SIEMENS Healthineers

HDL Cholesterol (HDLC)

Current Revision and Date[a]	Rev. 04, 2022-03	
Product Name	Atellica CH HDL Cholesterol (HDLC)	REF 11537213 (1792 tests)
Abbreviated Product Name	Atellica CH HDLC	
Test Name/ID	HDLC	
Systems	Atellica CH Analyzer	
Materials Required but Not Provided	Atellica CH HDLC Cal	REF 11537240
Specimen Types	Serum, EDTA plasma, lithium heparin plasma, sodium heparin plasma	
Sample Volume	5 µL	
Measuring Interval	5.0–200.0 mg/dL (0.13–5.18 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 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.

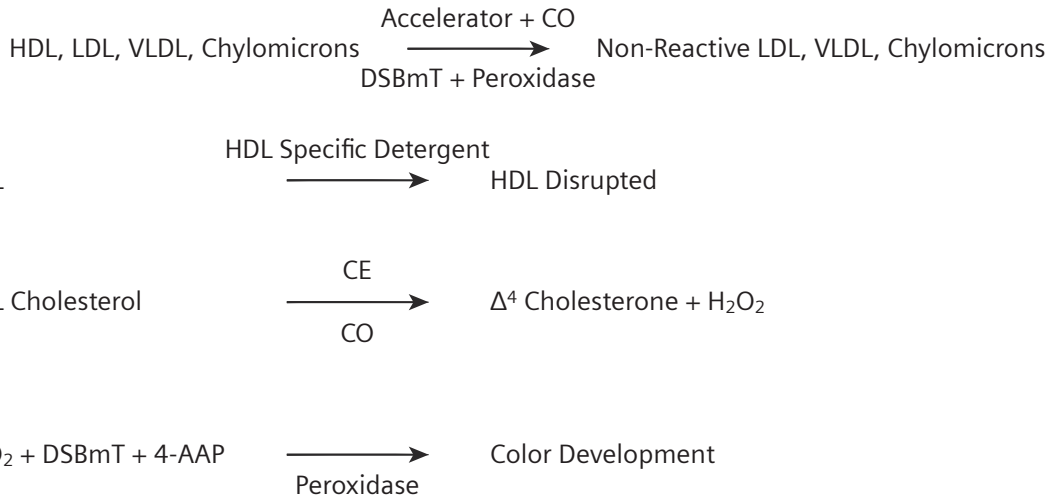
Summary and Explanation

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.

Principles of the Procedure

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.

Accelerator Selective Detergent Methodology



Reagents

Material Description	Storage	Stability[a]
Atellica CH HDLC **Pack 1 (P1)** Well 1 (W1) and Well 2 (W2) Reagent 1 (R1) 23.5 mL Buffer; cholesterol oxidase (<1000 U/L); peroxidase (<1300 ppg U/L); N,N-bis(4-sulfobutyl)-m-toluidine-disodium (DSBmT) (<1 mM); accelerator (<1 mM); preservative (<0.06%); ascorbic oxidase (<3000 U/L) **Pack 2 (P2)** Well 1 (W1) and Well 2 (W2) Reagent 2 (R2) 10.6 mL Buffer; cholesterol esterase (<1500 U/L); 4-aminoantipyrine (4-AAP) (<1 mM); detergent (<2%); preservative	Unopened at 2–8°C Onboard per well	Until expiration date on product 90 days

[a] Refer to *Storage and Stability*.

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 HDLC P1, P2)

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 reagents in an upright position, away from light and heat. Do not freeze reagents.

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.[1]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[2]
- Follow the instructions provided with your specimen collection device for use and processing.[3]
- Specimens with high turbidity or particulates should be centrifuged before analysis.
- Allow blood specimens to clot completely before centrifugation.[4]
- Keep tubes capped at all times.[4]

Storing the Specimen

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

Specimens may be frozen for up to 30 days at ≤ -20°C.[5] 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 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.[4]

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
11537213	Atellica CH HDLC **Pack 1 (P1)** Well 1 (W1) 23.5 mL of Reagent 1 Well 2 (W2) 23.5 mL of Reagent 1 **Pack 2 (P2)** Well 1 (W1) 10.6 mL of Reagent 2 Well 2 (W2) 10.6 mL of Reagent 2	4 x 448

Materials Required but Not Provided

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

REF	Description	
	Atellica CH Analyzer[a]	
11537240	Atellica CH HDLC CAL	3 x 1.0 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: Atellica CH Diluent, Atellica CH Wash, Atellica CH Conditioner, Atellica CH Cleaner, Atellica CH Reagent Probe Cleaner 1, Atellica CH Reagent Probe Cleaner 2, Atellica CH Reagent Probe Cleaner 4, Atellica CH Lamp Coolant, and Atellica CH Water Bath Additive. 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 80 µL of Reagent 1 into a reaction cuvette.
3. Dispenses 5 µL of pre-diluted sample into a reaction cuvette.
4. Measures the absorbance after sample addition.
5. Dispenses 27 µL of Reagent 2 into a reaction cuvette.
6. Mixes and incubates the mixture at 37°C.
7. Measures the absorbance after Reagent 2 addition.
8. Reports results.

Test Duration: 9.5 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 HDLC assay, use Atellica CH HDLC CAL. Use the calibrators in accordance with the calibrator instructions for use.

Calibration Frequency

Calibration Interval	Days
Lot Calibration	180
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

At least once each day of use, analyze two levels of quality control (QC) material with known HDL cholesterol 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.

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 HDLC assay is limited to the detection of HDL 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 on the Atellica CH Analyzer.[5,6]

Group	Specimen Type	Reference Interval Conventional Units (SI Units)
Adults[6]	Serum/plasma	Low (undesirable, high risk): < 40 mg/dL (< 1.04 mmol/L) High (desirable, low risk): ≥ 60 mg/dL (≥ 1.55 mmol/L)

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results.[7]

Performance Characteristics

Measuring Interval

The Atellica CH HDLC assay is linear from 5.0 mg/dL (0.13 mmol/L) to 200.0 mg/dL (5.18 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 400.0 mg/dL (10.36 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 HDL 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 HDL cholesterol in a sample at which the within-laboratory precision is ≤ 20% CV. 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.[8]

The following results were obtained:

Specimen Type	Detection Capability	Result mg/dL (mmol/L)
Serum	LoB	3.0 (0.08)
	LoD	4.0 (0.10)
	LoQ	5.0 (0.13)

The LoD was determined using 360 determinations, with 4 blank and 4 low-level replicates, and a LoB of 3.0 mg/dL (0.08 mmol/L).

The LoQ was determined using multiple patient samples in the interval 0.7–4.0 mg/dL (0.02–0.10 mmol/L). All samples were assayed in N=5 in 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 ≤ 3.5% at 30.0–49.9 mg/dL
  - CV ≤ 2.5% at 50.0–200.0 mg/dL
- Within-Laboratory:
  - CV ≤ 4.5% at 30.0–49.9 mg/dL
  - CV ≤ 3.5% at 50.0–200.0 mg/dL

Precision was determined in accordance with CLSI Document EP05-A3.[9] Samples were assayed on the Atellica CH Analyzer in duplicate in 2 runs per day for 20 days.

The following results were obtained:

			Repeatability		Within-Laboratory Precision	
Specimen 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	39.7 (1.03)	0.26 (0.007)	0.7	1.07 (0.028)	2.7
Serum QC	80	77.7 (2.01)	0.28 (0.007)	0.4	1.50 (0.039)	1.9
Serum 2	80	167.8 (4.35)	0.67 (0.017)	0.4	2.02 (0.052)	1.2

[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 reproducibility of CV ≤ 8% at 30.0–200.0 mg/dL.

Reproducibility was determined in accordance with CLSI Document EP05-A3.[10] 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 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

			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 (%)
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.

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

Assay Comparison

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 Atellica CH DHDL assay. Assay comparison was determined using the Weighted Deming regression model in accordance with CLSI Document EP09-A3.[11] The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum	Atellica CH DHDL	y = 1.02x + 3.1 mg/dL (y = 1.02x + 0.08 mmol/L)	23.1–178.7 mg/dL (0.60–4.63 mmol/L)	101	0.992

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

Agreement of the assays may vary depending on the study design, comparative assay, and sample population.

Specimen Equivalency

Specimen equivalency was determined using the Weighted Deming regression model in accordance with CLSI Document EP09-A3.[11] The following results were obtained:

Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Interval	N[a]	r[b]
Lithium heparin plasma	Serum	y = 1.01x - 1.2 mg/dL (y = 1.01x - 0.03 mmol/L)	35.7–191.4 mg/dL (0.92–4.96 mmol/L)	60	0.994
Sodium heparin plasma	Serum	y = 1.01x - 0.5 mg/dL (y = 1.01x - 0.01 mmol/L)	35.7–191.4 mg/dL (0.92–4.96 mmol/L)	60	0.994
EDTA plasma	Serum	y = 0.99x + 0.1 mg/dL (y = 0.99x + 0.00 mmol/L)	35.7–191.4 mg/dL (0.92–4.96 mmol/L)	60	0.995

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

Agreement of the specimen types may vary depending on the study design and sample population used.

Interferences

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:

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

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 HDLC 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	100 mg/dL (5680 µmol/L) 100 mg/dL (5680 µmol/L)	31.24 mg/dL (0.81 mmol/L) 77.92 mg/dL (2.02 mmol/L)	-1 0

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

Standardization

The assay is traceable to Ultracentrifugation- Heparin-Mn quantitation.[5]

Technical Assistance

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

siemens-healthineers.com

References

1. 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.
2. 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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4. Clinical and Laboratory Standards Institute. *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP44-A4.
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6. 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.
7. 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.
8. 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.
9. Clinical and Laboratory Standards Institute. *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. CLSI Document EP05-A2.
10. 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.
11. 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.
12. 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		Batch code
	Catalog number		Contains sufficient for <n> tests
	Consult Instructions for Use		Version of Instructions for Use
	Internet URL address to access the electronic instructions for use		Revision
	*In vitro* diagnostic medical device		Unique Device Identifier
	Prescription device (US only)		CE Marking

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

[a] Indicates Assay-*e*Note

Legal Information

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591
USA
siemens-healthineers.com

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens-healthineers.com