

INSTRUCTIONS FOR USE

VITROS Chemistry Products
mALB Performance Verifiers I and II

mALB Performance Verifiers I
and II

REF

6801746

6801747

Intended Use

For *in vitro* diagnostic use only.

VITROS Chemistry Products mALB Performance Verifiers are assayed controls used to monitor the performance of VITROS mALB Reagent on the VITROS 5,1 FS Chemistry System, the VITROS 4600 Chemistry System and the VITROS 5600 Integrated System.

Reagents

VITROS mALB Performance Verifiers are prepared from processed human serum to which inorganic salt, buffers, protein, surfactant and preservative have been added.

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 M29,¹ 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.

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)	Store tightly stoppered*

*Refer to the Assay Sheet for analyte-specific stability information.

Materials Provided

- 6 vials (2 mL each) of VITROS Chemistry Products mALB Performance Verifier I
- 6 vials (2 mL each) of VITROS Chemistry Products mALB Performance Verifier II

Procedure

The VITROS mALB Performance Verifier should be assayed in the same manner as a patient sample. The reported value can then be compared with the Range of Means and within-lab standard deviation (SD) on the assay sheet.

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. Remove vials from refrigerator.
2. Mix the vial thoroughly by gently inverting several times. DO NOT SHAKE.
3. Remove the seal and stopper from each vial just prior to use. Keep all vials tightly stoppered when not in use.
4. Place fluid in a cup and cover with a pierceable cap.
5. Restopper the vial and immediately return it to the refrigerator.
6. Bring the cup to room temperature, 18–28 °C (64–82 °F), before analysis (approximately 10 minutes for refrigerated material).
7. Analyze according to the operating instructions for your system.
8. Discard any unused portion in the cup following testing.

Assay Values

- Verify that the fluid lot number on the assay sheet is the same as the lot number printed on the vial label.
- Use the Range of Means provided for the reagent generation in use.
- Results exceeding the published Range of Means should be investigated.
- Each laboratory should establish its own analyte-specific mean.
- Each laboratory should evaluate and, if necessary, update the mean after each reagent lot change.
- The within-lab standard deviation (SD) published on the assay sheet for a given analyte may be used as the laboratory's baseline SD for any reagent lot.
- Refer to assay-specific instructions for use for additional performance information.

References

1. 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
	<i>In vitro</i> Diagnostic Medical Device		Der Grüne Punkt (the Green Dot). Manufacturer follows certain packaging material waste disposal management regulations		Estimated within-lab SD

Revision History

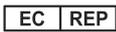
Date of Revision	Version	Description of Technical Changes*
2014-02-06	5.0	Glossary of Symbols: added Date of Manufacture
2012-02-28	4.0	Glossary of Symbols: updated
2010-11-01	3.0	Added information for the VITROS 4600 Chemistry System
2009-03-17	2.0	<ul style="list-style-type: none"> Added information for the VITROS 5600 Integrated System Warnings and Precautions – Removed subsections containing standard laboratory safety guidelines; added statement Procedure – Added Caution Assay Values – Added information References – Updated M29 Minor wording changes
2004-08-27	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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