



## HIV Ag/Ab Combo Calibrator

### INTENDED USE

The ARCHITECT HIV Ag/Ab Combo Calibrator is for the calibration of the ARCHITECT *i* System when used for the simultaneous qualitative detection of HIV p24 antigen and antibodies to human immunodeficiency virus type 1 and/or type 2 (HIV-1/HIV-2) in human serum or plasma. Refer to the ARCHITECT HIV Ag/Ab Combo reagent package insert for additional information.

### CONTENTS

1 Bottle (4 mL) of ARCHITECT HIV Ag/Ab Combo Calibrator 1 (**CAL 1**): Purified HIV viral lysate prepared in TRIS buffered saline with protein (bovine) stabilizer. Preservative: Sodium Azide.

Calibrator	Color
<b>CAL 1</b>	Red <sup>a</sup>

<sup>a</sup> Dye: Red D&C No. 33

### STANDARDIZATION

To maintain a consistent HIV-1 p24 antigen sensitivity of < 50 pg/mL, the ARCHITECT HIV Ag/Ab Combo Calibrator has a HIV-1 p24 antigen concentration referenced to the international standard Agence française de sécurité sanitaire des produits de santé (AFSSAPS) panel.

### PRECAUTIONS

- IVD**
- For *In Vitro* Diagnostic Use
- CAUTION:** This product contains human sourced and/or potentially infectious components. Refer to the **CONTENTS** section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens.<sup>1</sup> Biosafety Level 2<sup>2</sup> or other appropriate biosafety practices<sup>3,4</sup> should be used for materials that contain or are suspected of containing infectious agents.
- CONTAINS: AZIDE** This product contains sodium azide. Contact with acids liberates very toxic gas.
- This material and its container must be disposed of in a safe way.
- Safety Data Sheets are available at [www.abbottdiagnostics.com](http://www.abbottdiagnostics.com) or contact your local representative.

### STORAGE

- ARCHITECT HIV Ag/Ab Combo Calibrator is stable until the expiration date when stored and handled as directed.
- Do not use past expiration date.
- 2°C–8°C

### PREPARATION FOR ANALYSIS

- Calibrator may be used immediately after removal from 2–8°C storage. Prior to use, mix by gentle inversion (5–10 times). After each use, tightly close the caps and return the calibrator to 2–8°C storage.



### BIBLIOGRAPHY

- US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
- US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
- World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
- Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline—Third Edition*. CLSI Document M29-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.

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### Key to symbols used

**GTIN**

Global Trade Item Number

**PRODUCT OF GERMANY**

Product of Germany