July 26, 2024

Siemens Healthcare Diagnostics, Inc.
Justin Thomas
Regulatory Affairs, Senior Manager
500 GBC Drive, P.O. Box 6101
Newark, Delaware 19714

Re: K241800
Trade/Device Name: Atellica® CH LDL Cholesterol (LDLC), Atellica® CH HDL Cholesterol (HDLC)
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I, meets limitations per 21 CFR 862.9(c)(4)
Product Code: MRR, LBS
Dated: June 20, 2024
Received: June 21, 2024

Dear Justin Thomas:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Deputy Division 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241800

Device Name

Atellica® CH HDL Cholesterol (HDLC)& Atellica® CH LDL Cholesterol (LDLC)

Indications for Use *(Describe)*

Atellica CH HDL Cholesterol (HDLC) assay
The Atellica® CH HDL Cholesterol (HDLC) assay is for in vitro diagnostic use in the quantitative determination of HDL cholesterol in human serum and plasma (lithium heparin, EDTA, sodium Heparin) using the Atellica® CH Analyzer. HDLC measurements are used in the diagnosis and treatment of atherosclerosis.

Atellica CH LDL Cholesterol (LDLC) assay
The Atellica® CH LDL Cholesterol (LDLC) assay is for in vitro diagnostic use in the quantitative determination of LDL cholesterol in human serum and plasma (lithium heparin, EDTA, sodium heparin) using the Atellica® CH Analyzer. LDLC measurements are used in the diagnosis and treatment of atherosclerosis

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: K241800

1. Date Prepared

June 20, 2024

2. Applicant Information

Contact: Justin Thomas
Regulatory Affairs, Sr. Manager

Address: 500 GBC Drive, P.O. Box 6101
Mail Stop 514
Newark, DE 19714, USA

Email: Justin.E.Thomas@Siemens-Healthineers.com

3. Regulatory Information

Information	Atellica® CH HDL Cholesterol (HDLC)	Atellica® CH LDL Cholesterol (LDLC)
Trade Name	Atellica® CH HDL Cholesterol (HDLC)	Atellica® CH LDL Cholesterol (LDLC)
Device	Ldl & Vldl Precipitation, Cholesterol Via Esterase-Oxidase, Hdl	System, Test, Low Density, Lipoprotein
Regulation Description	Lipoprotein test system	Lipoprotein test system
FDA Device Classification	Class I, exceeds the limitations of exemption under 21 CFR 862.9(c)(4).	Class I, exceeds the limitations of exemption under 21 CFR 862.9(c)(4).
Review Panel	Clinical Chemistry	Clinical Chemistry
Product Code	LBS	MRR
Regulation Number	21 CFR 862.1475	21 CFR 862.1475

4. Predicate Device Information

Candidate Device	Predicate Device	Predicate 510(k) Clearance#
Atellica® CH HDL Cholesterol (HDLC)	Ultra N-geneous® HDL Cholesterol Reagent	K021316
Atellica® CH LDL Cholesterol (LDLC)	Dimension® Automated LDL Cholesterol (ALDL)	K020724

5. Intended Use / Indications For Use

Product	Intended Use
Atellica® CH HDL Cholesterol (HDLC) assay	The Atellica® CH HDL Cholesterol (HDLC) assay is for in vitro diagnostic use in the quantitative determination of HDL cholesterol in human serum and plasma (lithium heparin, EDTA, sodium Heparin) using the Atellica® CH Analyzer. HDLC measurements are used in the diagnosis and treatment of atherosclerosis.
Atellica® CH LDL Cholesterol (LDLC) assay	The Atellica® CH LDL Cholesterol (LDLC) assay is for in vitro diagnostic use in the quantitative determination of LDL cholesterol in human serum and plasma (lithium heparin, EDTA, sodium heparin) using the Atellica® CH Analyzer. LDLC measurements are used in the diagnosis and treatment of atherosclerosis.

Special Conditions for Use Statement(s): For Prescription Use Only.

6. Device Description

Product	Device Description
Atellica® CH HDL Cholesterol (HDLC) assay	The method is in a two reagent format and depends on the Accelerator Selective Detergent methodology. This method is based on accelerating the reaction of cholesterol oxidase (CO) with non-HDL unesterified cholesterol and dissolving HDL selectively using a specific detergent. In the first reagent, non-HDL unesterified cholesterol is subject to an enzyme reaction and the peroxide generated is consumed by a peroxidase reaction with DSBmT yielding a colorless product. The second reagent consists of a detergent capable of solubilizing HDL specifically, cholesterol esterase (CE) and chromogenic coupler to develop color for the quantitative determination of HDL cholesterol.
Atellica® CH LDL Cholesterol (LDLC) assay	The Atellica® CH LDLC assay is a homogeneous assay for directly measuring LDL-C levels in human serum or plasma, without the need for any off-line pretreatment or centrifugation steps. The assay is in a two reagent format and depends on the properties of detergent 1 which solubilizes only non- LDL particles. Cholesterol released is consumed by cholesterol esterase and cholesterol oxidase in a non-color forming reaction. Detergent 2 solubilizes the remaining LDL particles. The soluble LDL-C is then oxidized by the action of cholesterol esterase and cholesterol oxidase forming cholestenone and hydrogen peroxide (H2O2). The enzymatic action of peroxidase on H2O2 produces color in the presence of N,N-bis(4 sulfobutyl)-m-toluidine, disodium salt (DSBmT) and 4-aminoantipyrine (4-AA) that is measured using a bichromatic (545/694 nm) endpoint technique. The

Product	Device Description
	color produced is directly proportional to the amount of LDL-C present in the sample.

7. Purpose of Submission

The purpose of this submission is a premarket notification for the new devices:

- Atellica® CH HDL Cholesterol (HDLC) assay
- Atellica® CH LDL Cholesterol (LDLC) assay

8. Comparison of Candidate Device and Predicate Device

8.1 Atellica® CH HDL Cholesterol (HDLC) assay

The table below describes the similarities and differences between the Atellica® CH HDL Cholesterol (HDLC) assay (Candidate Device), and the Ultra N-geneous® HDL Cholesterol Reagent assay (Predicate Device).

The performance and accuracy of the Candidate Device are substantially equivalent to those of the Predicate Device. The method comparison of the Candidate Device and the Predicate Device demonstrates acceptable correlation between the two methods.

Table 1: Comparison Table of Candidate Device and Predicate Device

Feature	**Candidate Device**	**Predicate Device**
	Atellica® CH HDL Cholesterol (HDLC)	**Ultra N-geneous® HDL Cholesterol Reagent**
Intended Use	The Atellica® CH HDL Cholesterol (HDLC) assay is for in vitro diagnostic use in the quantitative determination of HDL cholesterol in human serum and plasma (lithium heparin, EDTA, sodium Heparin) using the Atellica® CH Analyzer.	For the quantitative measurement of high-density lipoprotein cholesterol in human serum or plasma.
Indications for Use	HDLC measurements are used in the diagnosis and treatment of atherosclerosis.	Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus, atherosclerosis and various liver and renal diseases).
Sample Type	Serum, Plasma (lithium heparin, sodium heparin and potassium EDTA)	Serum, Plasma (Lithium Heparin, EDTA)
Units of Measure	mg/dL	Same

Feature	Candidate Device	Predicate Device
	Atellica® CH HDL Cholesterol (HDLC)	**Ultra N-geneous® HDL Cholesterol Reagent**
Assay Range / Measuring Interval	5.0 to 200.0 mg/dL	2.5 to 200 mg/dL
Expected Values Serum/Plasma	Low (undesirable, high risk): < 40 mg/dL High (desirable, low risk): ≥ 60 mg/dL	Males: 30 - 70 mg/dL Females: 30 - 85 mg/dL
Assay Principle	Enzymatic	Same
Standardization	Ultracentrifugation- Heparin-Mn quantitation	Same
Calibration	2 point	Same
Calibrators	Atellica® CH HDLC CAL (HDLC CAL)	Same (Branded HDL Ultra Cholesterol Calibrator

8.2 Atellica® CH LDL Cholesterol (LDLC) assay

The table below describes the similarities and differences between the Atellica® CH LDL Cholesterol (LDLC) assay (Candidate Device), and the Dimension® Automated LDL Cholesterol (ALDL) assay (Predicate Device).

The performance and accuracy of the Candidate Device are substantially equivalent to those of the Predicate Device. The method comparison of the Candidate Device and the Predicate Device demonstrates acceptable correlation between the two methods.

Table 2: Comparison Table of Candidate Device and Predicate Device

Feature	Candidate Device	Predicate Device
	Atellica® CH LDL Cholesterol (LDLC)	**Dimension® Automated LDL Cholesterol (ALDL) (K020724)**
Intended Use	The Atellica® CH LDL Cholesterol (LDLC) assay is for in vitro diagnostic use in the quantitative determination of LDL cholesterol in human serum and plasma (lithium heparin, EDTA, sodium heparin) using the Atellica® CH Analyzer.	The ALDL method for the Dimension® clinical chemistry system is an in vitro diagnostic test intended for the quantitative determination of low-density lipoprotein cholesterol (LDL-C) in human serum and plasma.
Indications for Use	LDLC measurements are used in the diagnosis and treatment of atherosclerosis.	LDL-C measurements are used in the diagnosis and treatment of lipid disorders such as diabetes mellitus, atherosclerosis, and various liver and renal diseases.
Sample Type	Serum, plasma (lithium heparin, sodium heparin and potassium EDTA)	same
Units of Measure	mg/dL	Same
Assay Range / Measuring Interval	Serum/Plasma: 5 to 400 mg/dL	Serum/Plasma: 5 to 300 mg/dL
Expected Values Serum/Plasma	Optimal: < 100 mg/dL (< 2.59 mmol/L) Near optimal / above optimal: 100–129 mg/dL (2.59–3.34 mmol/L) Borderline high: 130–159 mg/dL (3.35–4.12 mmol/L) High: 160–189 mg/dL (4.13–4.91 mmol/L) Very high: ≥ 190 mg/dL (≥ 4.92 mmol/L)	same
Assay Principle	Enzymatic	Same
Standardization	The assigned values are traceable to the NCEP beta-quantification reference method for LDL cholesterol.	Same
Calibration	2 points	3 points

Feature	Candidate Device	Predicate Device
	Atellica® CH LDL Cholesterol (LDLC)	**Dimension® Automated LDL Cholesterol (ALDL) (K020724)**
Calibrators	Atellica® CH LDLC CAL (LDLC CAL)	Dimension® ALDL Calibrator

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 for both the Atellica® CH HDL Cholesterol (HDLC) assay and the Atellica® CH LDL Cholesterol (LDLC) assay:

- Evaluation of Precision of Quantitative Measurement Procedures–Third Edition. (CLSI EP05-A3).
- Interference Testing in Clinical Chemistry, 3rd Edition (CLSI EP07-ED3).
- Measurement Procedure Comparison and Bias Estimation Using Patient Samples, 3rd Edition (CLSI EP09C-ED3).
- Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline–Second Edition (EP17-A2).
- Evaluation of Stability of In Vitro Diagnostic Reagents, 1st Edition (CLSI EP25-A)
- Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Third Edition. (CLSI EP28-A3C).
- Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking, 1st Edition (CLSI EP34-ED1).
- Evaluation of the Linearity of Quantitative Measurement Procedures: A statistical Approach, 1st Edition (CLSI EP06-A).

10. Performance Characteristics for Atellica® CH HDL Cholesterol (HDLC) Assay

10.1 Detection Capability

10.1.1 Atellica® CH HDLC

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 HDL Cholesterol 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 HDL Cholesterol in a sample at which the within lab imprecision is ≤ 20%CV for serum and plasma. The assay is designed to have an LoQ ≤ 5.0 mg/dL for serum and plasma.

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

The following results were obtained:

Table 3: HDLC Instructions for Use Detection Capability Claims

Specimen Type	Detection Capability	Result mg/dL
Serum/plasma	LoB	3.0
	LoD	4.0
	LoQ	5.0

10.1.2 Atellica® CH LDLC

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 LDL Cholesterol that can be detected with a probability of 95%. The assay is designed to have an LoD ≤ LoQ.

The Limit of Quantitation (LoQ) corresponds to the lowest concentration of LDL Cholesterol in a sample at which the within lab imprecision is ≤ 20%CV for serum and plasma. The assay is designed to have an LoQ ≤ 5.0 mg/dL (≤0.13 mmol/L).

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

The following results were obtained:

Specimen Type	Detection Capability	Result mg/dL
Serum/plasma	LoB	3.0
	LoD	4.0
	LoQ	5.0

10.2 Precision

10.2.1 Atellica® CH HDLC

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:

Table 4: HDLC Instructions for Use Precision Claims

Specimen Type	N[a]		Repeatability		Within-Lab	
		Mean mg/dL	SD[b] mg/dL	CV[c] (%)	SD mg/dL	CV (%)
Serum 1	80	39.7	0.26	0.7	1.07	2.7
Serum QC	80	77.7	0.28	0.4	1.50	1.9
Serum 2	80	167.8	0.67	0.4	2.02	1.2

[a] Number of results.
[b] Standard deviation.
[c] Coefficient of variation.

10.2.2 Atellica® CH LDLC

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[a]		Repeatability		Within-Lab	
		Mean mg/dL	SD[b] mg/dL (mmol/L)	CV[c] (%)	SD mg/dL (mmol/L)	CV (%)
Serum 1	80	46	0.5	1.1	0.8	1.7
Serum QC	80	108	0.7	0.6	1.8	1.7

[a] Number of results.
[b] Standard deviation.
[c] Coefficient of variation.

10.3 Reproducibility

10.3.1 Atellica® CH HDLC

Reproducibility was determined in accordance with CLSI Document EP05-A3. Samples were assayed n=5 in 1 run for 5 days using 3 instruments and 3 reagent lots. The data were analyzed to calculate the following components of precision: repeatability, between-day, between-lot, between-instrument, and reproducibility (total). The following results were obtained:

Table 5: HDLC Instructions for Use Reproducibility Claims

				Reproducibility													
				Repeatability			Between Day			Between Lot			Between Instrument			Total Reproducibility		
		Mean		SD[b]		CV[c]	SD		CV	SD		CV	SD		CV	SD		CV
SAMPLE	N[a]	mg/dL	mmol/L	mg/dL	mmol/L	%	mg/dL	mmol/L	%	mg/dL	mmol/L	%	mg/dL	mmol/L	%	mg/dL	mmol/L	%
Serum 1	225	38.0	0.99	0.18	0.005	0.5	0.32	0.008	0.8	0.00	0.000	0.0	0.06	0.002	0.2	0.37	0.010	1.0
Serum 2	225	166.2	4.31	0.46	0.012	0.3	1.45	0.037	0.9	0.00	0.000	0.0	0.53	0.014	0.3	1.61	0.042	1.0
QC1	225	22.3	0.58	0.26	0.007	1.2	0.40	0.010	1.8	0.00	0.000	0.0	0.01	0.000	0.1	0.47	0.012	2.1
QC2	225	42.1	1.09	0.45	0.012	1.1	0.45	0.012	1.1	0.00	0.000	0.0	0.08	0.002	0.2	0.64	0.017	1.5
QC3	225	75.8	1.96	0.26	0.007	0.3	0.90	0.023	1.2	0.35	0.009	0.5	0.45	0.012	0.6	1.10	0.028	1.4

[a] Number of results.
[b] Standard deviation.
[c] Coefficient of variation.

10.3.2 Atellica® CH LDLC

Reproducibility was determined in accordance with CLSI Document EP05-A3. Samples were assayed n=5 in 1 run for 5 days using 3 instruments and 3 reagent lots. The data were analyzed to calculate the following components of precision: repeatability, between-day, between-lot, between-instrument, and reproducibility (total). The following results were obtained:

SAMPLE	N[a]	Mean		Reproducibility														
				Repeatability			Between Day			Between Lot			Between Instrument			Total Reproducibility		
				SD[b]		CV[c]	SD		CV	SD		CV	SD		CV	SD		CV
		mg/dL	mmol/L	mg/dL	mmol/L	%	mg/dL	mmol/L	%	mg/dL	mmol/L	%	mg/dL	mmol/L	%	mg/dL	mmol/L	%
Serum 1	225	96	2.49	0.4	0.009	0.4	0.5	0.014	0.6	0.8	0.021	0.8	0.0	0.000	0.0	1.0	0.027	1.1
Serum 2	225	330	8.54	1.1	0.029	0.3	1.9	0.048	0.6	4.4	0.113	1.3	0.0	0.000	0.0	4.9	0.126	1.5
QC1	225	57	1.48	0.4	0.012	0.8	0.7	0.017	1.2	0.1	0.002	0.2	0.0	0.000	0.0	0.8	0.021	1.4
QC2	225	106	2.75	0.8	0.022	0.8	0.7	0.017	0.6	0.4	0.009	0.3	0.0	0.000	0.0	1.1	0.029	1.1
QC3	225	149	3.85	0.6	0.015	0.4	1.4	0.036	0.9	0.0	0.000	0.0	0.0	0.000	0.0	1.5	0.039	1.0

[a] Number of results.

[b] Standard deviation.

[c] Coefficient of variation.

10.4 Assay Comparison

10.4.1 Atellica® CH HDLC

The Atellica® CH HDLC assay (y) was designed to have a correlation coefficient of ≥ 0.970 and a slope of 1.00 ± 0.05 compared to the Ultra N-Geneous HDL Cholesterol assay on the Hitachi® 911 analyzer. Assay comparison was determined using the Weighted Deming regression model in accordance with CLSI Document EP09C-ED3. The following results were obtained:

Table 6: HDLC Instructions for Use Method Comparison Claims

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum	Ultra N-Geneous HDL Cholesterol on Hitachi 911	y=1.00x+1.8 mg/dL (y=1.00x+0.05 mmol/L)	10.2-195.1 mg/dL (0.26-5.05 mmol/L)	105	0.998

[a] Number of samples tested.

[b] Correlation coefficient.

10.4.2 Atellica® CH LDLC

The Atellica® CH LDLC assay (y) was designed to have a correlation coefficient of ≥ 0.95 and a slope of 1.00 ± 0.06 compared to the Dimension® ALDL assay. Assay comparison was determined using the Weighted Deming regression model in accordance with CLSI Document EP09C-ED3. The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum	Dimension ALDL	y = 1.02x - 1 mg/dL y = 1.02x - 0.03 mmol/L	10 to 419 mg/dL (0.26 to 10.85 mmol/L)	132	0.996

[a] Number of samples tested.

[b] Correlation coefficient.

10.5 Specimen Equivalence

10.5.1 Atellica® CH HDLC

The specimen equivalency was determined using the Weighted Deming regression model in accordance with CLSI Document EP09-A3. The following results were obtained:

Table 7: HDLC Instructions for Use Specimen Equivalence Claims

Specimen (y)	Reference Specimen (x)	Regression Equation mg/dL (mmol/L)	Sample Interval mg/dL (mmol/L)	N[a]	r[b]
Lithium Heparin Plasma	Serum	y=1.01x - 1.2 (y=1.01x - 0.03)	35.7 to 191.4 (0.92 to 4.96)	60	0.994
Sodium Heparin Plasma	Serum	y=1.01x - 0.5 (y=1.01x - 0.01)	35.7 to 191.4 (0.92 to 4.96)	60	0.994
EDTA Plasma	Serum	y=0.99x + 0.1 (y=0.99x + 0.00)	35.7 to 191.4 (0.92 to 4.96)	60	0.994

[a] Number of samples tested.
[b] Correlation Coefficient.

10.5.2 Atellica® CH LDLC

The specimen equivalency was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3. The following results were obtained:

Specimen (y)	Reference Specimen (x)	Regression Equation mg/dL (mmol/L)	Sample Interval mg/dL (mmol/L)	N[a]	r[b]
Lithium Heparin Plasma	Serum	y=0.97x + 1 (y=0.97x + 0.03)	46 to 390 (1.19 to 10.10)	60	0.996
Sodium Heparin Plasma	Serum	y=0.98x + 0 (y=0.98x + 0.00)	46 to 390 (1.19 to 10.10)	60	0.997
EDTA Plasma	Serum	y=0.99x - 2 (y=0.99x – 0.05)	46 to 390 (1.19 to 10.10)	60	0.995

[a] Number of samples tested.
[b] Correlation Coefficient.

10.6 Interferences

10.6.1 Atellica® CH HDLC

10.6.1.1 Hemolysis, Icterus, and Lipemia (HIL)

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 percent. The Atellica® CH HDLC assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and lipemia. 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-A2.12 The following results were obtained:

Table 8: HDLC Instructions for Use Interference HIL Claims

Substance	Substance Concentration		Analyte Concentration mg/dL (mmol/L)	Bias %
Hemoglobin	375 mg/dL	3.75 g/L	32.12 (0.83)	2
Hemoglobin	375 mg/dL	3.75 g/L	80.12 (2.08)	0
Conjugated Bilirubin	30 mg/dL	513 µmol/L	31.68 (0.82)	-10
Conjugated Bilirubin	30 mg/dL	513 µmol/L	78.72 (2.04)	-1
Unconjugated Bilirubin	60 mg/dL	1026 µmol/L	31.58 (0.82)	3
Unconjugated Bilirubin	60 mg/dL	1026 µmol/L	78.12 (2.02)	-2
Lipemia (from Intralipid®)	1000 mg/dL	10 g/L	31.56 (0.82)	-4
Lipemia (from Intralipid®)	1000 mg/dL	10 g/L	77.58 (2.01)	1

10.6.1.2 Non-Interfering Substances

The following substances do not interfere with the Atellica® CH HDLC assay when present in serum and plasma at the concentrations indicated in the tables below. Bias due to these substances is ≤ 10%.

Table 9: HDLC Instructions for Use Non-Interfering Substance Claims

Substance	Substance Concentration		Analyte Concentration mg/dL (mmol/L)	Bias %
Ascorbic Acid	100 mg/dL	5680 µmol/L	31.24 (0.81)	-1
Ascorbic Acid	100 mg/dL	5680 µmol/L	77.92 (2.02)	0

10.6.2 Atellica® CH LDLC

10.6.2.1 Hemolysis, Icterus, and Lipemia (HIL)

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 percent. The Atellica® CH LDLC assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and lipemia. 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-A2.16 The following results were obtained:

Substance	Substance Concentration		Analyte Concentration mg/dL (mmol/L)	Bias %
Hemoglobin	1000 mg/dL	10 g/L	79.4 (2.06)	10
Hemoglobin	1000 mg/dL	10 g/L	165.2 (4.28)	5
Conjugated Bilirubin	20 mg/dL	342 µmol/L	85.0 (2.20)	-6
Conjugated Bilirubin	45 mg/dL	770 µmol/L	165.0 (4.27)	-10
Unconjugated Bilirubin	30 mg/dL	513 µmol/L	79.2 (2.05)	-9
Unconjugated Bilirubin	45 mg/dL	770 µmol/L	157.8 (4.09)	-8
Lipemia (from Intralipid®)	1000 mg/dL	10 g/L	84.2 (2.18)	-7
Lipemia (from Intralipid®)	1000 mg/dL	10 g/L	170.6 (4.42)	-8

10.6.2.2 Non-Interfering Substances

The following substances do not interfere with the Atellica® CH LDLC assay when present in serum and plasma at the concentrations indicated in the tables below. Bias due to these substances is ≤ 10%.

Substance	Substance Concentration		Analyte Concentration mg/dL (mmol/L)	Bias %
Ascorbic Acid	5 mg/dL	284 µmol/L	83.6 (2.17)	-2
Ascorbic Acid	5 mg/dL	284 µmol/L	167.6 (4.34)	3

11. Clinical Study

11.1.1 Atellica® CH HDLC

Not applicable.

11.1.2 Atellica® CH LDLC

Not Applicable

11.2 Expected Values

11.2.1 Atellica® CH HDLC

A reference interval for healthy adults was established by the National Cholesterol Education Program (NCEP) and verified on the Atellica® CH Analyzer[a].

Table 10: HDLC Instructions for Use Reference Interval Claims

Group	Specimen Type	Reference Interval Conventional Units (SI Units)
Adults	Serum/Plasma	Low (undesirable, high risk): < 40.0 mg/dL (< 1.04 mmol/L) High (desirable, low risk): ≥ 60.0 mg/dL (≥ 1.55 mmol/L)

[a] National Cholesterol Education Program. Third Report of the Expert Panel on Detection, Evaluation, and Treatment of the High Blood Cholesterol in Adults (Adult Treatment Panel III). National Institutes of Health; 2001. NIH Publication No. 01-3670.

11.2.2 Atellica® CH LDLC

A reference interval for healthy adults was established by the National Cholesterol Education Program (NCEP) and verified on the Atellica® CH Analyzer[a].

Group	Specimen Type	Reference Interval Conventional Units (SI Units)
Adults	Serum/Plasma	Optimal <100 mg/dL (< 2.59 mmol/L) Near optimal 100 - 129 mg/dL (2.59–3.34 mmol/L) Borderline high 130 - 159 mg/dL (3.35–4.12 mmol/L) High 160 - 189 mg/dL (4.13–4.91 mmol/L) Very high ≥ 190 mg/dL (≥ 4.92 mmol/L)

[a] National Cholesterol Education Program. Third Report of the Expert Panel on Detection, Evaluation, and Treatment of the High Blood Cholesterol in Adults (Adult Treatment Panel III). National Institutes of Health; 2001. NIH Publication No. 01-3670.

12. Standardization

12.1.1 Atellica® CH HDLC

The assay is traceable to Ultracentrifugation- Heparin-Mn quantitation.

12.1.2 Atellica® CH LDLC

The assigned values are traceable to the NCEP beta-quantification reference method for LDL cholesterol.

13. Clinical Cut-off

13.1.1 Atellica® CH HDLC

Not applicable.

13.1.2 Atellica® CH LDLC

Not applicable.

14. Conclusion

14.1 Atellica® CH HDL Cholesterol (HDLC) assay

The results from the performance studies support that the Candidate Device**,** Atellica® CH HDL Cholesterol (HDLC) assay, is substantially equivalent to the Predicate Device, Ultra N-geneous® HDL Cholesterol Reagent assay (K021316).

14.2 Atellica® CH LDL Cholesterol (LDLC) assay

The results from the performance studies support that the Candidate Device**,** Atellica® CH LDL Cholesterol (LDLC) assay, is substantially equivalent to the Predicate Device, Dimension® Automated LDL Cholesterol (ALDL) assay (K020724).