INTENDED USE

The ARCHITECT HIV Ag/Ab Combo Controls (CONTROL –, CONTROL + 1, CONTROL + 2, CONTROL + 3, CONTROL + 4) are used for monitoring the performance of the ARCHITECT *i* System (reagents, calibrator, and instrument) when 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.

PRECAUTIONS

For *In Vitro* Diagnostic Use

- **CAUTION:** This product contains human sourced and/or 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.
- The Negative Control is nonreactive for HBsAg, HIV-1 RNA, anti-HIV-1/HIV-2, and anti-HCV.
- Positive Control 1 is recalcified, inactivated plasma reactive for anti-HIV-1. Plasma is also tested for HIV-1 by HIV-1 NAT and may be reactive. Plasma is nonreactive for anti-HIV-2, HBsAg, and anti-HCV.
- Positive Control 2 is recalcified, inactivated plasma reactive for anti-HIV-2. Plasma is also tested for HIV-1 by HIV-1 NAT and is nonreactive. Plasma is nonreactive for anti-HIV-1, HBsAg, and anti-HCV.
- Positive Control 3 is purified HIV-1 viral lysate.
- The Positive Control 4 contains purified HIV-1 group O monoclonal antibody prepared in recalcified human plasma that is nonreactive for HBsAg, HIV-1 RNA, anti-HIV-1/HIV-2, and anti-HCV.
- 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

5 Bottles (8.0 mL each) ARCHITECT HIV Ag/Ab Combo Controls (1 negative control and 4 positive controls):

- Negative Control is recalcified negative human plasma. Preservatives: sodium azide and antimicrobial agent.
- Positive Control 1 is recalcified, inactivated human plasma reactive for anti-HIV-1 prepared in recalcified negative human plasma. Positive Control 1 is blue and contains Acid Blue No. 9 dye. Preservatives: sodium azide and antimicrobial agent.
- Positive Control 2 is recalcified, inactivated human plasma reactive for anti-HIV-2 prepared in recalcified negative human plasma. Positive Control 2 is yellow and contains Acid Yellow No. 23 dye. Preservatives: sodium azide and antimicrobial agent.

- Positive Control 3 is purified HIV-1 viral lysate prepared in TRIS buffered saline with protein (bovine serum albumin) additive. Positive Control 3 is purple and contains Acid Blue No. 9 and Red D&C No. 33 dyes. Preservative: sodium azide.
- Positive Control 4 is purified HIV-1 group O monoclonal antibody prepared in recalcified negative human plasma. Positive Control 4 is orange and contains Acid Yellow No. 23 and Red D&C No. 33 dyes. Preservatives: sodium azide and antimicrobial agent.

PREPARATION AND STORAGE

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

QUALITY CONTROL PROCEDURES

The recommended control requirement for the ARCHITECT HIV Ag/Ab Combo assay is that a single sample of (CONTROL –, CONTROL + 1, CONTROL + 2, CONTROL + 3, and CONTROL + 4) be tested once every 24 hours each day of use. Additional controls may be tested in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's quality control policy.

Control values must be within the ranges determined as specified in the **EXPECTED RESULTS** section of this insert. If a control result is out of its specified range, any test results generated since the last acceptable control results must be evaluated to determine if test results may have been adversely affected.[5,6] Adversely affected test results are invalid, and these samples must be retested. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

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

PROCEDURES

- ARCHITECT HIV Ag/Ab Combo Controls must be mixed by gentle inversion before use.
- To obtain the recommended volume requirements for the ARCHITECT HIV Ag/Ab Combo controls (150 µL for 1 replicate), hold the bottles **vertically** and dispense 10 drops of each control into each sample cup.
- For information on ordering patient specimens and controls and for general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- To troubleshoot control values that fall outside the control range, refer to the ARCHITECT System Operations Manual, Section 10.

EXPECTED RESULTS

The controls are within the following S/CO ranges, inclusive:

Control	Color	Range (S/CO)
CONTROL –	Natural	≤ 0.50
CONTROL + 1	Blue	1.20 – 11.50
CONTROL + 2	Yellow	1.52 – 8.30
CONTROL + 3	Purple	1.87 – 4.59
CONTROL + 4	Orange	1.23 – 4.92

Each laboratory should establish its own S/CO ranges for each control when using a new lot of controls.

Note: The insert ranges for the controls are not lot specific and represent the total range of values that may be generated throughout the life of the product. Using its own standard statistical quality control methods, each laboratory should establish its own S/CO ranges, which must fall within the above insert ranges for each control. The laboratory-derived S/CO ranges should be re-verified with each new lot of reagents, controls, and calibrator.

Note: Sources of variation that can be expected include:

- Calibration • Instrument • Calibrator Lot
- Control lot • Reagent lot

LIMITATIONS

- Controls values have not been established for assays other than the ARCHITECT HIV Ag/Ab Combo assay. If the user wishes to use this control material with other assays, it is their responsibility to establish the appropriate ranges.
- ARCHITECT HIV Ag/Ab Combo Negative Control, Positive Control 1, Positive Control 2, and Positive Control 4 are prepared using a serum matrix made from recalcified plasma. The user should provide alternate control material when necessary in accordance with local, state, and/or federal regulations or accreditation requirements and your laboratory's quality control policy.
- ARCHITECT HIV Ag/Ab Combo Positive Control 3 is prepared using a TRIS buffer matrix. The user should provide alternate control material when necessary in accordance with local, state, and/or federal regulations or accreditation requirements and your laboratory's quality control policy.
- The controls are not calibrators and should not be used for assay calibration.

BIBLIOGRAPHY

1. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
2. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; January 2007.
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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