March 20, 2023

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

Re: K222104
Trade/Device Name: Atellica® CH Diazo Total Bilirubin (D_TBil)
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (Total Or Direct) Test System
Regulatory Class: Class II
Product Code: CIG
Dated: December 22, 2022
Received: December 22, 2022

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 Caposino -S
Digitally signed by Paula Caposino -S
Date: 2023.03.20 16:51:17 -04'00'

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)*

K222104

Device Name

Atellica® CH Diazo Total Bilirubin (D_TBil)

Indications for Use *(Describe)*

The Atellica® CH Diazo Total Bilirubin (D_TBil) assay is for in vitro diagnostic use in the quantitative determination of total bilirubin in adults and children (non-neonates) in human serum and plasma using the Atellica® CH Analyzer. Measurement of total 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.

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: K222104

1. Date Prepared

December 14, 2022

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 Total Bilirubin (D_TBil) assay

Trade Name: Atellica® CH Diazo Total Bilirubin (D_TBil)
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: Dimension TBI Flex reagent cartridge
510(k) Number: K060628

5. Intended Use / Indications For Use

The Atellica® CH Diazo Total Bilirubin (D_TBil) assay is for in vitro diagnostic use in the quantitative determination of total bilirubin in adults and children (non-neonates) in human serum and plasma using the Atellica® CHAnalyzer. Measurement of total 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.

Special Conditions for Use Statement: For Prescription Use Only

6. Device Description

Atellica CH Diazo Total 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. A specific mixture of detergents enables the determination of the total bilirubin.

7. Purpose of Submission

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

8. Comparison of Candidate Device and Predicate Device

The table below describes the similarities and differences between the Atellica CH Diazo Total Bilirubin assay (Candidate Device) and the Dimension TBI Flex reagent cartridge (Predicate Device).

Substantial equivalence was demonstrated by testing several performance characteristics including measuring interval, expected values, reference interval, precision, method comparison, interference, and specimen equivalence by method comparison.

510(k) Summary of Safety and Effectiveness

Feature	Candidate Device	Predicate Device
	Atellica® CH Diazo Total Bilirubin (D_TBil)	**Dimension TBI Flex reagent cartridge (k060628)**
Intended Use	The Atellica® CH Diazo Total Bilirubin (D_TBil) assay is for in vitro diagnostic use in the quantitative determination of total bilirubin in adults and children (non-neonates) in human serum and plasma using the Atellica® CH Analyzer. Measurement of total 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.	The TBI method for the Dimension® clinical chemistry system is an in vitro diagnostic test intended to quantitatively measure total bilirubin in human serum and plasma. Measurements of total bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gallbladder disease.
Sample Type	Human serum and plasma (lithium heparin, sodium heparin, dipotassium EDTA)	Human Serum and plasma (Lithium heparin, EDTA)
Units of Measure	mg/dL	mg/dL
Assay Range / Measuring Interval	0.10 mg/dL – 25.0 mg/dL	0.10 mg/dL – 25.0 mg/dL
Expected Values	0.3mg/dL – 1.2 mg/dL	0.2 mg/dL – 1.0mg/dL

510(k) Summary of Safety and Effectiveness

Feature	Candidate Device	Predicate Device
	Atellica® CH Diazo Total Bilirubin (D_TBil)	**Dimension TBI Flex reagent cartridge (k060628)**
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. A specific mixture of detergents enables the determination of the total bilirubin.	Diazotized sulfanilic acid is formed by combining sodium nitrite and sulfanilic acid at low pH. Bilirubin (unconjugated) in the sample is solubilized by dilution in a mixture of caffeine/benzoate/acetate/EDTA. Upon addition of the diazotized sulfanilic acid, the solubilized bilirubin including conjugated bilirubins (mono and diglucoronides) and the delta form4 (biliprotein-bilirubin covalently bound to albumin) is converted to diazo-bilirubin, a red chromophore representing the total bilirubin which absorbs at 540 nm and is measured using a bichromatic (540, 700 nm) endpoint technique. A sample blank correction is used.
Traceability	NIST Standard Reference Material 916	Same
Calibration	Single level calibration	Multi-Level Calibration
Calibrators	Atellica CH Bilirubin Calibrator (BILI CAL)	Dimension TBI/DBI Calibrator
Reagents	Two liquid reagents, ready to use	Ready-for-use liquid reagents

Feature	Candidate Device	Predicate Device
	Atellica® CH Diazo Total Bilirubin (D_TBil)	**Dimension TBI Flex reagent cartridge (k060628)**
Composition	**Pack 1:** **Well 1 Reagent 1:** 23.5mL Phosphate buffer (50mmol/L) ; NaCl (150mmol/L) **Well 2 Reagent 1:** 23.5mL Phosphate buffer (50mmol/L) ; NaCl (150mmol/L) **Pack 2:** **Well 1 Reagent 2:** 8.8mL 2,4-Dichloroaniline (5 mmol/L); HCl (130 mmol/L); Na-Nitrite (0.5 mmol/L) **Well 2 Reagent 2:** 8.8mL 2,4-Dichloroaniline (5 mmol/L); HCl (130 mmol/L); Na-Nitrite (0.5 mmol/L)	Multi-Well liquid reagent cartridge that contains: **Wells 1, 4-6:** Acetate Buffer, Caffeine (168 mM), Sodium Benzoate (338 mM), Disodium EDTA (2.57mM) **Well 2:** Sulfanilic acid (25.89 mM), Hydrochloric acid (132 mM), **Well 3:** Sodium Nitrite (72.5 mM)
Interferences	**Hemoglobin:** No Interference ≤ 1000 mg/dL **Lipemia:** No Interference ≤ 1000 mg/dL	**Hemoglobin:** No Interference ≤ 1000 mg/dL **Lipemia:** No Interference ≤ 600mg/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; A Report (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 Total Bilirubin (D_TBil)

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 total 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 total bilirubin that met the required analyte level but did not reach 20% deviation The assay is designed to have an 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	0.01
	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	1.02	17.44	0.015	0.257	1.5	0.034	0.581	3.3
Serum 2	80	13.40	229.14	0.053	0.906	0.4	0.140	2.394	1.0
Serum 3	80	22.39	382.87	0.067	1.146	0.3	0.189	3.232	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.

Sample ID	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
1	Serum	225	1.03	17.61	0.012	0.205	1.2	0.009	0.154	0.9	0.013	0.222	1.3	0.011	0.188	1.1	0.023	0.393	2.2
2	Serum	225	13.24	226.40	0.037	0.633	0.3	0.062	1.060	0.5	0.028	0.479	0.2	0.047	0.804	0.4	0.091	1.556	0.7
3	Serum	225	22.14	378.59	0.057	0.975	0.3	0.106	1.813	0.5	0.053	0.906	0.2	0.063	1.077	0.3	0.146	2.497	0.7

10.4 Assay Comparison

The Atellica CH Diazo Total Bilirubin (D_TBil) assay was designed to have correlation coefficient of ≥ 0.950 and a slope of 1.00 ± 0.10 compared to the Dimension TBI assay. The following results were obtained.

Specimen Type	Comparison Assay (x)	Regression Equation	Sample Range mg/dL (µmol/L)	N	r
Serum	Dimension TBI	y=1.02x+0.08mg/dL (y=1.02x+1.37µmol/L)	0.14-22.55 (2.39-385.61)	103	0.997

10.5 Specimen Equivalency

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

Specimen Type	Comparison Assay (x)	Regression Equation (µmol/L)	Sample Range mg/dL (µmol/L)	N	r
Plasma (Lithium heparin)	Serum	y=0.98x + 0.05 mg/dL (y=0.98X + 0.86 µmol/L)	0.24-22.61 mg/dL (4.10 – 386.63 µmol/L)	57	0.997
Plasma (Sodium Heparin)	Serum	y=1.00x + 0.02 mg/dL (y=1.00X + 0.34 µmol/L)	0.24-22.61 mg/dL (4.10 – 386.63 µmol/L)	57	0.998
Plasma (K2 EDTA)	Serum	y=0.99x + 0.03 mg/dL (y=0.99X + 0.51 µmol/L)	0.24-22.61 mg/dL (4.10 – 386.63 µmol/L)	57	0.998

10.6 Interferences

10.6.1 Hemolysis, Icterus, and Lipemia (HIL)

The Atellica CH Diazo Total Bilirubin (D_TBil) assay is designed to have ≤ 10% interference from hemoglobin, 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	Interferent Concentration (SI)	Observed Analyte mg/dL (µmol/L)	Observed % Bias from Control
Hemoglobin	1000 mg/dL (10.0 g/L)	1.08 (18.47)	-9.3
Hemoglobin	1000 mg/dL (10.0 g/L)	13.86 (237.00)	-7.1
Lipemia (from High Fraction Triglyceride)	1000 mg/dL (10.0 g/L)	0.90 (15.39)	-7.8
Lipemia (from High Fraction Triglyceride)	1000 mg/dL (10.0 g/L)	12.94 (221.27)	0.5

10.6.2 Non-interfering Substances

The following substances do not interfere with Atellica CH Diazo Total Bilirubin (D_TBil) 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 mg/dL (µmol/L)	Acceptance Criteria	Observed % Bias	Acceptance Criteria
Acetaminophen	20 mg/dL 1323.1 µmol/L	1.04 (17.78)	1.00 mg/dL ± 15.0%	-1.9	≤10.0%
Acetaminophen	20 mg/dL 1323.1 µmol/L	13.85 (236.84)	14.00 mg/dL ± 15.0%	-0.4	≤10.0%
Carbenicillin	3 mg/dL 79.3 µmol/L	1.01 (17.27)	1.00 mg/dL ± 15.0%	2.0	≤10.0%
Carbenicillin	3 mg/dL 79.3 µmol/L	13.82 (236.32)	14.00 mg/dL ± 15.0%	0.1	≤10.0%
Ascorbic acid	5 mg/dL 284.1 µmol/L	1.01 (17.27)	1.00 mg/dL ± 15.0%	-2.0	≤10.0%
Ascorbic acid	5 mg/dL 284.1 µmol/L	13.51 (231.02)	14.00 mg/dL ± 15.0%	-0.4	≤10.0%
Acetylsalicylic acid	100 mg/dL 5555.6 µmol/L	1.01 (17.27)	1.00 mg/dL ± 15.0%	0.0	≤10.0%
Acetylsalicylic acid	100 mg/dL 5555.6 µmol/L	13.62 (232.90)	14.00 mg/dL ± 15.0%	0.1	≤10.0%
Ibuprofen	50 mg/dL	1.01	1.00 mg/dL	-5.0	≤10.0%

Interferent	Interferent Concentration (SI)	Observed Analyte mg/dL (µmol/L)	Acceptance Criteria	Observed % Bias	Acceptance Criteria
	2427.2 µmol/L	(17.27)	± 15.0%		
Ibuprofen	50 mg/dL 2427.2 µmol/L	13.50 (230.85)	14.00 mg/dL ± 15.0%	-0.3	≤10.0%
Rifampicin	6 mg/dL 72.9 µmol/L	1.02 (17.44)	1.00 mg/dL ± 15.0%	-2.0	≤10.0%
Rifampicin	6 mg/dL 72.9 µmol/L	13.66 (233.59)	14.00 mg/dL ± 15.0%	-3.5	≤10.0%
Diazepam	20 µg/mL 70.2 µmol/L	1.03 (17.61)	1.00 mg/dL ± 15.0%	-1.9	≤10.0%
Diazepam	20 µg/mL 70.2 µmol/L	13.81 (236.15)	14.00 mg/dL ± 15.0%	0.2	≤10.0%
Ethanol	800 mg/dL 173.5 mmol/L	1.04 (17.78)	1.00 mg/dL ± 15.0%	-1.9	≤10.0%
Ethanol	800 mg/dL 173.5 mmol/L	13.78 (235.64)	14.00 mg/dL ± 15.0%	-0.7	≤10.0%
Eltrombopag	25 µg/mL 56.6 µmol/L	0.99 (16.93)	1.00 mg/dL ± 15.0%	0.0	≤10.0%
Eltrombopag	25 µg/mL 56.6 µmol/L	13.67 (233.76)	14.00 mg/dL ± 15.0%	0.3	≤10.0%
Cholesterol	500 mg/dL 12.9 mmol/L	1.03 (17.61)	1.00 mg/dL ± 15.0%	-1.0	≤10.0%
Cholesterol	500 mg/dL 12.9 mmol/L	13.69 (234.10)	14.00 mg/dL ± 15.0%	-0.7	≤10.0%

Interferent	Interferent Concentration (SI)	Observed Analyte mg/dL (µmol/L)	Acceptance Criteria	Observed % Bias	Acceptance Criteria
Phenazopyridine HCl	80 µg/mL 32.04 µmol/L	0.98 (16.76)	1.00 mg/dL ± 15.0%	0.0	≤10.0%
Phenazopyridine HCl	80 µg/mL 32.04 µmol/L	12.99 (222.13)	14.00 mg/dL ± 15.0%	0.5	≤10.0%
Phloroglucinol	250 ng/mL 2 µmol/L	1.01 (17.27)	1.00 mg/dL ± 15.0%	0.0	≤10.0%
Phloroglucinol	250 ng/mL 2 µmol/L	13.77 (235.47)	14.00 mg/dL ± 15.0%	-0.9	≤10.0%
Cyanokit (Hydroxocobalamin)	40 µg/mL 29.7 µmol/L	1.01 (17.27)	1.00 mg/dL ± 15%	-4.0	≤10.0%
Cyanokit (Hydroxocobalamin)	40 µg/mL 29.7 µmol/L	13.58 (232.22)	14.00 mg/dL ± 15.0%	-2.0	≤10.0%
Levodopa	225 µg/mL 1142.1 µmol/L	0.93 (15.90)	1.00 mg/dL ± 15.0%	8.6	≤10.0%
Levodopa	300 µg/mL 1522.8 µmol/L	12.82 (219.22)	14.00 mg/dL ± 15%	0.5	≤10.0%
IgG	5 g/dL 333.3 µmol/L	0.96 (16.42)	1.00 mg/dL ± 15.0%	-1.0	≤10.0%
IgG	5 g/dL 333.3 µmol/L	12.90 (220.59)	14.00 mg/dL ± 15.0%	-0.2	≤10.0%
Indican	1.5 mg/dL 59.7 µmol/L	0.94 (16.07)	1.00 mg/dL ± 15.0%	7.9	≤10.0%
Indican	31.3 mg/dL	13.59	14.00 mg/dL	8.6	≤10.0%

Interferent	Interferent Concentration (SI)	Observed Analyte mg/dL (µmol/L)	Acceptance Criteria	Observed % Bias	Acceptance Criteria
	1245.5 µmol/L	(232.39)	± 15.0%		

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 Total Bilirubin assay, in accordance with CLSI Document EP28-A3c is 0.3 - 1.2mg/dL (5.13 - 20.52 µmol/L)

12. Traceability

The assay is traceable to the NIST Standard Reference Material 916.

13. Clinical Cut-off

Not applicable

14. Conclusion

The results from the performance studies support that the Candidate Device, Atellica CH Diazo Total Bilirubin (D_TBil) assay is substantially equivalent to the Predicate Device, Dimension TBI assay (K060628)