SIEMENS

Dimension Vista® System
Dimension® clinical chemistry system

Lipase Calibrator (LIP CAL)

Current Revision and Date[a]	Rev. 01, 2021-11	
Product Name	Dimension/Dimension Vista Lipase Calibrator (LIP CAL)	REF DC56B (11538127)
Abbreviated Product Name	Dimension/Dimension Vista LIP CAL	
Materials Provided	2 x 1.0 mL calibrator level 1/A 2 x 1.0 mL calibrator level 2/B 2 x 1.0 mL calibrator level 3/C Calibrator lot-specific value sheet	
Systems	Dimension clinical chemistry system Dimension Vista System	

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

CE

Intended Use

The LIP calibrator is an *in vitro* diagnostic product to be used to calibrate the Lipase (LIP) method for the Dimension® clinical chemistry systems and Dimension Vista® systems. This product was designed to meet the needs of users to assure accurate results over the assay range of the method.

Material Description

Material Description	Storage	Stability[a]
Dimension/Dimension Vista LIP CAL 1.0 mL/vial Bovine serum albumin-based; levels 2/B and 3/C contain human pancreatic lipase	Unopened at 2-8°C	Until expiration date on product
	Opened at 2–8°C	30 days
	Punctured at 2–8°C[b]	7 days

[a] Refer to *Storage and Stability*.
[b] Dimension Vista System.

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.

Contains: Levels 2/B and 3/C contain human pancreatic lipase.

Warning! Potential Biohazard

Contains human source material.

Caution: No known test method can ensure that products derived from human source materials will not transmit infection. These materials should be handled using good laboratory practices and universal precautions.[1-3]

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.

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

Storage and Stability

Store all calibrators in an upright position, away from light and heat. Do not use products beyond the expiration date printed on the product labeling.

Once the cap is removed, assigned values are stable when re-capped immediately after use and stored at 2–8°C.

Once the vial is punctured, assigned values are stable when stored onboard the Dimension Vista System. Do not use re-capped vials on board the instrument.

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

Calibrators are liquid and ready to use.

Allow to equilibrate to room temperature and mix thoroughly before use. Gently mix and invert the vials to ensure homogeneity of the material.

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

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

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

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References

1. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
2. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
3. 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.

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 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)
	Mixing of substances		Interval
	Non-sterile	CONTENTS	Contents
	Reconstitution volume	LEVEL	Level
SCALERS	Scalers	CAL LOT VAL	Calibrator lot value
CONTROL LOT VAL	Quality control lot value		

[a] Indicates Assay-eNote

Legal Information

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