INSTRUCTIONS FOR USE

VITROS Chemistry Products Calibrator Kit 18

Calibrator Kit 18

REF 680 1702

Rx ONLY

Intended Use

For *in vitro* diagnostic use only.
VITROS Chemistry Products Calibrator Kit 18 is used in conjunction with VITROS Chemistry Products FS Calibrator 1 to calibrate the VITROS 5,1 FS Chemistry System, the VITROS 4600 Chemistry System and the VITROS 5600 Integrated System for the calculation of percent glycated hemoglobin (%A1c).

Reagents

The calibrators are prepared from a hemolysate derived from human and ovine blood to which surfactants, stabilizer, and preservatives 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

	Calibrator Vial				Units	Calibrator Vial				Units
Analyte	2	3	4	5		2	3	4	5	
Hemoglobin	14	14	14	14	g/dL	140	140	140	140	g/L
Hemoglobin A1c	0.5	1.0	1.6	2.6	g/dL	5	10	16	26	g/L

Traceability of Values

Analyte/Chemistry		Reference Material	Reference Method
Hemoglobin	Hb	International Haemiglobincyanide Reference Preparation [1]	ICSH Standard 1986 [2]
Hemoglobin A1c	HbA1c	IFCC/IRMM Candidate Primary Reference Material [3]	IFCC Reference Method [4]

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, [5] or other published biohazard safety guidelines.

DANGER: ***Contains Tetradecyltrimethylammonium bromide (TTAB) (CAS 1119-97-7), Lauryl polyethylene glycol ether (CAS 9002-92-0) and 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (CAS 26172-54-3)[6]***

VITROS Calibrator Kit 18 contains Tetradecyltrimethylammonium bromide (TTAB), Lauryl polyethylene glycol ether, and 3(2H)-Isothiazolone, 2-methyl-, hydrochloride.

H314: Causes severe skin burns and eye damage. H317: May cause an allergic skin reaction. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. P280: Wear protective gloves/protective clothing/eye protection/face protection. P261: Avoid breathing dust/fume/gas/mist/vapors/spray. P310: Immediately call a POISON CENTER or doctor/physician. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P304 + P341: IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. P302 + P352: IF ON SKIN: Wash with plenty of soap and water.

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

DANGER DANGER

Not all products and systems are available in all countries.

Reconstitution

Caution: **Do not use visibly damaged product or product with incompletely sealed packaging.**

1. Materials should be at room temperature, 18–28 °C (64–82 °F), before reconstitution.
2. Gently tap the lyophilate vial on the counter several times to dislodge any material adhering to the stopper.
3. Remove the seal and stopper from each bottle just before adding the diluent. Do not leave vials unstoppered.
4. Add 2.0 mL of VITROS Chemistry Products FS Reconstitution Diluent to the lyophilate. A Class A volumetric pipette or an automated pipette of equivalent accuracy is recommended because of the importance of this reconstitution procedure to the accuracy of the results.
5. Replace the stopper and hold it firmly in place. Invert the vial gently. DO NOT SHAKE.
6. Reconstitution, with occasional inversion, may take up to 30 minutes. Visually verify that all freeze-dried material is dissolved prior to use.
7. Keep all fluids tightly stoppered when not in use. At the time of reconstitution, it is recommended the operator date and initial the vial.
8. Reconstituted product should be used immediately or stored in the refrigerator between 2–8 °C (36–46 °F).

Storage

Storage and Stability

Reagent	Storage Condition		Stability
Unopened	Refrigerated	2–8 °C (36–46 °F)	Until expiration date
Reconstituted	Refrigerated	2–8 °C (36–46 °F)	≤ 2 days

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

Materials Provided

VITROS Chemistry Products Calibrator Kit 18: 1 bottle each of lyophilized calibrator 2, 3, 4, and 5

Materials Required but Not Provided

- VITROS Chemistry Products FS Calibrator 1
- VITROS Chemistry Products FS Reconstitution Diluent
- A Class A volumetric pipette or an automated pipette of equivalent accuracy for addition of diluent to lyophilate

Testing Procedure

IMPORTANT: *Calibration is lot specific; reagent packs and calibrators are linked by lot number. Use only with VITROS d%A1c Reagent Kits of the same lot number.*

Note: There are five calibrator levels required to calibrate VITROS d%A1c Reagent (one level of FS Calibrator 1, and four levels of Calibrator Kit 18).

Note: Be sure to use components from a single Calibrator Kit 18 lot number.

1. Remove each level of calibrator from storage 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 storage.
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.

Note: Refer to the Instructions for Use for VITROS Chemistry Products FS Calibrator 1 for more information.

Limitations

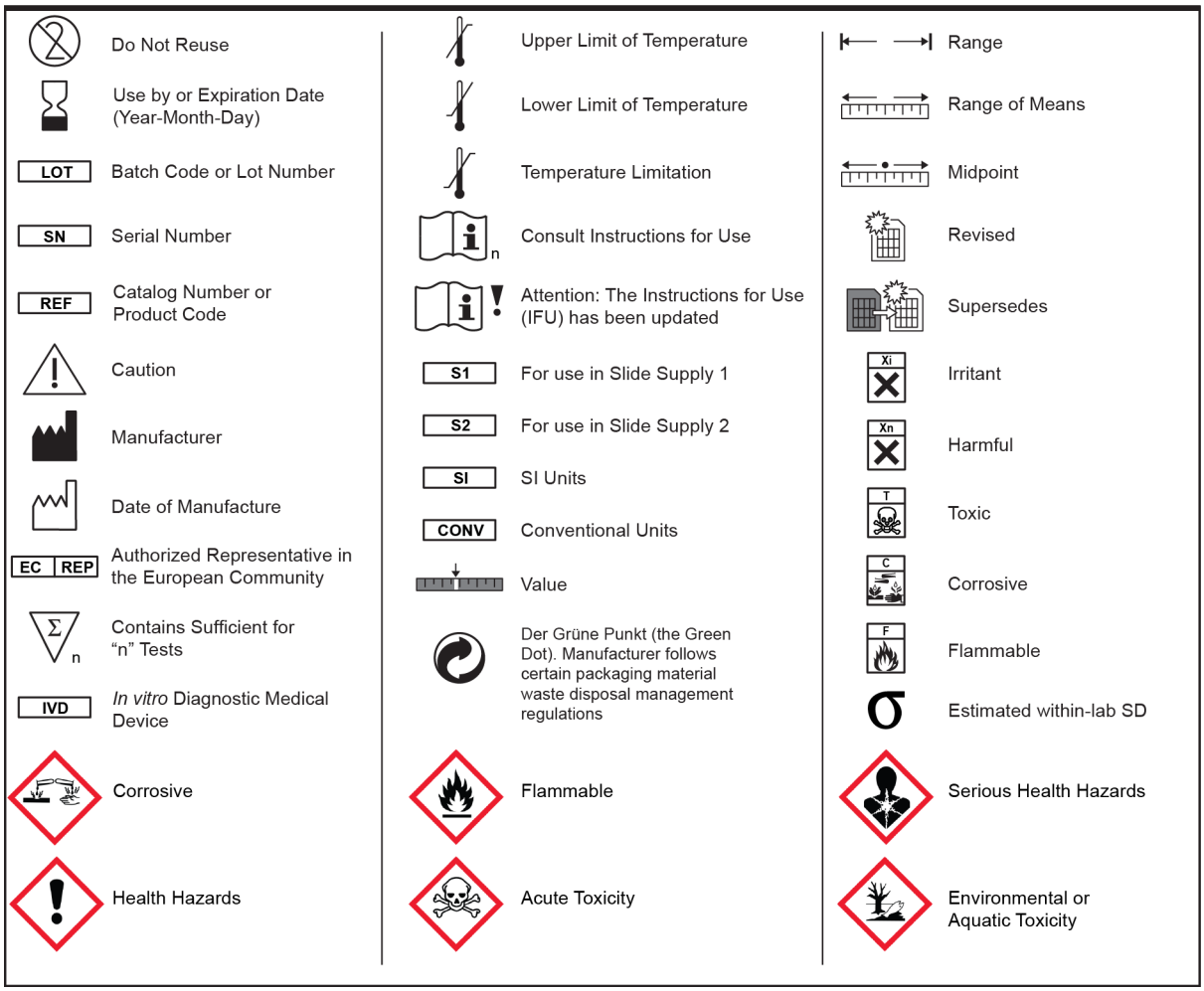
The commutability of the VITROS Chemistry Products Calibrator Kit 18 for %A1c has been demonstrated with VITROS MicroTip methods. Commutability of this calibrator has not been established with other %A1c methods.

References

1. Holtz AH. Some experience with a cyanhemiglobin solution. *Bibliotheca Haematologica* 1965; 21: 75-78.
2. Recommendations for reference method for haemoglobinometry in human blood (ICSH standard 1986) and specifications for international haemiglobincyanide reference preparation (3rd edition). International Committee for Standardization in Haematology; Expert Panel on Haemoglobinometry. *Clin. Lab Haemat.*1987; 9: 73-79.
3. Finke A, Kobold U, Hoelzel W, Weycamp C, Miedema K and Jeppsson J-O. Preparation of a candidate primary reference material for the international standardization of HbA1c determinations. *Clin.Chem. Lab Med* 1998; 36 (5): 299-308.
4. Jeppsson, Jan-Olof, et al, IFCC Scientific Working Group on HbA1c Standardisation and Network of Reference Laboratories for HbA1c, Approved IFCC Reference Method for the Measurement of HbA1c in Human Blood, *Clin Chem Lab Med* 2002; 40(1): 78-89.
5. CLSI. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Fourth Edition*. CLSI document M29-A4. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.
6. 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.



Revision History

Date of Revision	Version	Description of Technical Changes*
2015-10-12	8.0	Updated EC Representative address.
2015-08-31	7.0	• Prescription Use Statement added • Warnings and Precautions: – added reference – updated Hazard and Precaution Statements to align with the new Safety Data Sheets – added Globally Harmonized Symbols to comply with the Classification, Labelling and Packaging (CLP) Regulations • References: – updated M29 – added reference • Glossary of Symbols: added Globally Harmonized Symbols to comply with the Classification, Labelling and Packaging (CLP) Regulations
2014-09-05	6.0	Glossary of Symbols: added Date of Manufacture
2012-02-28	5.0	Glossary of Symbols: updated
2011-08-16	4.0	Warnings and Precautions – Added information

Date of Revision	Version	Description of Technical Changes*
2010-11-01	3.0	Added information for the VITROS 4600 Chemistry System
2008-06-10	2.0	• Added information for the VITROS 5600 Integrated System • Warnings and Precautions – Removed subsections containing standard laboratory safety guidelines; removed unnecessary warning; added statement • Reconstitution – Added Caution • Testing Procedure – Updated data • References – Updated M29 • Minor wording changes
2004-09-15	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

CE

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