

# INSTRUCTIONS FOR USE

VITROS Chemistry Products Calibrator Kit 11

Calibrator Kit 11

REF 680 1696

Rx ONLY

## Intended Use

For *in vitro* diagnostic use only.

VITROS Chemistry Products Calibrator Kit 11 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 vancomycin (VANC).

## Reagents

The calibrator is an aqueous solution containing vancomycin, buffer, inorganic salt, stabilizers and preservatives.

### 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	
Vancomycin (VANC)	0	5	10	20	30	50	µg/mL	0	3	7	13	20	34	µmol/L

#### Traceability of Values

Analyte/Chemistry	Reference Material	Reference Method
Vancomycin (VANC)	USP (U.S. Pharmacopeia) vancomycin reference standard catalog # 1709007	Gravimetric addition

## Warnings and Precautions

For *in vitro* diagnostic use only.

**WARNING:** *This product contains sodium azide. Disposal of reagents 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

**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)	Until expiration date*

\*Store tightly stoppered

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

### Materials Provided

VITROS Chemistry Products Calibrator Kit 11: 1 bottle each of liquid calibrator 1, 2, 3, 4, 5 and 6

- 5 mL Level 1
- 2 mL Levels 2–6

### 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 bottle 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. Cap the bottles and immediately return them to the refrigerator.
5. Place each cup on the system for analysis.
6. Analyze according to the operating instructions for system.
7. Discard any unused portions in the cups following calibration.

### Limitations

The commutability of VITROS Chemistry Products Calibrator Kit 11 for vancomycin has been demonstrated for the VITROS MicroTip method. Commutability of this calibrator has not been established with other vancomycin methods.

### 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
	Corrosive		Flammable		Serious Health Hazards
	Health Hazards		Acute Toxicity		Environmental or Aquatic Toxicity

### Revision History

Date of Revision	Version	Description of Technical Changes*
2015-05-13	6.0	<ul style="list-style-type: none"> <li>Prescription Use Statement added</li> <li>Warnings and Precautions: updated to align with the new Safety Data Sheets</li> <li>Glossary of Symbols: added Globally Harmonized Symbols to comply with the Classification, Labelling and Packaging (CLP) Regulations</li> </ul>
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
2008-06-02	2.0	<ul style="list-style-type: none"> <li>Added information for the VITROS 5600 Integrated System</li> <li>Warnings and Precautions – Updated data; removed subsections containing standard laboratory safety guidelines; added statement</li> <li>Testing Procedure – Added Caution</li> <li>Minor wording changes</li> </ul>

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Revision History

Calibrator Kit 11

Date of Revision	Version	Description of Technical Changes*
2004-09-09	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



EC REP

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