Alinity i

HIV Ag/Ab Combo Controls

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HIV Ag/Ab

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C8P070

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NAME

Alinity i HIV Ag/Ab Combo Controls (also referred to as HIV Ag/Ab Ctrls)

INTENDED USE

The Alinity i HIV Ag/Ab Combo Controls are for the estimation of test precision and the detection of systematic analytical deviations of the Alinity i analyzer 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.

For additional information, refer to the Alinity i HIV Ag/Ab Combo reagent package insert and the Alinity ci-series Operations Manual.

CONTENTS

CONTROL –, CONTROL +1, and CONTROL +2 are 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 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	Quantity	Color	RANGE (S/CO)
CONTROL –	1 x 8.0 mL	Natural	0.00 - 0.50
CONTROL +1	1 x 8.0 mL	Blue[a]	1.20 - 11.50
CONTROL +2	1 x 8.0 mL	Yellow[b]	1.52 - 8.30
CONTROL +3	1 x 8.0 mL	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

NOTE: The insert ranges for the controls are not lot specific and represent the total range of values which may be generated throughout the life of the product. It is recommended that each laboratory establish its own means and acceptable ranges which should fall within the package insert ranges. Sources of variation that can be expected include:

- Calibration
- Calibrator lot
- Control lot
- Instrument
- Reagent lot

PRECAUTIONS

- IVD
- For *In Vitro* Diagnostic Use

Safety Precautions

- **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. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[1-4]
- The human-sourced material used in the Negative Control is nonreactive for HBsAg, anti-HIV-1/HIV-2, anti-HCV and HIV-1 RNA or HIV-1 Ag.
- The human-sourced material used in the Positive Control 1 is reactive for anti-HIV-1. The human-sourced material is also tested for HIV-1 by either HIV-1 Ag and is nonreactive, or by HIV-1 RNA and may be reactive. The human-sourced material is nonreactive for anti-HIV-2, HBsAg and anti-HCV.
- The human-sourced material used in the Positive Control 2 is reactive for anti-HIV-2. The human-sourced material is also tested for HIV-1 by either HIV-1 Ag or by HIV-1 RNA and is nonreactive. The human-sourced material is nonreactive for anti-HIV-1, HBsAg, and anti-HCV.
- The Positive Control 3 is purified HIV-1 viral lysate.

The following warnings and precautions apply to: CONTROL –, CONTROL +1, CONTROL +2, and CONTROL +3	
Contains sodium azide.	
EUH032	Contact with acids liberates very toxic gas.
P501	Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 8.

PREPARATION FOR USE

- This product is liquid ready-to-use.
- This product may be used immediately after removal from 2 to 8°C storage.
- Prior to each use, mix by gentle inversion (5 to 10 times).

STORAGE

- Do not use past expiration date.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	
Opened	2 to 8°C	Until expiration date	Store tightly capped. Return to refrigerated storage after use.

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INSTRUMENT PROCEDURE

- To obtain the recommended volume requirements for the controls, hold the bottle vertically, and dispense 10 drops of the Negative Control, 10 drops of the Positive Control 1, 10 drops of the Positive Control 2, and 10 drops of the Positive Control 3 into each sample cup in the assigned position.
- For instructions on ordering and loading controls on the instrument, refer to the Alinity ci-series Operations Manual, Section 5.

INDICATIONS OF INSTABILITY OR DETERIORATION

Instability or deterioration should be suspected if there are precipitates, visible signs of leakage, turbidity, or if controls do not meet the appropriate package insert and/or Alinity ci-series Operations Manual criteria.

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 (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. CLSI Document M29-A4. Wayne, PA: CLSI; 2014.

Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

Key to Symbols

	Caution
	Consult instructions for use
	Manufacturer
	Temperature limitation
	Use by/Expiration date
CN	Control Number
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
CONTROL –	Negative Control
CONTROL + 1	Positive Control 1
CONTROL + 2	Positive Control 2
CONTROL + 3	Positive Control 3
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
PRODUCT OF GERMANY	Product of Germany
RANGE	Range
REF	List Number

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Customer Service: Contact your local representative or find country-specific contact information on www.abbottdiagnostics.com

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