## INTENDED USE

The ARCHITECT HIV Ag/Ab Combo Calibrator (CAL 1) is for the calibration of the ARCHITECT *i* System when the system is used for the simultaneous qualitative detection of human immunodeficiency virus (HIV) p24 antigen and antibodies to HIV type 1 (HIV-1 group M and group O) and/or type 2 (HIV-2) in human serum or plasma using the ARCHITECT HIV Ag/Ab Combo assay. The performance of the ARCHITECT HIV Ag/Ab Combo Calibrator has not been established with any other HIV assay.

## PRINCIPLES OF PROCEDURE

The ARCHITECT *i* System utilizes the relative light units (RLU) from one calibrator. The acceptability of the calibration is assessed against an assay file parameter. The acceptable calibration is stored by the ARCHITECT *i* System for use with any reagent kit of the lot used for testing. The calibration should be used in conjunction with control ranges to determine the validity of the calibration.

## PRECAUTIONS

- For *In Vitro* Diagnostic Use
- **CAUTION:** This product contains potentially infectious components. Refer to the **MATERIALS PROVIDED** 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 and inactivated microorganisms 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.[1] Biosafety Level 2[2] or other appropriate biosafety practices[3,4] should be used for materials that contain or are suspected of containing infectious agents.
- 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.
- For information on the safe disposal of sodium azide and a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

## MATERIALS PROVIDED

1 Bottle (4.0 mL) ARCHITECT HIV Ag/Ab Combo Calibrator 1: Purified HIV-1 viral lysate prepared in TRIS buffered saline with protein (bovine serum albumin) additive. Preservative: sodium azide. The calibrator is red and contains Red D&C No. 33.

## STANDARDIZATION

The ARCHITECT HIV Ag/Ab Combo Calibrator 1 is standardized to the Agence française de sécurité sanitaire des produits de santé (AFSSAPS) HIV-1 p24 antigen 50 pg/mL international standard.

## PREPARATION AND STORAGE

- The calibrator is liquid ready-to-use. No preparation is required.
- When stored and handled as directed, the calibrator is stable until the expiration date.
- The calibrator must be stored at 2-8°C in an upright position and may be used immediately after removal from 2-8°C storage.
- For the maximum onboard stability requirements, refer to the ARCHITECT HIV Ag/Ab Combo Reagent Kit package insert.

## QUALITY CONTROL PROCEDURES

A single sample of each control level must be tested to evaluate the assay calibration. For information on ordering controls, refer to the ARCHITECT System Operations Manual, Section 5.

Ensure that assay control values are within the ranges specified in the control package insert.

Once an ARCHITECT HIV Ag/Ab Combo calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:

- A reagent kit with a new lot number is used.
- Controls are out of range.

Refer to the ARCHITECT HIV Ag/Ab Combo Reagent Kit package insert and ARCHITECT System Operations Manual for additional information.

## PROCEDURE

- The ARCHITECT HIV Ag/Ab Combo Calibrator 1 must be mixed by gentle inversion before use.
- To perform a calibration, test the calibrator in triplicate. The calibrator should be priority loaded.
- To obtain the recommended volume requirement for the ARCHITECT HIV Ag/Ab Combo Calibrator 1 (350 µL for 3 replicates), hold the bottle **vertically** and dispense 20 drops in the sample cup.
- For information on ordering calibrations, refer to the ARCHITECT System Operations Manual, Section 6.

## BIBLIOGRAPHY


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3. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
4. 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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