INSTRUCTIONS FOR USE

VITROS Chemistry Products FS Calibrator 1

FS Calibrator 1

REF 680 1873

Rx ONLY

Intended Use

For *in vitro* diagnostic use only.

VITROS Chemistry Products FS Calibrator 1 is used in conjunction with VITROS Chemistry Products Calibrator Kits to calibrate the VITROS 5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System.

Reagents

The calibrator is prepared using sodium chloride (154 mM) and processed water.

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 Reagents, 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	FS Calibrator 1	Units
Antistreptolysin O	0	IU/mL
Benzoylecgonine	0	ng/mL
C-Reactive Protein	0	mg/dL
d-methamphetamine	0	ng/mL
Hemoglobin	0	g/dL
Hemoglobin A1c	0	g/dL
LDL Cholesterol	0	mg/dL
Lormetazepam	0	ng/mL
Phencyclidine	0	ng/mL
Rheumatoid Factor	0	IU/mL
Secobarbital	0	ng/mL
11-nor- Δ^9-THC-9-carboxylic acid	0	ng/mL

Traceability of Values

Analyte/Chemistry		Reference Material	Reference Method
Antistreptolysin O	ASO	NIBSC Reagent, Code 97/662 [4]	Latex-enhanced immunoturbidimetric
Benzoylecgonine	COCM	Cerilliant Reference Standard #B-028 benzoylecgonine [1]	GC/MS
C-Reactive Protein	CRP	BAM-IRMM-LGC ERM-DA470 [2]	Nephelometry [6]
d-methamphetamine	AMPH	USP Reference Standard #1399001 d-methamphetamine [3]	GC/MS
Hemoglobin	Hb	International Haemiglobincyanide Reference Preparation [7]	ICSH Standard 1986 [8]
Hemoglobin A1c	HbA1c	IFCC/IRMM Candidate Primary Reference Material [9]	IFCC Reference Method [10]
LDL Cholesterol	dLDL	N/A	CDC LDL-C Reference Measurement Procedure [11, 12]
Lormetazepam	BENZ	Cerilliant Reference Standard #L-910 lormetazepam [1]	GC/MS
Phencyclidine	PCP	Cerilliant Reference Standard #P-047 phencyclidine [1]	GC/MS
Rheumatoid Factor	RF	NIBSC 64/2 [5]	Latex-enhanced immunoturbidimetric
Secobarbital	BARB	Cerilliant Reference Standard #S-005 secobarbital [1]	GC/MS
11-nor- Δ^9-THC-9-carboxylic acid	THC	SRM 1507 (NIST)	GC/MS

Warnings and Precautions

For *in vitro* diagnostic use only.
This product is low hazard for usual handling.

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

No reconstitution is necessary.

Storage

Storage and Stability

Reagent	Storage Condition		Stability
Unopened	Refrigerator or Room Temperature	2–30 °C (36–86 °F)	Until expiration date
Opened	Refrigerator or Room Temperature	2–30 °C (36–86 °F)	≤ 24 hours if tightly stoppered

For additional information and instructions, refer to the operating instructions for your system.

Materials Provided

12 vials (3 mL each) of VITROS Chemistry Products FS Calibrator 1

Materials Required but Not Provided

None

Testing Procedure

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

1. Remove vials from storage. Bring any refrigerated vials to room temperature, 18–28 °C (64–82 °F).
2. Mix vials by gentle inversion several times. DO NOT SHAKE.
3. Refer to the analyte-specific calibrator Instructions for Use for VITROS Chemistry Products Calibrator Kit 16, 17, 18, 19, 26, 28, or 30.

Limitations

The commutability of VITROS Chemistry Products FS Calibrator 1 for hemoglobin and hemoglobin A1c (%A1c), d-methamphetamine (AMPH), antistreptolysin O (ASO), secobarbital (BARB), lormetazepam (BENZ), benzoylecgonine (COCM), c-reactive protein (hsCRP), LDL cholesterol (dLDL), phencyclidine (PCP), rheumatoid factor (RF), and 11-nor- Δ^9-THC-9-carboxylic acid (THC) has been demonstrated with VITROS MicroTip methods. Commutability of this calibrator has not been established with other methods.

References

1. Cerilliant Corporation, 811 Paloma Drive, Suite A, Round Rock, Texas 78664 USA.
2. European Commission. The Certification of a Matrix Reference Material for Immunochemical Measurement of 15 Serum Proteins, ERM-DA470, Report EUR 15243 EN and 16882 EN, European Communities, 2004.
3. U.S. Pharmacopeia, 12601 Twinbrook Pathway, Rockville, Maryland 20852 USA.
4. Spaun, J, Bentzon, MW, Olesen Larsen, S. and Hewitt, LF. *International standard for antistreptolysin-O*, Bulletin World Health Organization, 24, 271-279; 1961.
5. Anderson, S. G., M. W. Bentzon, V. Houba and P. Krag. *International Reference Preparation of Rheumatoid Arthritis Serum*. Bulletin World Health Organization, 42:311-318, 1970.
6. Dati F, et al. Referenzwerte für 18 Plasmaproteine am Behring-Nephelometer-System. *Lab. Med.* 13:87–90; 1989.
7. A. H. Holtz. Some experience with a cyanhemiglobin solution. *Bibliotheca Haematologica* 21: 75-78; 1965.
8. Recommendations for reference method for haemoglobinometry in human blood (ICSH standard 1986) and specifications for international haemiglobincyanide reference preparation (3rd edition). International Committee for Standardization in Haematology; Expert Panel on Haemoglobinometry. *Clin. Lab Haemat* 9: 73-79; 1987.
9. Finke A, Kobold U, Hoelzel W, Weycamp C, Miedema K, and Jeppsson J-O. Preparation of a candidate primary reference material for the international standardization of HbA1c determinations. *Clin. Chem. Lab Med* 36(5): 299-308; 1998.
10. Jeppsson, Jan-Olof, et al, IFCC Scientific Working Group on HbA1c Standardisation and Network of Reference Laboratories for HbA1c, Approved IFCC Reference Method for the Measurement of HbA1c in Human Blood, *Clin. Chem. Lab Med* ; 40(1): 78-89; 2002.
11. Bachorick PS, Ross JW. National Cholesterol Education Program Recommendations for Measurement of Low-Density Lipoprotein Cholesterol: Executive Summary. *Clin. Chem.* 41:1414-1420; 1995.
12. National Cholesterol Education Program. Recommendations on lipoprotein measurement (NIH Publication No. 95-3044). Bethesda, MD: National Heart, Lung, and Blood Institute. 1995.

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 Batch Code or 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
Caution	S1 For use in Slide Supply 1	Xi Irritant
Manufacturer	S2 For use in Slide Supply 2	Xn Harmful
Date of Manufacture	SI SI Units	T Toxic
EC REP Authorized Representative in the European Community	CONV Conventional Units	C Corrosive
Σ n Contains Sufficient for "n" Tests	Value	F Flammable
IVD *In vitro* Diagnostic Medical Device	Der Grüne Punkt (the Green Dot). Manufacturer follows certain packaging material waste disposal management regulations	σ Estimated within-lab SD

Revision History

Date of Revision	Version	Description of Technical Changes*
2015-10-12	9.0	• Prescription Use statement added • Updated EC Representative address
2014-04-04	8.0	• Traceability of Values: Updated Reference Material and Reference Method for dLDL • References: Added reference • Glossary of Symbols: Added Date of Manufacture
2012-02-28	7.0	Glossary of Symbols: Updated
2010-11-01	6.0	Added information for the VITROS 4600 Chemistry System
2008-06-18	5.0	• Added information for the VITROS 5600 Integrated System • Nominal Values – Removed dHDL • Traceability of Values: Reference Material – Updated name, removed dHDL • Warnings and Precautions – Removed subsections containing standard laboratory safety guidelines; added statement • Testing Procedure – Added Caution • Limitations – Removed dHDL • References – Added ERM-DA470 reference • Minor wording changes
2006-10-16	4.0	• Reagents: added THC • Procedure: added Calibrator Kit 30 • Limitations: added THC

Date of Revision	Version	Description of Technical Changes*
2006-09-29	3.0	• Intended Use: updated wording • Reagents: added AMPH, BARB, BENZ, COCM, PCP • Limitations: added AMPH, BARB, BENZ, COCM, PCP • References: added reference
2005-12-15	2.0	• Intended Use, Test Procedure: added Calibrator Kit 28 • Storage: corrected data • Reagents, Limitations: added ASO • References: added reference
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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