SIEMENS Healthineers

LDL Cholesterol (LDLC)

Current Revision and Date[a]	Rev. 05, 2022-11	
Product Name	Atellica CH LDL Cholesterol (LDLC)	REF 11537214 (1600 tests)
Abbreviated Product Name	Atellica CH LDLC	
Test Name/ID	LDLC	
Systems	Atellica CI Analyzer	
Materials Required but Not Provided	Atellica CH LDLC CAL	REF 11537241
Specimen Types	Serum, EDTA plasma, lithium heparin plasma, sodium heparin plasma	
Sample Volume	3.5 µL	
Measuring Interval	5–400 mg/dL (0.13–10.36 mmol/L)	

[a] A vertical bar in the page margin indicates technical content that differs from the previous version.

CE

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® CI Analyzer. LDLC measurements are used in the diagnosis and treatment of atherosclerosis.

Summary and Explanation

Plasma lipoproteins are spherical particles containing varying amounts of cholesterol, triglycerides, phospholipids and proteins. The phospholipid, free cholesterol and protein constitute the outer surface of the lipoprotein particle, while the inner core contains mostly esterified cholesterol and triglycerides. These particles serve to solubilize and transport cholesterol and triglycerides in the bloodstream.

The relative proportions of protein and lipid determine the density of these lipoproteins and provide a basis on which to begin their classification.[1] These classes are: chylomicrons, very-low-density lipoprotein (VLDL), low-density lipoprotein (LDL), intermediate density lipoprotein (IDL), high-density lipoprotein (HDL) and lipoprotein (a) (Lp(a)). LDL is the main cholesterol-containing particle in plasma. When present in excessive amounts, LDL cholesterol (LDL-C) can be deposited in the arterial wall resulting in atherosclerosis.[2]

Clinical studies have shown that the different lipoprotein classes have very distinct and varied effects on coronary artery disease (CAD) risk. Additionally, numerous studies all point to LDL cholesterol as a key factor in the development of atherosclerosis and CAD. For this reason, the Third Report of the National Cholesterol Education Program (NCEP) Expert panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III- ATP III) identified elevated LDL-C as the primary target of cholesterol-lowering therapy. As a result, the cutpoints for initiating treatment are stated in terms of LDL-C concentration.[3]

Methods for LDL-C measurement assume that total cholesterol is composed primarily of cholesterol in VLDL, IDL, LDL, HDL and Lp(a). LDL-C can be measured using both indirect and direct methods. The Friedewald equation developed in 1972 is the most frequently used indirect method for estimating LDL-C concentration. Using this equation, LDL-C concentration is calculated as follows:

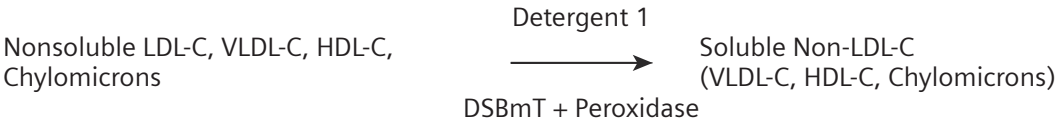
LDL -C = (Total Chol) – (HDL Chol) – (Triglyceride)/5

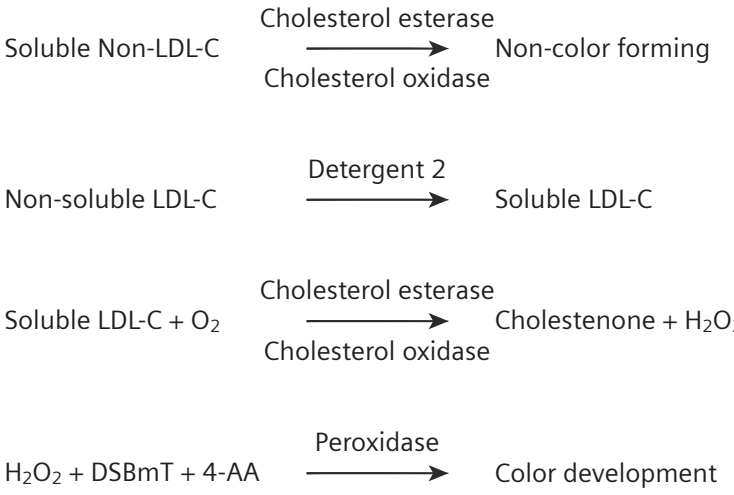
All concentrations are in mg/dL. The factor (Triglyceride)/5 is an estimate of VLDL cholesterol concentration and is based on the average ratio of triglyceride to cholesterol in VLDL. In practice, the Freidewald calculation works reasonably well. However, it should not be used with samples that have triglyceride concentrations above 400 mg/dL, when chylomicrons are present (i.e., non-fasting specimens) or in patients with dysbetalipoproteinemia (Type III hyperlipoproteineimia).[4] At high triglyceride concentrations, LDL-C concentrations are underestimated.

Principles of the Procedure

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 (H_2O_2). The enzymatic action of peroxidase on H_2O_2 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 color produced is directly proportional to the amount of LDL-C present in the sample.





Reagents

Material Description	Storage	Stability[a]
Atellica CH LDLC	Unopened at 2–8°C	Until expiration date on product
Pack 1 (P1)	Onboard per well	90 days
Well 1 (W1) and Well 2 (W1) Reagent 1 (R1) 16.0 mL MES buffer (pH 6.3); detergent 1; cholesterol esterase (trace); cholesterol oxidase (trace); peroxidase (trace); 4-aminoantipyrine (4-AA) (< 0.1%); ascorbic acid oxidase (trace); preservative; bovine serum albumin (< 1%)		
Pack 2 (P2)		
Well 1 (W1) and Well 2 (W1) Reagent 2 (R2) 6.4 mL MES buffer; detergent 2; DSBmT (< 0.1%);[b] preservative		

[a] Refer to *Storage and Stability*.

[b] N,N-bis(4-sulfobutyl)-m-toluidine, disodium salt.

Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

CAUTION

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

Safety data sheets (SDS) available on siemens-healthineers.com.

H317 **P280, P302+P352, P333+P313, P362+P364**	**Warning!** May cause an allergic skin reaction. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. **Contains:** reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1); (Atellica CH LDLC P1, P2)

CAUTION

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

Storage and Stability

Store all reagents in an upright position. Do not use products beyond the expiration date printed on the product labeling.

For details about product material description, storage, and stability, refer to *Reagents*.

Onboard Stability

Discard products at the end of the onboard stability interval.

For details about product onboard stability, refer to *Reagents*.

Do not use products beyond the expiration date printed on the product labeling.

Note Refer to the supplementary document "Atellica Sample Handler Calibrator and QC Storage and Stability" for information about storage and stability of materials in the Cal-QC tube storage area.

Specimen Collection and Handling

Serum, EDTA plasma, lithium heparin plasma, and sodium heparin plasma are the recommended specimen types for this assay.

The handling and storage information provided here is based on data or references maintained by the manufacturer. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.

Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[5]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[6]
- Follow the instructions provided with your specimen collection device for use and processing.[7]
- Specimens with high turbidity or particulates should be centrifuged before analysis.
- Allow blood specimens to clot completely before centrifugation.[8]
- Keep tubes capped at all times.[8]

Storing the Specimen

Specimens are stable for up to 5 days at 2–8°C.[9]

Specimens may be frozen for up to 14 days at ≤ -20°C.[9] Do not store in a frost-free freezer. Thoroughly mix thawed specimens and centrifuge before using.

Transporting the Specimen

Package and label specimens for shipment in compliance with applicable federal and international regulations covering the transport of clinical specimens and etiological agents.

Preparing the Samples

This assay requires 3.5 µL of sample for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For information about determining the minimum required volume, refer to the system operating instructions.

Do not use samples with apparent contamination.

Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.[8]

For a complete list of appropriate sample containers, refer to the system operating instructions.

Before placing samples on the system, ensure that samples are free of:

- Bubbles or foam.
- Fibrin or other particulate matter.

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
11537214	Atellica CH LDLC **Pack 1 (P1)** Well 1 (W1) 16.0 mL of Reagent 1 Well 2 (W2) 16.0 mL of Reagent 1 **Pack 2 (P2)** Well 1 (W1) 6.4 mL of Reagent 2 Well 2 (W2) 6.4 mLof Reagent 2	4 x 400

Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

REF	Description	
	Atellica CI Analyzer[a]	
11537241	Atellica CH LDLC CAL	3 x 2.0 mL calibrator CAL Calibrator lot-specific value sheet CAL LOT VAL
	Commercially available quality control materials	

[a] Additional system fluids are required to operate the system. For system fluid instructions for use, refer to the Document Library.

Assay Procedure

The system automatically performs the following steps:

1. For serum/plasma, dispenses 50 µL of primary sample and 200 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 70 µL of Reagent 1 and 9.2 µL of special reagent water into a reaction cuvette.
3. Dispenses 3.5 µL of pre-diluted sample into a reaction cuvette.
4. Measures the absorbance after sample addition.
5. Dispenses 23.3 µL of Reagent 2 and 2 µL of special reagent water into a reaction cuvette.
6. Mixes and incubates the mixture at 37°C.
7. Measures the absorbance after Reagent 2 addition.
8. Reports results.

Note For information about special reagent water, refer to the system operating instructions.

Test Duration: 8.4 minutes

Preparing the Reagents

All reagents are liquid and ready to use.

Preparing the System

For information about loading reagents, refer to the system operating instructions.

Performing Calibration

For calibration of the Atellica CH LDLC assay, use Atellica CH LDLC CAL. Use the calibrators in accordance with the calibrator instructions for use.

Calibration Frequency

Calibration Interval	Days
Lot Calibration	101
Pack Calibration	90

In addition, perform a calibration:

- When changing lot numbers of reagents.
- At the end of the lot calibration interval, for a specified lot of calibrated reagent on the system.
- At the end of the pack calibration interval, for a specified lot of calibrated reagent on the system.
- At the end of the pack calibration interval, for calibrated reagent packs on the system.
- When indicated by quality control results.
- After major maintenance or service.

Note When loading new reagents, recalibration is not required if there is a valid lot calibration. For information about the calibration interval, refer to the system operating instructions.

Follow government regulations or accreditation requirements for calibration frequency. Individual laboratory quality control programs and procedures may require more frequent calibration.

Performing Quality Control

For quality control of the Atellica CH LDLC assay, use at least two levels (low and high) of the appropriate quality control material of known analyte concentration. For assistance in identifying a quality control material, refer to the *Atellica CH Quality Control Material Supplement* available on siemens-healthineers.com. Additional quality control material can be used at the discretion of the laboratory. Use the quality control material in accordance with the quality control instructions for use.

In addition, perform quality control:

- Following a valid calibration.
- With use of a new lot of reagent.
- When troubleshooting test results that do not match clinical conditions or symptoms.

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing. Acceptable performance is achieved when the analyte values obtained are within the expected control interval for the system, as indicated by the manufacturer of the control material or within the interval determined by an internal laboratory quality control procedure.

Follow your laboratory's quality control procedures if the results obtained do not fall within the acceptable limits. For information about entering quality control definitions, refer to the system operating instructions.

Taking Corrective Action

If the quality control results do not fall within the expected control interval, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the system operating instructions.

Results

Calculation of Results

The system determines the result using the calculation scheme described in the system operating instructions. The system reports results in mg/dL (conventional units) or mmol/L (SI units [Systèm International d'Unités]), depending on the units defined when setting up the assay.

Conversion formula: mg/dL x 0.0259 = mmol/L

For information about results outside the specified measuring interval, refer to *Measuring Interval*.

Interpretation of Results

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Limitations

The following information pertains to limitations of the assay:

- The Atellica CH LDLC assay is limited to the detection of LDL cholesterol in human serum and plasma (lithium heparin, EDTA, sodium heparin).
- As with any chemical reaction, you must be alert to the possible effect of unknown interferences from medications or endogenous substances. The laboratory and physician must evaluate all patient results in light of the total clinical status of the patient.
- Venipuncture should occur prior to metamizole (sulpyrine) administration due to the potential for falsely depressed results.

Expected Values

Reference Interval

A reference interval for healthy adults was established by the National Cholesterol Education Program (NCEP) and verified by analysis for the Atellica CI Analyzer.[9,10]

Group	Specimen Type	Reference Interval (SI Units)
Adults[10]	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)

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results.[11] Consider these values as guidance only.

Performance Characteristics

Measuring Interval

The Atellica CH LDLC assay is linear from 5 mg/dL (0.13 mmol/L) to 400 mg/dL (10.36 mmol/L). The system flags all values that are outside the specified measuring interval.

Extended Measuring Interval

An automatic repeat condition for this assay extends the measuring interval to 1000 mg/dL (25.90 mmol/L) for serum and plasma. You may configure the system to trigger an automatic repeat. Automatic repeat results will be flagged **Autorepeat**.

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 < the 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-laboratory precision is ≤ 20% CV. The assay is designed to have an LoQ ≤ 5 mg/dL (≤ 0.13 mmol/L)

Detection capability was determined in accordance with CLSI Document EP17-A2.[12]

The following results were obtained:

Specimen Type	Detection Capability	Result mg/dL (mmol/L)
Serum	LoB	3 (0.08)
	LoD	4 (0.10)
	LoQ	5 (0.13)

The LoD was determined using 495 determinations, with 6 blank and 5 low-level replicates, and an LoB was determined using 270 determinations.

The LoQ was determined using multiple patient samples in the interval 2–3 mg/dL (0.05–0.08 mmol/L). All samples were assayed in N=5 in each of 1 run using 3 reagent lots, over a period of 5 days.

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

Precision

The assay is designed to have the following precision:

- Repeatability: CV ≤ 3% at 40–400 mg/dL
- Within–Laboratory: CV ≤ 4% at 40–400 mg/dL

Precision was determined in accordance with CLSI Document EP05-A3.[13] Samples were assayed on an Atellica CI Analyzer in duplicate in 2 runs per day for 20 days (N ≥ 80 for each sample). The following results were obtained:

			Repeatability		Within-Laboratory Precision	
Sample Type	N[a]	Mean mg/dL (mmol/L)	SD[b] mg/dL (mmol/L)	CV[c] (%)	SD mg/dL (mmol/L)	CV (%)
Serum 1	80	50 (1.30)	0.4 (0.01)	0.8	0.9 (0.02)	1.8
Serum QC	80	112 (2.89)	0.7 (0.02)	0.6	1.8 (0.05)	1.6
Serum 2	80	372 (9.64)	2.3 (0.06)	0.6	7.3 (0.19)	2.0

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

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

Reproducibility

The assay is designed to have the following reproducibility:

- CV ≤ 5% at 40–400 mg/dL

Reproducibility was determined in accordance with CLSI Document EP05-A3.[13] 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:

			Repeatability		Between-Day		Between-Lot		Between-Instrument		Total Reproducibility	
Sample	N[a]	Mean mg/dL (mmol/L)	SD[b] mg/dL (mmol/L)	CV[c] (%)	SD mg/dL (mmol/L)	CV (%)	SD mg/dL (mmol/L)	CV (%)	SD mg/dL (mmol/L)	CV (%)	SD mg/dL (mmol/L)	CV (%)
Serum QC 1	225	62 (1.61)	0.4 (0.01)	0.6	0.9 (0.02)	1.5	0.3 (0.01)	0.5	0.0 (0.00)	0.0	1.0 (0.03)	1.6
Serum QC 2	225	107 (2.77)	0.5 (0.01)	0.5	1.7 (0.04)	1.6	0.2 (0.01)	0.2	0.0 (0.00)	0.0	1.8 (0.05)	1.7
Serum 1	225	245 (6.35)	1.0 (0.03)	0.4	3.2 (0.08)	1.3	0.0 (0.00)	0.0	0.3 (0.01)	0.1	3.4 (0.09)	1.4

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

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

Assay Comparison

The performance of the Atellica CH LDLC assay on the Atellica CI Analyzer (y) was compared with the performance of the comparison assay on the indicated system (x) and is designed to have a correlation coefficient of ≥ 0.950 and a slope of 1.00 ± 0.06 for serum. Assay comparison was determined using the Deming linear regression model in accordance with CLSI Document EP09c.[14] The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum	Dimension® ALDL on Dimension® RxL Analyzer	y = 0.99x + 0 mg/dL (y = 0.99x + 0.00 mmol/L)	7–389 mg/dL (0.18–10.08 mmol/L)	104	0.998
Serum	Atellica CH LDLC on Atellica CH Analyzer	y = 1.04x - 1 mg/dL (y = 1.04x - 0.03 mmol/L)	7–390 mg/dL (0.18–10.10 mmol/L)	108	0.999

[a] Number of samples tested.

[b] Correlation coefficient.

The agreement of the assay may vary depending on the study design, comparative assay, and sample population. Assay results obtained at individual laboratories may vary from the data presented.

Specimen Equivalency

Specimen equivalency was determined using the Weighted Deming regression model in accordance with CLSI Document EP09-A3.[15] The following results were obtained:

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

[a] Number of samples tested.

[b] Correlation coefficient.

These data were generated on the Atellica CH Analyzer with assay reaction conditions that are equivalent to those on the Atellica CI Analyzer. Agreement of the specimen types may vary depending on the study design and sample population used. Assay results obtained at individual laboratories may vary from the data presented.

Interferences

These data were generated on the Atellica CH Analyzer with assay reaction conditions that are equivalent to those on the Atellica CI Analyzer.

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

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

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 table below. Bias due to these substances is ≤ 10%.

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

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

Standardization

The assigned values are traceable to the NCEP beta-quantification reference method for LDL cholesterol.[9]

Technical Assistance

For customer support, contact your local technical support provider or distributor.

siemens-healthineers.com

References

1. Gotto AM. Lipoprotein metabolism and the etiology of hyperlipedemia. Hospital Practice 1988:23: Suppl. 1,4.
2. Rifai N, Warnick GR, Dominiczak MH. Handbook of lipoprotein testing, Washington: AACC Press, 1997, pp. 14-15, 145, 273.
3. National Cholesterol Education Program. *Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III)*. Journal of American Medical Association, May 16, 2001, p. 3.
4. Burtis CA, Ashwood ER. *Tietz Textbook of Clinical Chemistry*. 3rd edition. Philadelphia, PA: W.B Saunders Company; 1999:42-72 (specimen collection and processing), 843-845 (Friedewald Equation), and 849 (specimen storage).
5. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.

6. Clinical and Laboratory Standards Institute. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2007. CLSI Document GP41-A6.
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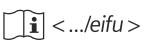
9. Data on file at Siemens Healthcare Diagnostics.
10. National Cholesterol Education Program. *Third Report of the Expert Panel on Detection, Evaluation, and Treatment of the High Blood Cholesterol in Adults (Adult Treatment Panel III)*. National Institutes of Health; 2001. NIH Publication No. 01-3670.
11. Clinical and Laboratory Standards Institute. *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document EP28-A3c.
12. Clinical and Laboratory Standards Institute. *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2012. CLSI Document EP17-A2.
13. Clinical and Laboratory Standards Institute. *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document EP05-A3.
14. Clinical and Laboratory Standards Institute. *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2018. CLSI Document EP09c.
15. Clinical and Laboratory Standards Institute. *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2013. CLSI Document EP09-A3.
16. Clinical and Laboratory Standards Institute. *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI Document EP07-A2.

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Symbol	Symbol Title
	Manufacturer		Authorized representative in the European Community
	Use-by date		Authorized representative in Switzerland
	Catalog number		Batch code
	Consult Instructions for Use		Contains sufficient for <n> tests
	Internet URL address to access the electronic instructions for use		Version of Instructions for Use
	*In vitro* diagnostic medical device		Revision

Symbol	Symbol Title	Symbol	Symbol Title
RxOnly	Prescription device (US only)	UDI	Unique Device Identifier
CE XXXX	CE Marking with Notified Body	CE	CE Marking
	Temperature limit		Keep away from sunlight
	Upper limit of temperature		Lower limit of temperature
	Do not re-use		Do not freeze
	Recycle		This way up
	Biological risks		Caution
UNITS C	Common Units	UNITS SI	International System of Units
YYYY-MM-DD	Date format (year-month-day)	**YYYY-MM**	Date format (year-month)
	Document face up[a]		Handheld barcode scanner
	Target		Mixing of substances
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.		Interval
MATERIAL ID	Unique material identification number	MATERIAL	Material
CONTROL TYPE	Type of control	CONTROL NAME	Name of control
CONTROL LOT VAL	Quality control lot value	CAL LOT VAL	Calibrator lot value

[a] Indicates Assay-eNote

Legal Information

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