VITROS® Immunodiagnostic Products

Intended for Use in the United States

INSTRUCTIONS FOR USE

aHIV

VITROS Immunodiagnostic Products
Anti-HIV 1+2 Controls

Control

REF **680 1863**

Intended Use

For use in monitoring the performance of the VITROS ECi/ECiQ Immunodiagnostic System when used for the qualitative *in vitro* detection of antibodies to Human Immunodeficiency Virus types 1 and/or 2 (anti-HIV-1 and anti-HIV-2) in human serum and plasma (heparin, EDTA or citrate) when using the VITROS Immunodiagnostic Products Anti-HIV 1+2 Reagent Pack on the VITROS ECi/ECiQ Immunodiagnostic System. The performance of the VITROS Immunodiagnostic Products Anti-HIV 1+2 Controls has not been established with any other anti-HIV 1+2 assays.

WARNING: ***These controls have not been FDA cleared, licensed or approved for blood or plasma donor screening assays.***

Warnings and Precautions

For *in vitro* Diagnostic Use Only

WARNING: **Potentially Infectious Material**

The* VITROS *Anti-HIV 1+2 Controls 2 and 3 contain HIV antibody positive plasma obtained from donors who were tested individually and who were found to be negative for hepatitis B surface antigen (HBsAg), and for antibodies to hepatitis C virus (HCV), using FDA approved methods (enzyme immunoassays, EIA). The HIV antibody positive plasma has been treated in order to reduce the titer of potentially infectious virus. However, as no testing method can rule out the risk of potential infection, handle as if capable of transmitting infection.

Human blood products provided as components of Control 1 have been obtained from donors who were tested individually and who were found to be negative for hepatitis B surface antigen (HBsAg), and for antibodies to human immunodeficiency virus (HIV 1+2) and hepatitis C virus (HCV), using FDA approved methods (enzyme immunoassays, EIA).

Care should be taken when handling material of human origin. All samples should be considered potentially infectious. No test method can offer complete assurance that hepatitis B virus, HCV, HIV 1+2 or other infectious agents are absent. Handling of samples and assay components, their use, storage, and solid and liquid waste disposal should be done at a biological safety level 2 and be in accordance with the procedures defined by the appropriate national biohazard safety guideline[1] or regulation (e.g.CLSI document M29).[2]

WARNING: **Contains Kathon**

The* VITROS *Anti-HIV 1+2 Controls contain Kathon. R43: May cause sensitization by skin contact. S24: Avoid contact with skin. S37: Wear suitable gloves.

Materials Provided

3 sets of controls 1, 2 and 3 (freeze-dried human plasma with antimicrobial agent), reconstitution volume 1 mL.

Materials Required but not Provided

Pipette, distilled water, sample containers.

Reagent Preparation and Storage

Store unopened at 2–8 °C (36–46 °F). Do not use beyond the expiration date. Reconstitute with 1 mL of distilled water. After reconstitution store for up to 5 days at 2–8 °C (36–46 °F) or 4 weeks at -20 °C (-4 °F). Avoid repeated freezing and thawing.

Quality Control and Procedural Notes

- The Controls are not calibrators and should not be used for assay calibration.
- Mix thoroughly by inversion and bring to room temperature before use.
- Handle controls in stoppered containers to avoid contamination and evaporation. To avoid evaporation, limit the amount of time controls are on board the VITROS ECi/ECiQ Immunodiagnostic System. Refer to the VITROS ECi/ECiQ Immunodiagnostic System Operator's Guide for further information. Return to 2–8 °C (36–46 °F) as soon as possible after use, or load only sufficient volume for a single determination.
- Baseline statistics for controls should be entered onto the VITROS ECi/ECiQ Immunodiagnostic System via the Quality Control - Define Controls screen.
- The expiration date for the Controls must be entered onto the VITROS ECi/ECiQ Immunodiagnostic System via the Quality Control - Define Controls screen.

Procedure

Load each Control onto the VITROS ECi/ECiQ Immunodiagnostic System by transferring an aliquot into a sample container (taking account of the volume required by the assay and the minimum fill volume of the container). Process in the same manner as samples, according to the instructions in the appropriate VITROS Immunodiagnostic Products Reagent Pack instructions for use. Do not use damaged product.

For further information on quality control procedures refer to the VITROS ECi/ECiQ Immunodiagnostic System Operator's Guide.

Interpretation of Results (Baseline Statistics)

For lot specific values, refer to the Controls Values booklet provided with the VITROS Anti-HIV 1+2 Controls.

When assayed with other manufacturer's anti-HIV 1/2 assays, the QC levels (ranges) may not be met. It is the user's responsibility to determine appropriate QC ranges when using other manufacturer's anti-HIV 1/2 assays.

References

1. CDC-NIH. *Biosafety in Microbiological and Biomedical Laboratories-3rd edition*, HHS Publication No. (CDO93-8395. U.S. Government Printing Office, Washington, D.C. 1993
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, Pennsylvania 19087–1898 USA, 2005.

Glossary of Symbols

The following symbols may have been used in the labeling of this product.

	Do Not Reuse	IVD	*In vitro* Diagnostic Medical Device	Xi	Irritant
	Use by or Expiration Date (Year-Month-Day)	EC REP	Authorized Representative in the European Community	Xn	Harmful
LOT	Lot Number	Σ n	Contains Sufficient for "n" Tests	C	Corrosive
SN	Serial Number		Upper Limit of Temperature	F	Flammable
REF	Catalog Number or Product Code		Lower Limit of Temperature		Der Grüne Punkt (the Green Dot). Manufacturer follows certain packaging material waste disposal management regulations
	Attention: See Instructions for Use		Temperature Limitation		
	Manufacturer	n	Consult Instructions for Use, "n" Version		

Revision History

Date of Revision	Version	Description of Technical Changes*
2008-04-01	1.0	• Initial version of Instructions for Use.

* 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

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