

# INSTRUCTIONS FOR USE

VITROS Chemistry Products Calibrator Kit 17

Calibrator Kit 17

REF 680 1701

Rx ONLY

## Intended Use

For *in vitro* diagnostic use only.

VITROS Chemistry Products Calibrator Kit 17 is used in conjunction with VITROS Chemistry Products FS Calibrator 1 to calibrate VITROS 5,1 FS Chemistry System, the VITROS 4600 Chemistry System and the VITROS 5600 Integrated System for the quantitative measurement of C-reactive protein (CRP) using VITROS hsCRP Reagent.

## Reagents

The calibrator is prepared from stabilized human and ovine serum to which human C-reactive protein 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

Analyte	Calibrator Kit 17	Units
C-Reactive Protein (CRP)	100	mg/L

#### Traceability of Values

Analyte/Chemistry	Reference Material	Reference Method
C-Reactive Protein (hsCRP)	BAM-IRMM-LGC ERM-DA470 <sup>1</sup>	Nephelometry

## 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,<sup>2</sup> or other published biohazard safety guidelines.*

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)	≤ 30 days

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

## Materials Provided

VITROS Chemistry Products Calibrator Kit 17: 5 bottles of liquid calibrator; 1 mL/bottle

## Materials Required but Not Provided

- VITROS Chemistry Products FS Calibrator 1
- VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline) (Refer to "Test Procedure.")

## Testing Procedure

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

There are two calibrator levels required to calibrate VITROS Chemistry Products hsCRP Reagent:

- VITROS Chemistry Products FS Calibrator 1
- An 8-fold dilution of the single level calibrator in VITROS Chemistry Products Calibrator Kit 17 is automatically performed by the VITROS 5,1 FS Chemistry System, the VITROS 4600 Chemistry System and the VITROS 5600 Integrated System at the time of calibration using saline from VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline).

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 17 for C-reactive protein has been demonstrated with VITROS MicroTip method. Commutability of this calibrator has not been established with other C-reactive protein 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
	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

### Revision History

Date of Revision	Version	Description of Technical Changes*
2015-10-12	8.0	<ul style="list-style-type: none"> <li>Prescription Use statement added</li> <li>Updated EC Representative address.</li> </ul>
2015-01-28	7.0	<ul style="list-style-type: none"> <li>Reagents: added ovine serum</li> <li>Testing Procedure: added VITROS 5600 Integrated System</li> </ul>
2014-09-05	6.0	Glossary of Symbols: added Date of Manufacture
2012-02-28	5.0	Glossary of Symbols: updated
2010-11-01	4.0	Added information for the VITROS 4600 Chemistry System
2008-06-10	3.0	<ul style="list-style-type: none"> <li>Added information for the VITROS 5600 Integrated System</li> <li>Traceability of Values: Reference Material – Updated name</li> <li>Warnings and Precautions – Removed subsections containing standard laboratory safety guidelines; added statement</li> <li>Testing Procedure – Added Caution</li> <li>References – Updated ERM-DA470, M29</li> <li>Minor wording changes</li> </ul>
2005-07-29	2.0	<ul style="list-style-type: none"> <li>Materials Required But Not Provided — added information</li> <li>Test Procedure — updated the Note</li> <li>References — corrected 1</li> </ul>

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Revision History

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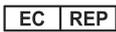
Date of Revision	Version	Description of Technical Changes*
2004-09-15	1.0	Note: Date corrected after release (from 2003 to 2004). First release of document

\* 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.

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Signature

\_\_\_\_\_  
Obsolete Date



Ortho-Clinical Diagnostics  
Felindre Meadows  
Pencoed  
Bridgend  
CF35 5PZ  
United Kingdom



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

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