

INSTRUCTIONS FOR USE

VITROS Chemistry Products Calibrator Kit 24

Calibrator Kit 24

REF 680 1708

Intended Use

For *in vitro* diagnostic use only.

VITROS Chemistry Products Calibrator Kit 24 is used to calibrate the VITROS 5,1 FS Chemistry System and the VITROS 5600 Integrated System for the quantitative measurement of albumin in urine (mALB).

Reagents

The calibrators are prepared from processed human serum to which inorganic salt, buffers, protein, surfactant and preservative have 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 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	Calibrator Vial						Units	Calibrator Vial						Units
	1	2	3	4	5	6		1	2	3	4	5	6	
Microalbumin (mALB)	0.6	1.3	2.5	5.0	10.0	20.0	mg/dL	6.0	13.0	25.0	50.0	100.0	200.0	mg/L

Traceability of Values

Analyte/Chemistry	Reference Material	Comparative Method
Microalbumin mALB	ERM-DA470 ¹	Nephelometry

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.

Not all products and systems are available in all countries.

Reconstitution

No reconstitution is necessary.

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Storage

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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)	≤ 14 days

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

Materials Provided

VITROS Chemistry Products Calibrator Kit 24: 1 vial each of liquid calibrator 1, 2, 3, 4, 5 and 6; 1 mL/ vial

Testing Procedure

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. There are six calibrator levels. Remove each level of calibrator from refrigerator 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 the refrigerator.
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.

Limitations

The commutability of VITROS Chemistry Products Calibrator Kit 24 for microalbumin has been demonstrated for the VITROS MicroTip™ method. Commutability of this calibrator has not been established with other microalbumin methods.

References

1. 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.
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.

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Glossary of Symbols

Calibrator Kit 24

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 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
	Attention: See Instructions for Use		For use in Slide Supply 1		Irritant
	Manufacturer		For use in Slide Supply 2		Harmful
	Authorized Representative in the European Community		SI Units		Toxic
	Contains Sufficient for "n" Tests		Conventional Units		Corrosive
	<i>In vitro</i> Diagnostic Medical Device		Value		Flammable
			Der Grüne Punkt (the Green Dot). Manu- facturer follows certain packaging material waste disposal management regulations		Estimate within-lab SD

Revision History

Date of Revision	Version	Description of Technical Changes*
2009-03-17	3.0	<ul style="list-style-type: none"> Added information for the VITROS 5600 Integrated System Traceability of Values – Updated data Warnings and Precautions – Removed subsections containing standard laboratory safety guidelines; added statement Testing Procedure – Added Caution References – Updated M29, ERM-DA470 Minor wording changes
2005-01-25	2.0	Calibrator Kit Storage and Stability: updated data: ≤ 30 days → ≤14 days
2004-09-14	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



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