

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.

INSTRUCTIONS FOR USE

Glossary of Symbols

Calibrator Kit 12

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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