in vitro* diagnostic use in the quantitative determination of acetaminophen in human serum and plasma (K2 EDTA, lithium heparin, sodium heparin) using the Atellica CH Analyzer. Measurements obtained by this device are used in the diagnosis and treatment of acetaminophen overdose.

8. Special Condition For Use Statement

For Professional Use.
CAUTION
Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

9. Device Description Summary

The following catalog numbers are provided for the Atellica CH Acetaminophen 2 (ACTM) assay:

Device	Catalog Number
Atellica CH Acetaminophen 2 (ACTM) (800 tests)	11537411

Summary of the Components and Materials

Device	Volume	Ingredients
Provided in Atellica CH ACTM		
Pack 1 (P1) Well 1 (W1) Well 2 (W2) Reagent 1 (R1)	23.4 mL	Sodium periodate (1.88 mmol/L)
Pack 2 (P2) Well 1 (W1) Well 2 (W2) Reagent 2 (R2)	13.5 mL	Arylacylamidase (≥ 6000 U/L); Ethyl-N-(3-sulfopropyl)-m-anisidin (10 mmol/L)
Materials required but not provided		
Atellica CH TOX CAL	3.0mL/vial	Human serum albumin; ethanol; acetaminophen; salicylate; sodium azide; MIT (< 0.1%)

10. Assay Principle

The assay is a fully automated photometric assay that measures the concentration of acetaminophen in serum and plasma. Acetaminophen is hydrolyzed by Arylacylamidase to p-aminophenol and acetate. Subsequently, in the presence of ethyl-N-(3-sulfopropyl)-m-anisidin and a periodate catalyst, the p-aminophenol is converted to an indophenol derivate and the reaction is measured colorimetrically at 694/545 nm. The increased absorbance at 694/545 nm is directly proportional to the concentration of acetaminophen in the sample.

11. Predicate Device and Comparison

The predicate device for the Atellica CH Acetaminophen 2 (ACTM) assay is the Emit tox Acetaminophen assay, which was submitted and cleared by FDA under 510(k) K002974 on October 11, 2000.

Details for the predicate device are outlined below:

Predicate Device Product Name	Clearance	Manufacturer
Emit tox Acetaminophen	K002974	Dade Behring, Inc.

11.1. Predicate Device and Comparison

The following table describes the similarities and differences between the Atellica CH Acetaminophen 2 (ACTM) assay and the predicate device, Emit tox Acetaminophen assay.

Attribute	Candidate Device Atellica CH Acetaminophen 2 (ACTM)	Predicate Device Emit tox Acetaminophen (K002974)
Intended Use	The Atellica CH Acetaminophen 2 (ACTM) assay is for *in vitro* diagnostic use in the quantitative determination of acetaminophen in human serum and plasma (K2 EDTA, lithium heparin, sodium heparin) using the Atellica CH Analyzer. Measurements obtained by this device are used in the diagnosis and treatment of acetaminophen overdose.	The Emit tox Acetaminophen Assay is a homogeneous enzyme immunoassay intended for use in the quantitative analysis of acetaminophen in human serum or plasma. These reagents are packaged specifically for use on a variety of AU Clinical Chemistry Systems.
Similarities		
Sample Handling/Processing	Same	Automated
Detection Technology	Same	Photometric
Calibrators	Same	1 Level
Measurement	Same	Quantitative
Measuring Range	2.0 – 200.0 µg/mL (13.2 – 1322.0 µmol/L)	0.2 – 20.0 mg/dL (13.2 – 1322.0 µmol/L)
Differences		
Reagent Composition	R1: Sodium periodate (1.88 mmol/L); R2: Arylacylamidase (≥6000 U/L) Ethyl-N-(3-sulfopropyl-m-anisidin) (10 mmol/L)	Sheep antibodies reactive to acetaminophen (73 µg/mL), acetaminophen labeled with bacterial G6PDH (0.42 U/mL), glucose-6-phosphate (22 mM), nicotinamide adenine dinucleotide (20 mM), Tris buffer, bovine serum albumin, preservatives, and stabilizers.
Units of Measure	µg/mL (µmol/L)	mg/dL (µmol/L)

Attribute	Candidate Device Atellica CH Acetaminophen 2 (ACTM)	Predicate Device Emit tox Acetaminophen (K002974)
Sample Type	Human serum and plasma (K2 EDTA, lithium heparin, sodium heparin)	Human serum and plasma

12. Performance Evaluation Summary

The following FDA-recognized consensus standards were used in the development and evaluation of the Atellica CH Acetaminophen 2 (ACTM) assay.

- CLSI EP17-A2 2nd Edition: *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures*, FDA Recognition Number: 7-233
- CLSI EP05-A3: *Evaluation of Precision Performance of Quantitative Measurement Methods,* FDA Recognition Number: 7-251
- ISO 17511 2nd Edition: *In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators trueness control materials and human samples*, FDA Recognition Number: 7-305
- CLSI EP09c 3rd Edition: *Measurement Procedure Comparison and Bias Estimation Using Patient Samples,* FDA Recognition Number: 7-296
- CLSI EP06 2nd Edition: *Evaluation of the Linearity of Quantitative Measurement Procedures,* FDA Recognition Number: 7-306
- CLSI EP07 3rd Edition: *Interference Testing in Clinical Chemistry*, FDA Recognition Number: 7-275
- CLSI EP37 1st Edition: *Supplemental Tables for Interference Testing in Clinical Chemistry*, FDA Recognition Number: 7-284
- CLSI EP34 1st Edition: *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking,* FDA Recognition Number: 7-290
- CLSI EP25 2nd Edition: *Evaluation of Stability of In Vitro Medical Laboratory Test Reagents* FDA Recognition Number: 7-318

The assay was evaluated for the following performance characteristics:

- Detection Capability (LoB, LoD, LoQ) in accordance with CLSI EP17-A2
- Precision and Reproducibility in accordance with CLSI EP05-A3
- Method Comparison and Specimen Equivalency in accordance with CLSI EP09c-ED3
- Linearity in accordance with CLSI EP06-ED2
- Interference in accordance with CLSI EP07-ED3 and CLSI EP37-ED1
- Shelf-Life Stability of Reagents and Calibrators in accordance with CLSI EP25-ED2
- Calibration interval and Reagent On-Board Stability in accordance with CLSI EP25-ED2
- Dilution Recovery in accordance with CLSI EP34-ED1

13. Performance Characteristics

13.1. Precision

A Within-Lab and Repeatability study was performed according to CLSI EP05-A3. Four (4) samples with varying concentrations of acetaminophen were assayed in duplicate (2), two (2) runs per day, for twenty (20) days, yielding a total of 80 measurements per sample.

Table 1. Atellica CH ACTM Precision Results

Sample	N	Mean µg/mL (µmol/L)	Repeatability SD µg/mL (µmol/L)	Repeatability CV (%)	Within-Lab SD µg/mL (µmol/L)	Within-Lab CV (%)
Serum 1	80	4.7 (31)	0.07 (0.5)	1.5	0.15 (1.0)	3.2
Serum 2	80	45.3 (300)	0.18 (1.2)	0.4	0.71 (4.7)	1.6
Serum 3	80	165.1 (1093)	0.48 (3.2)	0.3	2.37 (15.7)	1.4
Serum 4	80	98.1 (649)	0.29 (1.9)	0.3	1.42 (9.4)	1.4

A Reproducibility study was performed according to CLSI EP05-A3. Four (4) samples with varying concentrations of acetaminophen were assayed in replicates of five (5), one (1) run per day, for five (5) days, on three (3) reagent lots on three (3) Atellica CH analyzers, yielding a total of 225 measurements per sample.

Table 2. Atellica CH ACTM Reproducibility Results

Sample	N	Mean µg/mL (µmol/L)	Repeatability		Between-Day		Between-Lot		Between-Instrument		Reproducibility	
			SD µg/mL (µmol/L)	%CV	SD µg/mL (µmol/L)	%CV	SD µg/mL (µmol/L)	%CV	SD µg/mL (µmol/L)	%CV	SD µg/mL (µmol/L)	%CV
Serum 1	225	4.6 (30)	0.12 (0.8)	2.6	0.10 (0.7)	2.2	0.06 (0.4)	1.3	0.11 (0.7)	2.4	0.20 (1.3)	4.3
Serum 2	225	44.4 (294)	0.21 (1.4)	0.5	0.15 (1.0)	0.3	0.13 (0.9)	0.3	0.29 (1.9)	0.7	0.41 (2.7)	0.9
Serum 3	225	162.3 (1074)	0.50 (3.3)	0.3	0.44 (2.9)	0.3	0.55 (3.6)	0.3	1.06 (7.0)	0.7	1.37 (9.1)	0.8
Serum 4	225	96.4 (638)	0.45 (3.0)	0.5	0.37 (2.4)	0.4	0.17 (1.1)	0.2	0.59 (3.9)	0.6	0.85 (5.6)	0.9

13.2. Linearity

A linearity study was performed according to CLSI EP06-ED2. A dilution series with nine (9) levels was prepared by mixing high human serum and blank native human serum in a known mathematical relationship. Each level was assayed in replicates of four (4) on (1) one test day using one (1) reagent lot on one (1) Atellica CH analyzer.

The assay was demonstrated to be linear from 2.0 – 200.0 µg/mL (13 – 1324 µmol/L).

13.3. Detection Capability

Detection capability studies were performed according to CLSI EP17-A2. The Limit of Blank (LoB) is defined as the highest measurement result that is likely to be observed for a blank sample. The Limit of Detection (LoD) is defined as the lowest concentration of acetaminophen that can be detected with a probability of 95%. The Limit of Quantitation (LoQ) is defined as the lowest amount of acetaminophen in a sample at which the total CV is ≤ 15%.

Table 3. Atellica CH ACTM Detection Capability Results

Detection Capability	Result (µg/mL) (µmol/L)
LoB	0.1 (1)
LoD	0.5 (3)
LoQ	2.0 (13)

13.4. Measuring Interval

The assay measuring interval was determined by Linearity (Section 5.2) and Limit of Quantification (LoQ) (Section 5.3).

The measuring interval is 2.0 – 200.0 µg/mL (13 – 1324 µmol/L).

13.5. Interferences

Interference studies including endogenous interference and exogenous interference were performed according to CLSI EP07-ED3 and CLSI EP37-ED1.

Clinically significant interference as defined by bias greater than 10% or 2.0 µg/mL (whichever is greater) was not observed for the following substances when tested at analyte concentrations at approximately 7.5 to 12.5 µg/mL and 22.5 to 37.5 µg/mL.

Table 4. Interference Results (Hemolysis, Icterus, Lipemia [HIL])

Interferent	Substance Concentration Conventional Units (SI Unit)	Analyte Concentration µg/mL (µmol/L)	Bias
Hemoglobin	500 mg/dL (5.0 g/L)	9.4 (62)	1.2 µg/mL
	1000 mg/dL (10.0 g/L)	28.3 (187)	5%
Conjugated Bilirubin	60 mg/dL (1026 µmol/L)	9.7 (64)	-0.8 µg/mL
	60 mg/dL (1026 µmol/L)	28.4 (188)	-5%
Unconjugated Bilirubin	30 mg/dL (513 µmol/L)	9.6 (64)	0.6 µg/mL
	30 mg/dL (513 µmol/L)	28.4 (188)	-5%
Lipemia (from Intralipid®)	500 mg/dL (5.0 g/L)	9.7 (64)	1.4 µg/mL
	500 mg/dL (5.0 g/L)	28.5 (189)	8%
Lipemia (from Human Triglyceride Fraction)	1500 mg/dL (15 g/L)	8.6 (57)	-1.3 µg/mL
	2250 mg/dL (22.5 g/L)	25.1 (166)	-9%

Clinically significant interference as defined by bias greater than 10% or 2.0 µg/mL (whichever is greater) was not observed for the following substances when tested at analyte concentrations at approximately 7.5 to 12.5 µg/mL and 22.5 to 37.5 µg/mL.

Table 5. Interference Results (Exogenous Substances)

Interferent	Substance Concentration Conventical Units (SI Unit)	Analyte Concentration µg/mL (µmol/L)	Bias
Acetylsalicylic Acid	117.3 mg/dL (6.51 mmol/L)	10.4 (69)	-0.1 µg/mL
	117.3 mg/dL (6.51 mmol/L)	29.3 (194)	0%
Amitriptyline	0.1 mg/dL (3.61 µmol/L)	10.4 (69)	-0.2 µg/mL
	0.1 mg/dL (3.61 µmol/L)	29.3 (194)	1%
Ampicillin	33.3 mg/dL (953.1 µmol/L)	9.6 (64)	0.3 µg/mL
	33.3 mg/dL (953.1 µmol/L)	29.0 (192)	0%
Benzocaine	560 mg/L (3390 µmol/L)	9.6 (64)	0.0 µg/mL
	560 mg/L (3390 µmol/L)	29.0 (192)	0%
Cefoxitin	69 mg/dL (1614.2 µmol/L)	9.5 (63)	-0.3 µg/mL
	69 mg/dL (1614.2 µmol/L)	28.4 (188)	-1%
Codeine	0.141 mg/dL (4.7 µmol/L)	9.7 (64)	0.0 µg/mL
	0.141 mg/dL (4.7 µmol/L)	28.5 (189)	0%
Cyclosporine	1.2 mg/dL (10.0 µmol/L)	10.4 (69)	-0.4 µg/mL
	1.2 mg/dL (10.0 µmol/L)	29.3 (194)	1%
Cysteamine	17.0 µg/mL (220 µmol/L)	9.5 (63)	-0.1 µg/mL
	17.0 µg/mL (220 µmol/L)	28.4 (188)	-1%
Dapsone	5.9 mg/L (23.8 µmol/L)	9.6 (64)	0.0 µg/mL
	5.9 mg/L (23.8 µmol/L)	29.0 (192)	0%

Interferent	Substance Concentration Conventical Units (SI Unit)	Analyte Concentration µg/mL (µmol/L)	Bias
Dipyrone/Metamizole	10 mg/dL (321.2 µmol/L)	9.5 (63)	-0.4 µg/mL
	10 mg/dL (321.2 µmol/L)	28.4 (188)	0%
2,5-Dihydrobenzoic Acid	18.0 µg/mL (117 µmol/L)	9.6 (64)	-0.4 µg/mL
	18.0 µg/mL (117 µmol/L)	28.7 (190)	-5%
Doxycycline	4.5 mg/dL (101.3 µmol/L)	10.4 (69)	-0.5 µg/mL
	4.5 mg/dL (101.3 µmol/L)	29.3 (194)	0%
Ibuprofen	50 mg/dL (2425 µmol/L)	10.4 (69)	-0.2 µg/mL
	50 mg/dL (2425 µmol/L)	29.3 (194)	0%
Imipramine	0.0315 mg/dL (1.1 µmol/L)	9.5 (63)	-0.1 µg/mL
	0.0315 mg/dL (1.1 µmol/L)	28.4 (188)	0%
L-Ascorbic Acid	324 mg/dL (18396.5 µmol/L)	8.8 (58)	-0.7 µg/mL
	324 mg/dL (18396.5 µmol/L)	26.5 (175)	5%
L-Cysteine	2 mg/mL (16507.1 µmol/L)	8.9 (59)	-1.9 µg/mL
	1 mg/mL (8253.5 µmol/L)	26.8 (177)	-9%
Levodopa	0.75 mg/dL (38 µmol/L)	9.6 (64)	-0.1 µg/mL
	0.75 mg/dL (38 µmol/L)	28.2 (187)	-1%

Interferent	Substance Concentration Conventical Units (SI Unit)	Analyte Concentration µg/mL (µmol/L)	Bias
L-Methionine	500 µg/mL (3351 µmol/L)	9.6 (64)	0.1 µg/mL
	500 µg/mL (3351 µmol/L)	28.7 (190)	2%
Methyldopa	2.25 mg/dL (106.5 µmol/L)	9.5 (63)	-0.1 µg/mL
	2.25 mg/dL (106.5 µmol/L)	28.4 (188)	-1%
Metoclopramide	0.225 mg/dL (7.5 µmol/L)	9.6 (64)	0.0 µg/mL
	0.225 mg/dL (7.5 µmol/L)	28.7 (190)	-1%
Metronidazole	12.3 mg/dL (718.7 µmol/L)	9.6 (64)	-0.1 µg/mL
	12.3 mg/dL (718.7 µmol/L)	28.2 (187)	1%
N-Acetylcysteine	100 mg/dL (6.1 mmol/L)	9.7 (64)	-1.5 µg/mL
	100 mg/dL (6.1 mmol/L)	34.2 (226)	-7%
N-Acetylprocainamide	4.8 mg/dL (173.1 µmol/L)	9.5 (63)	0.0 µg/mL
	4.8 mg/dL (173.1 µmol/L)	28.4 (188)	-1%
NAPQI (N-Acetyl-4-benzoquinoneimine)	0.375 mg/dL (25.1 µmol/L)	9.7 (64)	1.3 µg/mL
	0.75 mg/dL (50.3 µmol/L)	29.3 (194)	8%
p-Aminosalicylic Acid	81.2 mg/dL (5.3 mmol/L)	9.6 (64)	0.2 µg/mL
	81.2 mg/dL (5.3 mmol/L)	29.0 (192)	0%

Interferent	Substance Concentration Conventical Units (SI Unit)	Analyte Concentration µg/mL (µmol/L)	Bias
Phenylbutazone	89.1 mg/dL (2.89 mmol/L)	10.4 (69)	-0.5 µg/mL
	89.1 mg/dL (2.89 mmol/L)	29.3 (194)	-2%
Procainamide	4.8 mg/dL (204 µmol/L)	9.5 (63)	0.0 µg/mL
	4.8 mg/dL (204 µmol/L)	28.4 (188)	-2%
Rifampicin	7.5 mg/dL (91.1 µmol/L)	10.4 (69)	-1.7 µg/mL
	7.5 mg/dL (91.1 µmol/L)	29.3 (194)	-3%
Salicylic Acid	60.8 mg/dL (4.4 mmol/L)	9.6 (64)	0.3 µg/mL
	60.8 mg/dL (4.4 mmol/L)	29.0 (192)	1%
Tetracycline	2.4 mg/dL (54 µmol/L)	9.5 (63)	0.1 µg/mL
	2.4 mg/dL (54 µmol/L)	28.4 (188)	-1%
Theophylline	6.0 mg/dL (333 µmol/L)	9.6 (64)	0.0 µg/mL
	6.0 mg/dL (333 µmol/L)	28.2 (187)	-1%
Total Protein	10 g/dL (100 g/L)	10.5 (70)	-0.8 µg/mL
	10 g/dL (100 g/L)	35.9 (238)	-5%

13.6. Traceability

Traceability was established in accordance with ISO 17511.

The assay standardization is traceable to an internal standard manufactured using the highly purified U.S. Pharmacopeia Acetaminophen Reference Standard.

13.7. Stability

Stability studies were performed in accordance with CLSI EP25-ED2.

The Atellica CH Acetaminophen 2 (ACTM) reagents are stable until the date printed on the box label when stored at 2-8°C.

Table 6. Reagent Stability Results

Attribute	Stability
Pack Calibration Interval	3 days
Lot Calibration Interval	30 days
On-Board Stability	15 days

13.8. Dilution Recovery

A Dilution Recovery study was performed in accordance with CLSI EP34-ED1. Five (5) high samples were assayed in replicates of five (5) on one (1) test day using one (1) reagent lot on two (2) Atellica CH analyzers and evaluated for the 3X dilution factor.

Table 7. Dilution Recovery Results

Sample	Dilution
Serum and Plasma	1:3

The extended measuring interval is 2.0 – 600.0 µg/mL (13 – 3972 µmol/L).

13.9. Method Comparison

A Method Comparison study was performed in accordance with CLSI EP09c-ED3. 104 native human serum patient samples were assayed in singlicate (1) using one (1) reagent lot for a minimum of three (3) test days on one (1) Atellica CH analyzer using the Atellica CH ACTM assay and one (1) Beckman Coulter AU680 Clinical Chemistry analyzer using the Syva EMIT tox Acetaminophen assay.

Table 8. Method Comparison Results

Specimen	Comparative Assay	Regression Equation	Sample Interval	N	r
Serum	AU680 EMIT tox Acetaminophen	y = 1.00x + 0.1 µg/mL (y = 1.00x + 1 µmol/L)	2.1 - 181.6 µg/mL (14 - 1202 µmol/L)	104	0.998

13.10. Matrix Comparison

A Matrix Comparison study was performed in accordance with CLSI EP09c-ED3. 51 matched sets of serum, lithium heparin plasma, and sodium heparin plasma, and K2 EDTA plasma were assayed in singlicate (1) using and one (1) reagent lot over seven (7) test days on one (1) Atellica CH analyzer.

Table 9. Matrix Comparison Results

Reference Specimen (X)	Specimen (Y)	Regression Equation µg/mL (µmol/L)	Sample Range µg/mL (µmol/L)	N	r
Serum	Lithium Heparin Plasma	y = 1.01x - 0.1 (y = 1.01x - 1)	3.7 - 184.7 (24 - 1223)	51	1.000
	Sodium Heparin Plasma	y = 1.00x - 0.1 (y = 1.00x - 1)	3.7 - 184.7 (24 - 1223)	51	1.000
	K2 EDTA Plasma	y = 1.01x - 0.5 (y = 1.01x - 3)	3.7 - 184.7 (24 - 1223)	51	1.000

13.11. Sample Stability

The labeling lists the following sample stability for serum and plasma

Table 10. Sample Stability Results

Storage Conditions	Storage Duration
Room Temperature (20-25°C)	8 hours
2-8°C	14 days
Frozen at -20ºC	45 days

13.12. Expected Values/Reference Range

The labeling lists the following therapeutic and toxic acetaminophen concentrations:

Table 11. Reference Range Results

Status	Reference Values
Therapeutic Range	10.0 - 30.0 µg/mL (66 – 199 µmol/L)
Toxic Concentration 4 hours post ingestion	> 200.0 µg/mL (1324 µmol/L)
Toxic Concentration 12 hours post ingestion	> 50.0 µg/mL (331 µmol/L)

Rifai, Nader, Horvath Andrea Rita, Wittwer Carl T. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*. 6th ed. Elsevier; 2018:1801.

14. Conclusion

The Atellica CH Acetaminophen 2 (ACTM) assay is substantially equivalent to the predicate, Emit tox Acetaminophen assay (K002974).