

LDL Cholesterol Calibrator (LDLC CAL)

Current Revision and Date ^a	Rev. 02, 2022-02	
Product Name	Atellica CH LDL Cholesterol Calibrator (LDLC CAL)	REF 11537241
Abbreviated Product Name	Atellica CH LDLC CAL	
	3 x 2.0 mL calibrator CAL	
	Calibrator lot-specific value sheet CAL LOT VAL	
Systems	Atellica CH Analyzer	

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



Intended Use

The Atellica® CH LDL Cholesterol Calibrator (LDLC CAL) is for *in vitro* diagnostic use in the calibration of the Atellica CH LDL Cholesterol (LDLC) assay using an Atellica® chemistry analyzer.

Material Description

Material Description	Storage	Stability ^a
Atellica CH LDLC CAL Lyophilized; reconstituted to 2.0 mL/vial Lyophilized buffered bovine serum albumin-based product supplemented with a human low density lipoprotein cholesterol	Unopened at 2-8°C Reconstituted at 2-8°C	Until expiration date on product 48 hours

^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](https://www.siemens-healthineers.com).

H412 P273, P501	Harmful to aquatic life with long lasting effects. Avoid release to the environment. Dispose of contents and container in accordance with all local, regional, and national regulations. Contains: polyhexamethylene biguanide hydrochloride
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Caution Potential Biohazard

Contains human source material.

Caution: Contains human source material. Each donation of human blood or blood component was tested by FDA-approved methods for the presence of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2), as well as for hepatitis B surface antigen (HBsAg) and antibody to hepatitis C virus (HCV). The test results were negative (not repeatedly reactive). Not test offers complete assurance that these or other infectious agents are absent; this material should be handled using good laboratory practices and universal precautions.¹⁻³

The Packaging of This Product Contains Dry Natural Rubber.

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.

Note For information about calibrator preparation, refer to *Preparing the Calibrators*.

Storage and Stability

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

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

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

Performing Calibration

Calibration Frequency

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

For information about calibration frequency, refer to the assay instructions for use.

Preparing the Calibrators

Allow the vial to equilibrate to room temperature before reconstitution.

Prepare the calibrator using the following steps:

1. Open the vial carefully.
2. Using a precision pipet, add exactly 2.0 mL of distilled/deionized water into the vial. Replace the stopper.


Note Calibration uses Atellica CH Diluent automatically on an Atellica chemistry analyzer for level 0.

3. Let the vial stand for 15 minutes at room temperature to allow the lyophilized material to completely dissolve.

4. Prior to use, for 60 seconds swirl and gently invert the vials at least 10 times to ensure homogeneity and avoid foam formation. Let stand for 5 minutes.
5. Refrigerate any unused material. Prior to reuse, swirl vial gently.

Calibration Procedure

Use the following lot-specific materials to perform calibration:

- For the assigned values and calibrator definitions, refer to the calibrator lot-specific value sheet  provided. The assigned values are traceable to the standardization of the assay.
- Generate lot-specific barcode labels to use with the calibrator samples, if necessary.

For instructions about how to perform the calibration procedure, refer to the system operating instructions.

Technical Assistance

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













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References

1. Centers for Disease Control. Perspectives in disease prevention and health promotion update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. *MMWR*. 1988;37(24):377–382, 387–388.
2. 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.
3. 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.

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
 siemens.com/eifu	Internet URL address to access the electronic instructions for use		Revision
	In vitro diagnostic medical device		Unique Device Identifier

Symbol	Symbol Title	Symbol	Symbol Title
RxOnly	Prescription device (US only)		CE Marking
	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
	Common Units		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
	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.		Material
	Unique material identification number		Name of control
	Type of control		Calibrator lot value
	Quality control lot value		

^a Indicates Assay-eNote

Legal Information

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