

INSTRUCTIONS FOR USE

VITROS Chemistry Products Calibrator Kit 28

Calibrator Kit 28

REF 680 2323

Intended Use

For *in vitro* diagnostic use only.

VITROS Chemistry Products Calibrator Kit 28 is used 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 antistreptolysin O (ASO).

Reagents

The calibrator is an aqueous solution containing processed human serum, bovine serum albumin, 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	Antistreptolysin O	
	Conventional Units	SI Units
Concentration	500 IU/mL	500 IU/mL

Traceability of Values

Analyte	Chemistry	Reference Material	Comparative Method
Antistreptolysin O	ASO	NIBSC 97/662 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 M29² 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: *This product contains bovine blood components and 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.

Reconstitution

No reconstitution is necessary.

Storage

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)	Until expiration date

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

Materials Provided

VITROS Chemistry Products Calibrator Kit 28: 1 bottle of liquid calibrator; 5 mL

Materials Required but Not Provided

VITROS Chemistry Products FS Calibrator 1

Testing Procedure

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

Note: There are two calibrator levels required to calibrate ASO (one level of FS Calibrator 1, and one level of Calibrator Kit 28).

1. Remove each level of calibrator from storage and bring to room temperature, 18–28 °C (64–82 °F).
2. Mix thoroughly by gently inverting several times. DO NOT SHAKE.
3. Place calibrator fluid in a separate cup and cover each cup with a pierceable cap.
4. Replace the cap on 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 28 and VITROS Chemistry Products FS Calibrator 1 for antistreptolysin O has been demonstrated for the VITROS MicroTip™ method. Commutability of this calibrator has not been established with other antistreptolysin O methods.

References

1. Spaun, J., Bentzon, MW, Olesen Larsen, S. and Hewitt, LF. *International standard for antistreptolysin O*, Bulletin World Health Organization, 24, 271-279; 1961.
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
	Batch Code or Lot Number		Temperature Limitation		Midpoint
	Serial Number		Consult Instructions for Use		Revised
	Catalog Number or Product Code		Attention: The Instructions for Use (IFU) has been updated		Supersedes
	Caution		For use in Slide Supply 1		Irritant
	Manufacturer		For use in Slide Supply 2		Harmful
	Date of Manufacture		SI Units		Toxic
	Authorized Representative in the European Community		Conventional Units		Corrosive
	Contains Sufficient for "n" Tests		Value		Flammable
	In vitro Diagnostic Medical Device		Der Grüne Punkt (the Green Dot). Manufacturer follows certain packaging material waste disposal management regulations		Estimated within-lab SD

Revision History

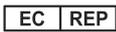
Date of Revision	Version	Description of Technical Changes*
2014-09-05	5.0	Glossary of Symbols: added Date of Manufacture
2012-02-28	4.0	Glossary of Symbols: updated
2010-11-01	3.0	Added information for the VITROS 4600 Chemistry System
2009-03-02	2.0	<ul style="list-style-type: none"> Added information for the VITROS 5600 Integrated System Warnings and Precautions – Removed subsections containing standard laboratory safety guidelines; added statement Storage and Stability – Opened: Updated Testing Procedure – Added Caution Glossary of Symbols – Updated Minor wording changes
2005-12-15	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



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