INSTRUCTIONS FOR USE

VITROS Chemistry Products ASO/RF Performance Verifiers I and II

ASO/RF Performance Verifiers I and II

REF 680 2411
680 2412

Intended Use

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

Reagents

VITROS Chemistry Products ASO/RF Performance Verifiers I and II are prepared from processed human serum to which purified human proteins, bovine serum albumin 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.***
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.***
WARNING:	***This product contains bovine blood components and should be handled using the same precautions as with any other blood or blood-derived product.***

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 3.0 mL of VITROS Chemistry Products FS Reconstitution Diluent to each vial. Use a clean, dry pipette for each vial. 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 lyophilized 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
Opened	Refrigerated	2–8 °C (36–46 °F)	≤ 7 days if tightly stoppered

Materials Provided

- 5 vials of lyophilized VITROS Chemistry Products ASO/RF Performance Verifier I
- 5 vials of lyophilized VITROS Chemistry Products ASO/RF Performance Verifier II

Materials Required but Not Provided

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

Procedure

VITROS ASO/RF 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.

Note: Be sure to use components from the same kit lot number.

1. If necessary, remove reconstituted material stored in the refrigerator.
2. Mix the vial thoroughly by gently inverting several times. DO NOT SHAKE.
3. Place fluid in a cup and cover with a pierceable cap.
4. Restopper the vial and immediately return it to the refrigerator.
5. Bring the cup to room temperature, 18–28 °C (64–82 °F), before analysis (approximately 10 minutes for refrigerated material).
6. Analyze according to the operating instructions for your system.
7. 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
2009-03-17	2.0	• Added information for the VITROS 5600 Integrated System • Warnings and Precautions – Removed subsections containing standard laboratory safety guidelines; added statement • Reconstitution – Added Caution • Assay Values – Added information • Minor wording changes
2005-12-15	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

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