VITROS Products Chemistry

INSTRUCTIONS FOR USE

VITROS Chemistry Products Calibrator Kit 25

Calibrator Kit 25

REF 680 1896

Intended Use

For *in vitro* diagnostic use only.

VITROS Chemistry Products Calibrator Kit 25 is used to calibrate VITROS 250/350/950 and 5,1 FS Chemistry Systems and the VITROS 5600 Integrated System for the quantitative measurement of HDL cholesterol using VITROS Chemistry Products dHDL Slides.

Reagents

The calibrators are prepared from processed human serum and purified human HDL cholesterol to which organic analytes, inorganic salts, electrolytes, stabilizers, and preservatives have been added.

The diluents are prepared from processed water to which a preservative has been added.

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 Slides and is provided on the calibration media. Refer to the operating instructions for your system and the analyte-specific Instructions for Use for additional calibration information.

Nominal Values

Analyte	Calibrator Vial 1	Calibrator Vial 2	Calibrator Vial 3	Units	Calibrator Vial 1	Calibrator Vial 2	Calibrator Vial 3	Units
High density lipoprotein cholesterol	7	40	110	mg/dL	0.18	1.03	2.84	mmol/L

* Concentration after calibrator is reconstituted with 3.0 mL of corresponding diluent.

Traceability of Values

Analyte/Chemistry	Reference Material	Comparative Method
HDL cholesterol	SRM 911 (NIST)	CRMLN Designated Comparison 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.

WARNING: ***This product diluent contains ProClin 300 (0.05% w/v). R43 – May cause sensitization by skin contact. S37 – Wear suitable gloves. S24– Avoid contact with skin.***

WARNING: ***The packaging (vial stopper) of this product contains dry natural rubber, which may cause allergic reactions in some individuals.***

Not all products and systems are available in all countries.

Reconstitution

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

Note: Be sure to use components from the same kit lot number.

1. Materials should be at room temperature, 18–28 °C (64–82 °F), before reconstitution. Vials should sit out at room temperature approximately 60 minutes when taken from freezer storage.
2. Slowly invert the diluent bottle several times to mix the contents thoroughly. DO NOT SHAKE.
3. Gently tap the lyophilate vial on the counter several times to dislodge any material adhering to the stopper.
4. Remove the seal and stopper from each bottle just before adding the diluent. Do not leave vials unstoppered.
5. Add 3.0 mL of the appropriate diluent to each vial. Use a clean, dry pipette for each vial. 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. Discard any remaining diluent.
6. Replace the stopper and hold it firmly in place. Invert the vial gently. DO NOT SHAKE.
7. Reconstitution, with occasional inversion, may take up to 30 minutes. Visually verify that all freeze-dried material is dissolved prior to use.
8. Keep all fluids tightly stoppered when not in use. At the time of reconstitution, it is recommended to write your initials and the date on the vial.
9. Reconstituted product should be used immediately or stored in the refrigerator between 2–8 °C (36–46 °F).

Storage

Storage and Stability

Reagent	Storage Condition		Stability
Unopened	Frozen	≤-18 °C (≤0 °F)	Until expiration date
Reconstituted	Refrigerated	2–8 °C (36–46 °F)	≤ 24 hours if tightly stoppered

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

Materials Provided

VITROS Chemistry Products Calibrator Kit 25

- 2 vials each of lyophilized calibrator 1, 2, and 3
- 2 vials each of calibrator diluent 1, 2, and 3
- 6 calibrator bar code labels (For use on VITROS 5600 Integrated Systems only)

Materials Required but Not Provided

A Class A volumetric pipette or an automated pipette of equivalent accuracy for addition of diluent to lyophilate

Testing Procedure

Note: Be sure to use components from the same kit lot number.

1. If necessary, remove reconstituted material stored in the refrigerator.
2. Mix the vial thoroughly by gently inverting several times. DO NOT SHAKE.
3. Place fluid in a cup and cover with a pierceable cap.
4. Restopper the vial and immediately return it to the refrigerator.
5. Bring the cup to room temperature, 18–28 °C (64–82 °F), before analysis (approximately 10 minutes for refrigerated material).
6. Analyze according to instructions found in the operating instructions for your system.
7. Discard any unused portion in the cup following testing.
8. Use refrigerated fluid within 24 hours.

Limitations

The commutability of the VITROS Chemistry Products Calibrator Kit 25 for VITROS Chemistry Products dHDL Slides has been demonstrated among VITROS MicroSlide™ methods. Commutability of this calibrator has not been established with other HDL Cholesterol methods.

References

1. Kimberley M.M., Leary E.T., Cole T.G., Waymack P.P. Selection, Validation, Standardization and Performance of a Designated Comparison Method for HDL-Cholesterol for Use in the Cholesterol Reference Laboratory Network. *Clin. Chem*. (45) 10:1803-1812; 1999.
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*
2009-03-04	3.0	Materials Provided – Updated
2008-06-18	2.0	• Added information for the VITROS 5600 Integrated System • Warnings and Precautions – Removed subsections containing standard laboratory safety guidelines; added statement • Reconstitution – Added Caution • Minor wording changes
2005-10-14	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

Ortho-Clinical Diagnostics
Johnson & Johnson
50-100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4DP
United Kingdom

Ortho Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101

Brasil:
Johnson & Johnson do Brasil Ind. e Com. de Prod.
para Saúde Ltda.
Divisão: Johnson & Johnson Medical Brasil
Rod. Presidente Dutra, Km 154, São José dos Campos - SP -
CEP: 12240-908 - Brasil
CNPJ: 54.516.661/0002-84
Resp. Técnico.: Nancy M.R.B Lopes C.R.F.-SP Nº 10965
Somente Para Uso Diagnóstico *In Vitro*
SAC: 08007075420

Ortho Clinical Diagnostics
a Johnson & Johnson company