

INSTRUCTIONS FOR USE

VITROS Chemistry Products Calibrator Kit 12

Calibrator Kit 12

REF 680 1697

Rx ONLY

Intended Use

For *in vitro* diagnostic use only.

VITROS Chemistry Products Calibrator Kit 12 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 valproic acid (VALP).

Reagents

The calibrator is an aqueous solution containing valproic acid, 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	
Valproic Acid (VALP)	0	10	25	50	100	150	µg/mL	0	69	173	347	693	1040	µmol/L

Traceability of Values

Analyte/Chemistry	Reference Material	Reference Method
Valproic Acid (VALP)	USP (U.S. Pharmacopeia) valproic acid reference standard catalog #1708707	Gravimetric addition

Warnings and Precautions

For *in vitro* diagnostic use only.

WARNING: *Contains 5-chloro-2-methyl-3(2h)-isothiazolone mixt. with 2-methyl-3(2h)-isothiazolone (CAS 55965-84-9)¹*

VITROS Calibrator Kit 12 contains 5-chloro-2-methyl-3(2h)-isothiazolone mixt. with 2-methyl-3(2h)-isothiazolone. H317: May cause an allergic skin reaction. P280: Wear protective gloves/protective clothing/eye protection/face protection. P272: Contaminated work clothing should not be allowed out of the workplace. P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P501: Dispose of contents/container to an approved incineration plant.

Refer to www.orthoclinical.com for the Safety Data Sheets and for OCD contact information.

WARNING



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 12: 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. Recap 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 your system.
7. Discard any unused portions in the cups following calibration.

Limitations

The commutability of VITROS Chemistry Products Calibrator Kit 12 for valproic acid has been demonstrated for the VITROS MicroTip method. Commutability of this calibrator has not been established with other valproic acid methods.

References

1. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

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

Revision History

Date of Revision	Version	Description of Technical Changes*
2015-04-28	6.0	<ul style="list-style-type: none"> Prescription Use Statement added Warnings and Precautions: <ul style="list-style-type: none"> added reference updated Hazard and Precaution Statements to align with the new Safety Data Sheets added Globally Harmonized Symbol to comply with the Classification, Labelling and Packaging (CLP) Regulations References: added reference Glossary of Symbols: added Globally Harmonized Symbols to comply with the Classification, Labelling and Packaging (CLP) Regulations
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

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Revision History

Calibrator Kit 12

Date of Revision	Version	Description of Technical Changes*
2008-06-02	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 Testing Procedures – Added caution Minor wording 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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