VITROS Products Chemistry

INSTRUCTIONS FOR USE

VITROS Chemistry Products Calibrator Kit 16

Calibrator Kit 16

REF 680 1700

Intended Use

For *in vitro* diagnostic use only.

VITROS Chemistry Products Calibrator Kit 16 is used in conjunction with VITROS Chemistry Products FS Calibrator 1 to calibrate the VITROS 5,1 FS Chemistry System, the VITROS 4600 Chemistry System and the VITROS 5600 Integrated System for the quantitative measurement of rheumatoid factor (RF).

Reagents

The calibrator is an aqueous solution containing processed human serum, buffer, protein, inorganic salt, and preservative.

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	Units	Calibrator Vial				
		2	3	4	5	6
RF	IU/mL	10	20	40	80	120

Traceability of Values

Analyte/Chemistry	Reference Material	Comparative Method
Rheumatoid factor (RF)	NIBSC 64/2 [1]	Latex-enhanced immunoturbidimetric

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 contains sodium azide. Disposal of product into sinks with copper or lead plumbing should be followed with plenty of water to prevent formation of potentially explosive metallic azides.***

WARNING: ***The calibrators contain bovine blood components. This product should be handled using the same precautions as with any other blood or blood-derived product.***

Not all products and systems are available in all countries.

Storage

IMPORTANT: *Do not freeze.*

Storage and Stability

Reagent	Storage Condition		Stability
Unopened	Refrigerated	2–8 °C (36–46 °F)	Until expiration date
Opened	Refrigerated	2–8 °C (36–46 °F)	≤ 7 days if tightly stoppered

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

Materials Provided

VITROS Chemistry Products Calibrator Kit 16: 1 vial each of liquid calibrator 2, 3, 4, 5 and 6; 1 mL/ vial

Materials Required but Not Provided

VITROS Chemistry Products FS Calibrator 1

Reconstitution

No reconstitution is necessary.

Testing Procedure

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

Note: There are six calibrator levels required to calibrate RF (one level of FS Calibrator 1, and five levels of Calibrator Kit 16).

Note: Be sure to use components from a single Calibrator Kit 16 lot number .

1. Remove each level of calibrator from storage and bring to room temperature, 18–28 °C (64–82 °F).
2. Mix each vial thoroughly by gently inverting several times. DO NOT SHAKE.
3. Place each level of calibrator fluid in a separate cup and cover each cup with a pierceable cap.
4. Restopper the vials and immediately return them to storage.
5. Place each cup on the system for analysis.
6. Analyze according to the operating instructions for your system.
7. Discard any unused portions in the cups following calibration.

Note: Refer to the Instructions for Use for VITROS Chemistry Products FS Calibrator 1 for more information.

Limitations

The commutability of the VITROS Chemistry Products Calibrator Kit 16 and VITROS Chemistry Products FS Calibrator 1 for rheumatoid factor has been demonstrated with VITROS MicroTip method. Commutability of this calibrator has not been established with other rheumatoid factor methods.

References

1. Anderson SG, , Bentzon MW, Houba V and Krag P. *International Reference Preparation of Rheumatoid Arthritis Serum*. Bulletin World Health Organization, 42:311-318, 1970
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 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
Σn 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*
2014-09-05	6.0	Glossary of Symbols: added Date of Manufacture
2012-02-28	5.0	Glossary of Symbols: updated
2010-11-01	4.0	Added information for the VITROS 4600 Chemistry System
2009-03-17	3.0	• Added information for the VITROS 5600 Integrated System • Warnings and Precautions — Removed subsections containing standard laboratory safety guidelines; added statement • Testing Procedure – Added Caution • Limitations – Added section • Minor wording changes
2004-11-16	2.0	Revised Storage Requirements
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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