INSTRUCTIONS FOR USE

VITROS Chemistry Products hsCRP Performance Verifier I, II, and III

hsCRP Performance Verifier I, II, and III

REF 680 1742
680 1888
680 2049

Intended Use

For *in vitro* diagnostic use only.
VITROS Chemistry Products hsCRP Performance Verifiers are assayed controls used to monitor performance of VITROS hsCRP Reagent on the VITROS 5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System.

Reagents

VITROS hsCRP Performance Verifiers are prepared from human plasma and plasma proteins to which stabilizers and preservative have been added.

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[1], 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)	Store tightly stoppered*

*Refer to the Assay Sheet for analyte-specific stability information.

Materials Provided

- 6 bottles (1 mL each) of VITROS Chemistry Products hsCRP Performance Verifier I
- 6 bottles (1 mL each) of VITROS Chemistry Products hsCRP Performance Verifier II
- 6 bottles (1 mL each) of VITROS Chemistry Products hsCRP Performance Verifier III

Procedure

VITROS hsCRP Performance Verifiers should be assayed in the same manner as a patient sample. The reported value can then be compared with the Range of Means and within-lab standard deviation (SD) on the assay sheet.

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

1. Remove bottles from refrigerator.
2. Mix each bottle thoroughly by gently inverting several times. DO NOT SHAKE.
3. Remove the seal and cap from each bottle just prior to use. Keep all bottles tightly capped when not in use.
4. Place fluid in a cup and cover with a pierceable cap.
5. Recap the bottle and immediately return it to the refrigerator.
6. Bring the cup to room temperature, 18–28 °C (64–82 °F), before analysis (approximately 10 minutes for refrigerated material).
7. Analyze according to the operating instructions for your system.
8. Discard any unused portion in the cup following testing.

Assay Values

- Verify that the fluid lot number on the assay sheet is the same as the lot number printed on the vial label.
- Use the Range of Means provided for the reagent generation in use.
- Results exceeding the published Range of Means should be investigated.
- Each laboratory should establish its own analyte-specific mean.
- Each laboratory should evaluate and, if necessary, update the mean after each reagent lot change.
- The within-lab standard deviation (SD) published on the assay sheet for a given analyte may be used as the laboratory's baseline SD for any reagent lot.
- Refer to assay-specific instructions for use for additional performance information.

References

1. 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*
2014-02-06	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
2008-06-04	2.0	• Added information for the VITROS 5600 Integrated System • Warnings and Precautions – Removed subsections containing standard laboratory safety guidelines; added statement • Procedure – Added Caution • Assay Values – Added information • 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.

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Signature Obsolete Date

CE

EC REP

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