VITROS Products Chemistry

INSTRUCTIONS FOR USE

VITROS Chemistry Products Calibrator Kit 19

Calibrator Kit 19

REF 680 1703

Intended Use

For *in vitro* diagnostic use only.

VITROS Chemistry Products Calibrator Kit 19 is used in conjunction with VITROS FS Calibrator 1 to calibrate the VITROS 5,1 FS Chemistry System and the VITROS 5600 Integrated System for the quantitative measurement of LDL cholesterol using VITROS dLDL Reagent.

Reagents

The calibrators are prepared from lyophilized human serum.

Nominal Values and Traceability

Nominal values are representative target concentrations used during the calibrator manufacturing process. The particular calibrator value for an analyte in each vial is the generation-specific assigned concentration for VITROS Chemistry Products Reagent Packs, and is provided on the Assay Data Disk. To view this value, touch Options, then touch Review/Edit Calibrations. Select a body fluid/assay combination, then touch Review Cal Definition. Refer to the analyte-specific Instructions for Use for additional calibration information.

Nominal Values

Analyte	Nominal Value	Conventional Units	Nominal Value	SI Units
Low density lipoprotein cholesterol	130	mg/dL	3.4	mmol/L

Traceability of Values

Analyte/Chemistry		Reference Material	Reference Method
LDL Cholesterol	dLDL	JCCRM-211-1	NIH/NCEP LDL Cholesterol Reference Method[1]

Warnings and Precautions

For *in vitro* diagnostic use only.

WARNING: ***HANDLE AS IF CAPABLE OF TRANSMITTING DISEASE.***
This product is prepared from human components. Testing at the individual donor level was nonreactive for hepatitis B surface antigen (HBsAg), antibody to HCV, and antibody to HIV using FDA approved methods. However, since no test can offer complete assurance that infectious agents are absent, this product should be handled following the recommendations made in CLSI Guideline M29,[2] or other published biohazard safety guidelines.

Not all products and systems are available in all countries.

Reconstitution

Caution: **Do not use visibly damaged product or product with incompletely sealed packaging.**

1. Materials should be at room temperature, 18–28 °C (64–82 °F), before reconstitution.
2. Gently tap the lyophilate vial on the counter several times to dislodge any material adhering to the stopper.
3. Remove the seal and stopper from each bottle just before adding the diluent. Do not leave vials unstoppered.
4. Add 1.0 mL of VITROS Chemistry Products FS Reconstitution Diluent to the lyophilate. A Class A volumetric pipette or an automated pipette of equivalent accuracy is recommended because of the importance of this reconstitution procedure to the accuracy of the results.
5. Replace the stopper and hold it firmly in place. Invert the vial gently. DO NOT SHAKE.
6. Reconstitution, with occasional inversion, may take up to 30 minutes. Visually verify that all freeze-dried material is dissolved prior to use.
7. Keep all fluids tightly stoppered when not in use. At the time of reconstitution, it is recommended the operator date and initial the vial.
8. Reconstituted product should be used immediately or stored in the refrigerator between 2–8 °C (36–46 °F).

Storage

IMPORTANT: *Do not freeze.*

Storage and Stability

Reagent	Storage Condition		Stability
Unopened	Refrigerated	2–8 °C (36–46 °F)	Until expiration date
Reconstituted	Refrigerated	2–8 °C (36–46 °F)	≤ 48 hours if tightly stoppered

Refer to the analyte specific Instructions for Use for special calibration precautions.

Materials Provided

VITROS Chemistry Products Calibrator Kit 19: 5 vials each of lyophilized calibrator

Materials Required but Not Provided

- VITROS Chemistry Products FS Calibrator 1
- VITROS Chemistry Products FS Reconstitution Diluent
- A Class A volumetric pipette or an automated pipette of equivalent accuracy for addition of diluent to lyophilate

Testing Procedure

1. Remove reconstituted material from the refrigerator if necessary and bring to room temperature, 18–28 °C (64–82 °F).
2. Mix vials by gentle inversion several times. DO NOT SHAKE.
3. Place reconstituted fluid in a cup and cover with a pierceable cap.
4. Immediately re-stopper vials used and return to storage.
5. Place the cup on the system for analysis.
6. Calibrate system according to the operating instructions for your system.
7. Discard any unused portion in the cup following calibration.

Limitations

The commutability of the VITROS Chemistry Products Calibrator Kit 19 and VITROS Chemistry Products FS Calibrator 1 for low-density lipoprotein cholesterol has been demonstrated with the VITROS MicroTip™ method. Commutability of these calibrators has not been established with other low-density lipoprotein cholesterol methods.

References

1. Bachorick PS, Ross JW. National Cholesterol Education Program recommendations for measurement of low-density lipoprotein cholesterol: Executive Summary. *Clin Chem.*41:1414-20.
2. CLSI. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Third Edition.* CLSI document M29-A3 (ISBN 1-56238-567-4). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; 2005.

Glossary of Symbols

The following symbols may have been used in the labeling of this product.

Do Not Reuse	Upper Limit of Temperature	Range
Use by or Expiration Date (Year-Month-Day)	Lower Limit of Temperature	Range of Means
LOT Lot Number	Temperature Limitation	Midpoint
SN Serial Number	Consult Instructions for Use	Revised
REF Catalog Number or Product Code	Attention: The Instructions For Use (IFU) has been updated	Supersedes
Attention: See Instructions for Use	S1 For use in Slide Supply 1	Xi Irritant
Manufacturer	S2 For use in Slide Supply 2	Xn Harmful
EC REP Authorized Representative in the European Community	SI SI Units	T Toxic
Σ n Contains Sufficient for "n" Tests	CONV Conventional Units	C Corrosive
IVD *In vitro* Diagnostic Medical Device	Value	F Flammable
	Der Grüne Punkt (the Green Dot). Manufacturer follows certain packaging material waste disposal management regulations	σ Estimate within-lab SD

Revision History

Date of Revision	Version	Description of Technical Changes*
2008-06-10	3.0	• Added information for the VITROS 5600 Integrated System • Removed information for dHDL • Warnings and Precautions – Removed subsections containing standard laboratory safety guidelines; added statement • Reconstitution – Added Caution • Limitations – Added section • References – Updated M29 • Minor wording changes
2005-02-07	2.0	Calibrator Kit Storage and Stability: updated data: ≤ 24 hours→≤ 48 hours if tightly stoppered
2004-09-15	1.0	First release of document

* The change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.

When this Instructions For Use is replaced, sign and date below and retain as specified by local regulations or laboratory policies, as appropriate.

Signature

Obsolete Date

CE

EC REP

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