June 12, 2023

Siemens Healthcare Diagnostics Inc.
Anthony Calabro
Regulatory Affairs Specialist
500 GBC Drive,
M/S 514, PO Box 6101
Newark, Delaware 19714

Re: K223078
Trade/Device Name: Atellica® CH Diazo Direct Bilirubin (D_DBil)
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (Total Or Direct) Test System
Regulatory Class: Class II
Product Code: CIG
Dated: February 21, 2023
Received: February 21, 2023

Dear Anthony Calabro:

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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Director
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K223078

Device Name

Atellica® CH Diazo Direct Bilirubin (D_DBil)

Indications for Use *(Describe)*

The Atellica® CH Diazo Direct Bilirubin (D_DBil) assay is for in vitro diagnostic use in the quantitative determination of direct bilirubin in human serum and plasma using the Atellica® CH Analyzer. Measurement of direct bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic-hematological, and metabolic disorders, including hepatitis and gall bladder block.

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 of Safety and Effectiveness

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

The assigned 510(k) Number is: K223078

1. Date Prepared

June 9, 2023

2. Applicant Information

Contact:	Anthony Calabro Regulatory Affairs Specialist
Address:	Siemens Healthcare Diagnostics Inc. P.O. Box 6101, M/S 514 Newark, DE 19714-1601
Email:	anthony.calabro@siemens-healthineers.com

3. Regulatory Information

Atellica® CH Diazo Direct Bilirubin (D_DBil) assay

Trade Name: Atellica® CH Diazo Direct Bilirubin (D_DBil)
Common Name: Bilirubin (total or direct) test system
Classification Name: Diazo Colorimetry, Bilirubin
FDA Classification: Class II
Review Panel: Chemistry
Product Code: CIG
Regulation Number: 21 CFR 862.1110

4. Predicate Device Information

Predicate Device Name: Wako Direct Bilirubin V
510(k) Number: K053132

510(k) Summary of Safety and Effectiveness

5. Intended Use / Indications For Use

The Atellica® CH Diazo Direct Bilirubin (D_DBil) assay is for *in vitro* diagnostic use in the quantitative determination of direct bilirubin in human serum and plasma using the Atellica® CH Analyzer. Measurement of direct bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic-hematologcial, and metabolic disorders, including hepatitis and gall bladder block.

Special Conditions for Use Statement: For Prescription Use Only

6. Device Description

Atellica® CH Diazo Direct Bilirubin is a Photometric test using 2,4-dichloroaniline (DCA). Direct bilirubin in presence of diazotized 2,4-dichloroaniline forms a red colored azocompound in acidic solution. Absorbance is measured at 545/658 nm.

7. Purpose of Submission

The purpose of this submission is a premarket notification for a new device:
Atellica CH Diazo Direct Bilirubin (D_DBil) assay

8. Comparison of Candidate Device and Predicate Device

The table below describes the similarities and differences between the Atellica CH Diazo Direct Bilirubin assay (Candidate Device) and the Wako Direct Bilirubin V (Predicate Device).

Substantial equivalence was demonstrated by testing several performance characteristics including intended use/indications for use, specimen types, units of measure, expected values, and measuring interval.

510(k) Summary of Safety and Effectiveness

Feature	Candidate Device	Predicate Device
	Atellica® CH Diazo Direct Bilirubin (D_DBil)	**Wako Direct Bilirubin V (K053132)**
Intended Use	The Atellica CH Diazo Direct Bilirubin (D_DBil) assay is for *in vitro* diagnostic use in the quantitative determination of direct bilirubin in human serum and plasma using the Atellica CH Analyzer. Measurement of direct bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic-hematologcial, and metabolic disorders, including hepatitis and gall bladder block.	For in vitro diagnostic use in the quantitative determination of direct bilirubin in human serum or plasma. Such measurements are useful in the screening of liver function disorders or in the diagnosis of jaundice.
Sample Type	Human serum and plasma (lithium heparin, sodium heparin, dipotassium EDTA)	Human Serum and plasma (Lithium heparin)
Units of Measure	mg/dL	mg/dL
Assay Range / Measuring Interval	0.10 mg/dL -12.00 mg/dL	0.1–20.0 mg/dL
Expected Values	≤ 0.30 mg/dL (5.13 µmol/L).	≤ 0.30 mg/dL (5.13 µmol/L).

Feature	Candidate Device	Predicate Device
	Atellica® CH Diazo Direct Bilirubin (D_DBil)	**Wako Direct Bilirubin V (K053132)**
Assay Principle	Photometric test using 2,4-dichloroaniline (DCA). Direct bilirubin in presence of diazotized 2,4-dichloroaniline forms a red colored azocompound in acidic solution. Absorbance is measured at 545/658 nm.	Bilirubin is oxidized by vanadate at about pH 3 to produce biliverdin. In the presence of detergent and vanadate, conjugated (direct) bilirubin is oxidized. This oxidation reaction causes a decrease in the optical density of the yellow color, which is specific to bilirubin. The decrease in optical density at 451/545 nm is proportional to the direct bilirubin concentration in the sample. The concentration is measured as an endpoint reaction.
Traceability	Traceable to internal reference standards manufactured by gravimetric methods	Traceable to reference method, which uses reference materials from the National Institute of Standards and Technology (NIST).

510(k) Summary of Safety and Effectiveness

Feature	Candidate Device	Predicate Device
	Atellica® CH Diazo Direct Bilirubin (D_DBil)	**Wako Direct Bilirubin V (K053132)**
Calibration	Single level calibration	Single level calibration
Calibrators	Atellica CH Bilirubin Calibrator (BILI CAL)	Siemens Chemistry Calibrator
Reagents	Two liquid reagents, ready to use	Ready-for-use liquid reagents
Composition	**Pack 1:** **Well 1 Reagent 1:** 23.5mL EDTA-NA2(0.1 mmoll/L); NaCl (150mmol/L) ; sulfamic acid (100 mmol/L) **Well 2 Reagent 1:** 23.5mL EDTA-NA2(0.1 mmoll/L); NaCl (150mmol/L) ; sulfamic acid (100 mmol/L) **Pack 2:** **Well 1 Reagent 2:** 8.8mL 2,4-Dichloroaniline (5 mmol/L); HCl (920mmol/L); EDTA-Na2 (0.13mmol/L); Na-Nitrite (0.5 mmol/L) **Well 2 Reagent 2:** 8.8mL 2,4-Dichloroaniline (5 mmol/L); HCl (920mmol/L); EDTA-Na2 (0.13mmol/L); Na-Nitrite (0.5 mmol/L)	**Direct Bilirubin Reagent 1:** 68 mL in 70-mLcontainers Tartrate buffer, pH 2.9 (0.1 mol/L)Detergent **Direct Bilirubin Reagent 2:** 25 mL in 70-mL containers Phosphate buffer, pH 7.0(10 mmol/L)Sodium metavanadate (4 mmol/L)
Interferences	**Hemoglobin:** No Interference ≤ 12.5 mg/dL **Lipemia:** No Interference ≤ 1000 mg/dL	**Hemoglobin:** No Interference ≤ 750 mg/dL **Lipemia:** No Interference ≤ 1000mg/dL

9. Standard/Guidance Document References

The following recognized standards from Clinical Laboratory Standards Institute (CLSI) were used as a basis of the study procedures described in this submission:

• Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline–Third Edition. (CLSI EP05-A3).
• Interference Testing in Clinical Chemistry (CLSI EP07).
• Measurement Procedure Comparison and Bias Estimation Using Patient Samples (CLSI EP09-A3).
• Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline–Second Edition (EP17-A2).
• Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline (CLSI EP25-A).
• Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition (CLSI EP28-A3c).
• Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking (CLSI EP34-ED1)
• Metrological Traceability and Its Implementation; CLSI EP32-R)
• Supplemental tables for Interference Testing in Clinical Chemistry (CLSI EP37-ED1)
• Evaluation of the Linearity of Quantitative Measurement Procedures -2nd Edition (CLSI EP06 ED2)

10. Performance Characteristics for Atellica ® CH Diazo Direct Bilirubin (D_DBil)

10.1 Detection Capability

The Limit of Blank (LoB) corresponds to the highest measurement result that is likely to be observed for a blank sample. The assay is designed to have an LoB ≤ Limit of Detection (LoD).

The Limit of Detection (LoD) corresponds to the lowest concentration of direct bilirubin that can be detected with a probability of 95%. The assay is designed to have an LoD ≤ Limit of Quantitation(LoQ).

The Limit of Quantitation (LoQ) corresponds to the lowest concentration of direct bilirubin that met the required analyte level but did not reach 20%CV. The assay is designed to have a LoQ of ≤ 0.10mg/dL.

Detection capability was determined in accordance with CLSI Documents EP17-A2.

The following results were obtained:

Specimen Type	Detection Capability	Result mg/dL
Serum/Plasma	LoB	0.00
	LoD	0.02
	LoQ	0.10

10.2 Precision

Precision was determined in accordance with CLSI Document EP05-A3. Samples were assayed on the Atellica CH Analyzer in duplicate in 2 runs per day for 20 days. The following results were obtained.

Specimen Type	N	Mean		Repeatability			Within-Lab		
		Mean (mg/dL)	Mean (µmol/L)	SD (mg/dL)	SD (µmol/L)	CV (%)	SD (mg/dL)	SD (µmol/L)	CV (%)
Serum 1	80	0.37	6.33	0.007	0.120	1.9	0.007	0.120	1.9
Serum 2	80	0.99	16.93	0.004	0.068	0.4	0.007	0.120	0.7
Serum 3	80	4.95	84.65	0.014	0.239	0.3	0.037	0.633	0.7
Serum 4	80	9.16	156.64	0.031	0.530	0.3	0.070	1.197	0.8

10.3 Reproducibility

Reproducibility was determined in accordance with CLSI Document EP05-A3. Samples were assayed with 5 replicates per run for 5 days using 3 instruments/sites and 3 reagent lots. The data was analyzed to calculate the following components of precision: repeatability, between-day, between-lot, between-instrument, and reproducibility (total). The following results were obtained.

Specimen Type	N	Mean mg/dL	Mean µmol/L	Repeatability			Between-Day			Between-LOT			Between SYSTEM			Reproducibility		
				SD mg/dL	SD µmol/L	% CV	SD mg/dL	SD µmol/L	% CV	SD mg/dL	SD µmol/L	% CV	SD mg/dL	SD µmol/L	% CV	SD mg/dL	SD µmol/L	% CV
Serum	225	0.36	6.16	0.006	0.103	1.7	0.001	0.017	0.3	0.009	0.154	2.5	0.002	0.034	0.6	0.011	0.188	3.1
Serum	225	0.97	16.59	0.005	0.086	0.5	0.005	0.086	0.5	0.012	0.205	1.2	0.008	0.137	0.8	0.016	0.274	1.6
Serum	225	5.02	85.84	0.017	0.291	0.3	0.016	0.274	0.3	0.118	2.018	2.4	0.051	0.872	1.0	0.131	2.240	2.6
Serum	225	9.37	160.23	0.027	0.462	0.3	0.026	0.445	0.3	0.290	4.959	3.1	0.072	1.231	0.8	0.301	5.147	3.2

10.4 Assay Comparison

The Atellica CH Diazo Direct Bilirubin (D_DBil) assay was designed to have correlation coefficient of ≥ 0.950 and a slope of 1.00 ± 0.10 compared to the Wako Direct Bilirubin V assay. The following results were obtained.

Specimen Type	Comparison Assay (x)	Regression Equation mg/dL (µmol/L)	Sample Range mg/dL (µmol/L)	N	r
Serum	Wako Direct Bilirubin V	y=0.95x-0.03mg/dL (y=0.95x-.51)umol/L	0.10 - 11.10 (1.71 - 189.81)	100	0.993

N – Number of samples
r – Correlation coefficient

10.5 Specimen Equivalency

The specimen equivalency was determined using the Deming regression model in accordance with CLSI Document EP90c. The following results were obtained:

Specimen Type	Reference Specimen	Regression Equation mg/dL (µmol/L)	Sample Range mg/dL (µmol/L)	N	r
Plasma (Lithium heparin)	Serum	y=1.00x - 0.02 (y=1.00x - 0.34)	0.10 - 10.27 (1.71 - 175.62)	53	0.999
Plasma (Sodium Heparin)	Serum	y=0.98x + 0.00 (y=0.98 + 0.00)	0.10 - 10.27 (1.71 - 175.62)	53	0.999
Plasma K2(EDTA)	Serum	y=0.98x - 0.02 (y=0.98x - 0.34)	0.10 - 10.27 (1.71 - 175.62)	53	0.999

10.6 Interferences

10.6.1 Hemolysis, Icterus, and Lipemia (HIL)

The Atellica CH Diazo Direct Bilirubin (D_DBil) assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and lipemia. Bias is the difference in the results between the control sample (does not contain the interferent) and the test sample (contains the interferent) expressed in a percentage. Bias > 10% is considered interference. Analyte results should not be corrected based on this bias.

Interference testing was performed in accordance with CLSI Document EP07. The following results were obtained:

Interferent concentrations in the table below are the highest concentration tested with no interference.

Substance	Substance Concentration Conventional Units (SI Units)	Analyte Concentration Conventional Units (SI Units)	Bias
Hemoglobin	12.5 mg/dL (0.125 g/L)	0.33 mg/dL (5.64 µmol/L)	-0.10 mg/dL
	12.5 mg/dL (0.125 g/L)	4.84 mg/dL (82.76 µmol/L)	-6.2%
Hemoglobin	25.0 mg/dL (0.250 g/L)	0.31 mg/dL (5.30 µmol/L)	-0.07 mg/dL
	25.0 mg/dL (0.250 g/L)	4.50 mg/dL (76.95 µmol/L)	-8.0%
Hemoglobin	37.5 mg/dL (0.375 g/L)	0.31 mg/dL (5.30 µmol/L)	-0.11 mg/dL
	37.5 mg/dL (0.375 g/L)	4.50 mg/dL (76.95 µmol/L)	-12.2%
Hemoglobin	50.0 mg/dL (0.500 g/L)	0.31 mg/dL (5.30 µmol/L)	-0.14 mg/dL
	50.0 mg/dL (0.500 g/L)	4.50 mg/dL (76.95 µmol/L)	-15.1%
Hemoglobin	75.0 mg/dL (0.750 g/L)	0.31 mg/dL (5.30 µmol/L)	-0.17 mg/dL
	75.0 mg/dL (0.750 g/L)	4.50 mg/dL (76.95 µmol/L)	-22.3%
Hemoglobin	112.5 mg/dL (1.125 g/L)	0.31 mg/dL (5.30 µmol/L)	-0.19 mg/dL
	112.5 mg/dL (1.125 g/L)	4.50 mg/dL (76.95 µmol/L)	-30.8%
Hemoglobin	125.0 mg/dL (1.250 g/L)	0.31 mg/dL (5.30 µmol/L)	-0.20 mg/dL
	125.0 mg/dL (1.250 g/L)	4.50 mg/dL (76.95 µmol/L)	-32.8%
Hemoglobin	150.0 mg/dL (1.500 g/L)	0.31 mg/dL (5.30 µmol/L)	-0.20 mg/dL
	150.0 mg/dL (1.500 g/L)	4.50 mg/dL (76.95 µmol/L)	-36.8%
Hemoglobin	250.0 mg/dL (2.500 g/L)	0.31 mg/dL (5.30 µmol/L)	-0.25 mg/dL
	250.0 mg/dL (2.500 g/L)	4.50 mg/dL (76.95 µmol/L)	-46.2%
Hemoglobin	375.0 mg/dL (3.750 g/L)	0.31 mg/dL (5.30 µmol/L)	-0.26 mg/dL
	375.0 mg/dL (3.750 g/L)	4.50 mg/dL (76.95 µmol/L)	-54.0%
Hemoglobin	500.0 mg/dL (5.000 g/L)	0.31 mg/dL (5.30 µmol/L)	-0.26 mg/dL
	500.0 mg/dL (5.000 g/L)	4.50 mg/dL (76.95 µmol/L)	-59.0%
Lipemia	1000mg/dL (10.00g/L)	0.31 mg/dL (3.50 µmol/L)	-0.07 mg/dL
	1000mg/dL (10.00g/L)	4.55 mg/dL (77.81 µmol/L)	-4.8%

Do not use hemolyzed samples, as they may cause significant interference with this assay. Hemolyzed samples will give falsely negative results.

An H index above 0 (≥1) indicates hemolysis has been detected and results should not be reported out of the laboratory. It is strongly recommended that the HIL index capability be turned on in order to detect hemolysis in samples.

Assay results obtained at individual laboratories may vary from the data presented.

10.6.2 Non-interfering Substances

The following substances do not interfere with Atellica CH Diazo Direct Bilirubin (D_DBil) assay when present in serum and plasma at the concentrations indicated in the table below. Bias due to these substances is ≤ 10%.

Interference testing was performed in accordance with CLSI Document EP07. The following results were obtained:

Interferent	Interferent Concentration (SI)	Observed Analyte (SI)	Observed Bias from Control
Acetaminophen	20 mg/dL (1323.1 µmol/L)	0.29 mg/dL (4.96 µmol/L)	-0.01 mg/dL
Acetaminophen	20 mg/dL (1323.1 µmol/L)	5.23 mg/dL (89.43 µmol/L)	-1.0%
Acetylsalicylic acid	100 mg/dL (5555.6 µmol/L)	0.29 mg/dL (4.96 µmol/L)	-0.01 mg/dL
Acetylsalicylic acid	100 mg/dL (5555.6 µmol/L)	5.21 mg/dL (89.09 µmol/L)	0.0%
Albumin	6 g/dL (60 g/L)	0.29 mg/dL (4.96 µmol/L)	-0.01 mg/dL
Albumin	6 g/dL (60 g/L)	5.48 mg/dL (93.71 µmol/L)	-4.0%
Ascorbic acid	5 mg/dL (284.1 µmol/L)	0.30 mg/dL (5.13 µmol/L)	-0.02 mg/dL
Ascorbic acid	5 mg/dL (284.1 µmol/L)	5.18 mg/dL (88.58 µmol/L)	-1.0%
Carbenicillin	3 mg/dL (79.3 µmol/L)	0.29 mg/dL (4.96 µmol/L)	0.00 mg/dL
Carbenicillin	3 mg/dL	5.23 mg/dL	0.0%

Interferent	Interferent Concentration (SI)	Observed Analyte (SI)	Observed Bias from Control
	(79.3 µmol/L)	(89.43 µmol/L)	
Cholesterol	500 mg/dL	0.30 mg/dL	
	(12.9 mmol/L)	(5.13 µmol/L)	0.00 mg/dL
Cholesterol	500 mg/dL	5.52 mg/dL	
	(12.9 mmol/L)	(94.39 µmol/L)	-1.0%
Diazepam	20 µg/mL	0.27 mg/dL	
	(70.2 µmol/L)	(4.62 µmol/L)	0.00 mg/dL
Diazepam	20 µg/mL	5.09 mg/dL	
	(70.2 µmol/L)	(87.04 µmol/L)	0.0%
Eltrombopag	25 µg/mL	0.28 mg/dL	
	(56.6 µmol/L)	(4.79 µmol/L)	-0.01 mg/dL
Eltrombopag	25 µg/mL	5.03 mg/dL	
	(56.6 µmol/L)	(86.01 µmol/L)	-1.0%
Ethanol	800 mg/dL	0.28 mg/dL	
	(173.5 mmol/L)	(4.79 µmol/L)	0.00 mg/dL
Ethanol	800 mg/dL	5.08 mg/dL	
	(173.5 mmol/L)	(86.87 µmol/L)	-1.0%
Ibuprofen	50 mg/dL	0.29 mg/dL	
	(2427.2 µmol/L)	(4.96 µmol/L)	-0.01 mg/dL
Ibuprofen	50 mg/dL	5.18 mg/dL	
	(2427.2 µmol/L)	(88.58 µmol/L)	-1.0%
IgG	5 g/dL	0.28 mg/dL	
	(333.3 µmol/L)	(4.79 µmol/L)	-0.01 mg/dL
IgG	5 g/dL	4.97 mg/dL	
	(333.3 µmol/L)	(84.99 µmol/L)	-1.0%
Levodopa	300 µg/mL	0.27 mg/dL	
	(1522.8 µmol/L)	(4.62 µmol/L)	0.05mg/dL

Interferent	Interferent Concentration (SI)	Observed Analyte (SI)	Observed Bias from Control
Levodopa	300 µg/mL	4.85 mg/dL	
	(1522.8 µmol/L)	(82.94 µmol/L)	1.0%
Oxytetracycline	50 mg/dL	0.28 mg/dL	
	(1085.9 µmol/L)	(4.79 µmol/L)	0.01 mg/dL
Oxytetracycline	50 mg/dL	5.19 mg/dL	
	(1085.9 µmol/L)	(88.75 µmol/L)	0.0%
Phloroglucinol	1500 ng/mL	0.27 mg/dL	
	(11.9 µmol/L)	(4.62 µmol/L)	0.01 mg/dL
Phloroglucinol	1500 ng/mL	5.26 mg/dL	
	(11.9 µmol/L)	(89.95 µmol/L)	-1.0%
Rheumatoid Factor	510 IU/mL	0.28 mg/dL	
	(510 IU/mL)	(4.79 µmol/L)	0.00 mg/dL
Rheumatoid Factor	510 IU/mL	5.05 mg/dL	
	(510 IU/mL)	(86.36 µmol/L)	0.0%
Rifampicin	6 mg/dL	0.30 mg/dL	
	(72.9 µmol/L)	(5.13 µmol/L)	0.08 mg/dL
Rifampicin	6 mg/dL	5.24 mg/dL	
	(72.9 µmol/L)	(89.60 µmol/L)	0.0%
Total Protein	12 g/dL	0.30 mg/dL	
	(120 g/L)	(5.13 µmol/L)	-0.01 mg/dL
Total Protein	12 g/dL	5.46 mg/dL	
	(120 g/L)	(93.37 µmol/L)	-8.0%

11. Clinical Study

Not applicable.

11.1 Expected Values

Siemens Healthineers has verified the reference interval for serum and plasma for the Atellica CH Diazo Direct Bilirubin assay, in accordance with CLSI Document EP28-A3c is ≤ 0.30 mg/dL (5.13 µmol/L).

12. Traceability

The Atellica CH D_DBil assay is traceable to internal reference standards manufactured by gravimetric methods

13. Clinical Cut-off

Not applicable

14. Conclusion

The results from the performance studies support that the Candidate Device, Atellica CH Diazo Direct Bilirubin (D_DBil) assay is substantially equivalent to the Predicate Device, Wako Direct Bilirubin V (K053132)