Intended for Use in the United States

INSTRUCTIONS FOR USE

VITROS Immunodiagnostic Products
Anti-HIV 1+2 Calibrator

aHIV

Calibrator

REF **680 1862**

Intended Use

For *in vitro* use in the calibration of the VITROS ECi/ECiQ Immunodiagnostic System for the qualitative 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).

Summary and Explanation of the Test

The VITROS Immunodiagnostic Products Anti-HIV 1+2 Calibrator has been validated for use on the VITROS ECi/ECiQ Immunodiagnostic System with the VITROS Immunodiagnostic Products Anti-HIV 1+2 Reagent Pack. Refer to the VITROS Anti-HIV 1+2 Reagent Pack instructions for use for further details.

Principles of Procedure

Calibration is lot specific; Reagent Packs and Calibrators are linked by lot number. A Master Calibration is established for each new reagent lot by performing multiple assays on a number of VITROS ECi/ECiQ Immunodiagnostic Systems. This is the process by which a lot-specific parameter [a], which links the cut-off value to the Calibrator signal, is determined.

Cut-off value = (a x Signal of CAL)

The lot-specific parameter, the expected Calibrator signal and the data, which enable a VITROS ECi/ECiQ Immunodiagnostic System to calculate the cut-off value, are encoded on the lot calibration card.

Scanning the lot calibration card loads the encoded data onto the VITROS ECi/ECiQ Immunodiagnostic System. When the Calibrator is processed, the validity of the calibration is assessed against a quality parameter which compares the actual signal of the Calibrator with the expected signal. If the calibration is acceptable, the cut-off value is calculated and stored for use with any Reagent Pack of that lot. The quality of calibration cannot be completely described by a single parameter. The calibration report should be used in conjunction with control values to determine the validity of the calibration. Recalibration is required after a pre-determined calibration interval, or when a different Reagent Pack or Calibrator lot is loaded or at least once every 28 days. The VITROS Anti-HIV 1+2 assay may also need to be recalibrated after specified service procedures have been performed (see the VITROS ECi/ECiQ Immunodiagnostic System Operator's Guide) and if quality control results are consistently outside of the manufacturer's or your acceptable range.

Warnings and Precautions

For *in vitro* Diagnostic Use Only

WARNING: **Potentially Infectious Material**

Treat as if capable of transmitting infection.

Handling of samples and assay components, their use, storage, and solid and liquid waste disposal should be in accordance with the procedures defined by the appropriate national biohazard safety guideline or regulation (e.g. CLSI Guideline M29). [1,2]

The* VITROS *Anti-HIV 1+2 Calibrator contains:

HIV antibody positive plasma obtained from donors who were tested individually and 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.

HIV antibody negative plasma obtained from donors who were tested individually and found to be negative for hepatitis B surface antigen (HBsAg), and for antibodies to hepatitis C virus (HCV) and HIV, 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.

WARNING: **Contains Kathon**

The VITROS Anti-HIV 1+2 Calibrator contains Kathon (2.0% w/w).

R43: May cause sensitisation by skin contact. S24: Avoid contact with skin. S37: Wear suitable gloves. [3]

Materials Provided

- 1 VITROS Anti-HIV 1+2 calibrator (2 mL anti-HIV 1+2 positive human plasma treated with β- propriolactone ultraviolet radiation in anti-HIV 1+2 negative human plasma with antimicrobial agent – [2.0% Kathon w/w]).
- Lot calibration card.
- Protocol card - Major Protocol Version 1.
- 8 calibrator bar code labels.

Reagent Preparation and Storage

The VITROS Anti-HIV 1+2 Calibrator is supplied ready for use. Store unopened at 2–8 °C (36–46 °F). Do not use beyond the expiration date. After opening store for up to 13 weeks at 2–8 °C (36–46 °F) or 13 weeks at -20 °C (-4 °F) (with no more than 1 freeze-thaw cycle).

Quality Control and Procedural Notes

- Use only with reagent packs of the same lot number. Mix thoroughly by inversion and bring to 15–30 °C (59–86 °F) before use. Each pack contains sufficient volume for a minimum of 6 calibration events.
- The VITROS Anti-HIV 1+2 calibrator is automatically processed in duplicate.
- Handle Calibrator in stoppered containers to avoid contamination and evaporation. To avoid evaporation, calibrators should not be stored on board the VITROS ECi/ECiQ System. Calibrators must be stored at 2-8 °C (36-46 °F) or -20 °C (-4 °F) and should only be loaded onto the system when preparing to perform a calibration. Return to 2-8 °C (36-46 °F) as soon as possible after use, or load only sufficient quantities for a single use. The Calibrator may be aliquoted into alternative containers, which may be barcoded with the labels provided. Refer to the VITROS ECi/ECiQ Immunodiagnostic System Operator's Guide for complete details on the calibration procedure.

Procedure

Refer to the VITROS ECi/ECiQ Immunodiagnostic System Operator's Guide for detailed instructions on the calibration process.

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.
3. European 'Dangerous Preparations Directive (1999/45/EC)'.

Glossary of Symbols

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

Do Not Reuse	*In vitro* Diagnostic Medical Device	Irritant
Use by or Expiration Date (Year-Month-Day)	Authorized Representative in the European Community	Harmful
Lot Number	Contains Sufficient for "n" Tests	Corrosive
Serial Number	Upper Limit of Temperature	Flammable
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	Consult Instructions for Use, "n" Version	

Revision History

Date of Revision	Version	Description of Technical Changes*
2008-03-26	DRAFT 1.0	• Principles of Procedure – stylistic adjustment
2008-03-25	DRAFT 1.0	• Principles of Procedure - Updated information on when to calibrate • Quality Control and Procedural Notes – Updated information on calibrator handling
2008-03-06	DRAFT 1.0	Updated Glossary of Symbols
2008-XX-XX	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

Conditions of supply: all supplies are made subject to the standard terms and conditions of Ortho-Clinical Diagnostics or its distributors. Copies of these are available on request.

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