VITROS Products Chemistry

INSTRUCTIONS FOR USE

VITROS Chemistry Products Calibrator Kit 20

Calibrator Kit 20

REF 6801704

Intended Use

For *in vitro* diagnostic use only.

VITROS Chemistry Products Calibrator Kit 20 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 transferrin, C3, C4, IgA, IgG and IgM.

Reagents

The calibrators are prepared from processed human serum to which inorganic salts, buffers, 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 Reagent Packs, 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 1	2	3	4	5	Units	Calibrator Vial 1	2	3	4	5	Units
Complement 3	(C3)	37	93	187	280	373	mg/dL	370	930	1870	2800	3730	mg/L
Complement 4	(C4)	7	18	36	54	72	mg/dL	70	180	360	540	720	mg/L
Immunoglobulin A	(IgA)	56	141	282	422	563	mg/dL	0.56	1.41	2.82	4.22	5.63	g/L
Immunoglobulin G	(IgG)	280	700	1400	2100	2800	mg/dL	2.80	7.00	14.00	21.00	28.00	g/L
Immunoglobulin M	(IgM)	26	66	132	197	263	mg/dL	0.26	0.66	1.32	1.97	2.63	g/L
Transferrin	(TRFRN)	75	188	375	563	750	mg/dL	0.75	1.88	3.75	5.63	7.50	g/L

Traceability of Values

Analyte	Chemistry	Reference Material	Comparative Method
C3	(C3)	BAM-IRMM-LGC ERM-DA470 [1]	Nephelometry
C4	(C4)		
Immunoglobulin A	(IgA)		
Immunoglobulin G	(IgG)		
Immunoglobulin M	(IgM)		
Transferrin	(TRFRN)		

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.

Storage

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)	≤ 4 weeks

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

Materials Provided

VITROS Chemistry Products Calibrator Kit 20: 1 vial each of liquid calibrator 1, 2, 3, 4 and 5; 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 five 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 20 for IgG, IgM, IgA, C3, C4 and transferrin has been demonstrated with the VITROS MicroTip method. Commutability of this calibrator has not been established with other 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.

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 Batch Code or Lot Number	Temperature Limitation	Midpoint
SN Serial Number	Consult Instructions for Use	Revised
REF Catalog Number or Product Code	Attention: The Instructions for Use (IFU) has been updated	Supersedes
Caution	S1 For use in Slide Supply 1	Xi Irritant
Manufacturer	S2 For use in Slide Supply 2	Xn Harmful
Date of Manufacture	SI SI Units	T Toxic
EC REP Authorized Representative in the European Community	CONV Conventional Units	C Corrosive
Σ n Contains Sufficient for "n" Tests	Value	F Flammable
IVD *In vitro* Diagnostic Medical Device	Der Grüne Punkt (the Green Dot). Manufacturer follows certain packaging material waste disposal management regulations	σ Estimated within-lab SD

Revision History

Date of Revision	Version	Description of Technical Changes*
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
2008-05-28	2.0	• Added information for the VITROS 5600 Integrated System • Traceability of Values: Reference Material – Updated name • Warnings and Precautions – Removed subsections containing standard laboratory safety guidelines; added statement • Testing Procedure – Added Caution • References – Updated M29, ERM-DA470 • Minor wording changes
2004-10-05	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

EC REP

Ortho-Clinical Diagnostics
50-100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4DP
United Kingdom

Ortho Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626

Ortho Clinical Diagnostics