ARCHITECT SYSTEM

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Read Highlighted Changes
Revised September 2012

HIV Ag/Ab Combo Controls

INTENDED USE

The ARCHITECT HIV Ag/Ab Combo Controls are for the estimation of test precision and the detection of systematic analytical deviations 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

4 Bottles (8 mL each) of ARCHITECT HIV Ag/Ab Combo Controls: Negative Control (CONTROL −), Positive Control 1 (CONTROL +1), and Positive Control 2 (CONTROL +2) prepared in recalcified human plasma. The Positive Control 1 (inactivated) is reactive for anti-HIV-1. The Positive Control 2 (inactivated) is reactive for anti-HIV-2. The Positive Control 3 (CONTROL +3) is purified HIV viral lysate prepared in TRIS buffered saline with protein (bovine) stabilizer. Preservatives for Negative Control, Positive Control 1 and Positive Control 2: sodium azide and antimicrobial agent. Preservative for Positive Control 3: sodium azide.

The controls are at the following S/CO ranges:

Control	Color	Control Range (S/CO) RANGE
CONTROL −	Natural	0.00 - 0.50
CONTROL +1	Blue[a]	1.20 - 11.50
CONTROL +2	Yellow[b]	1.52 - 8.30
CONTROL +3	Purple[c]	1.87 - 4.59

[a] Dye: Acid Blue No. 9

[b] Dye: Acid Yellow No. 23

[c] Dye: Acid Blue No. 9 and Red D&C No. 33

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.[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 human plasma used in the Positive Control 1 is reactive for anti-HIV-1 and nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, and anti-HCV.
- The human plasma used in the Positive Control 2 is reactive for anti-HIV-2 and nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, and anti-HCV.
- The human plasma used in the Negative Control is nonreactive for HBsAg, HIV-1 Ag or HIV-1 RNA, anti-HCV, and anti-HIV-1/HIV-2.
- 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 or contact your local representative.

STORAGE

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

PREPARATION FOR ANALYSIS

- Controls 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 controls to 2-8°C storage.

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; December 2009.
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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Abbott

Key to symbols used

GTIN	Global Trade Item Number
PRODUCT OF GERMANY	Product of Germany