Alinity i

HAVAb IgG Controls

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HAVAb IgG
REF 08P2610
G71334R03
C8P260

Read Highlighted Changes: Revised February 2021.

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

For laboratory professional use only.

NAME

Alinity i HAVAb IgG Controls (also referred to as HAVAb IgG Ctrls)

INTENDED USE

The Alinity i HAVAb IgG Controls are for the estimation of test precision and the detection of systematic analytical deviations of the Alinity i analyzer when used for the qualitative detection of IgG antibody to hepatitis A virus (IgG anti-HAV) in human serum and plasma.

For additional information, refer to the Alinity i HAVAb IgG reagent package insert and the Alinity ci-series Operations Manual.

CONTENTS

The CONTROL – contains recalcified human plasma with protein (bovine) stabilizer.

The CONTROL + contains recalcified human plasma reactive for IgG anti-HAV.

Preservatives: ProClin 300 and sodium azide.

The controls are at the following S/CO ranges:

Control	Quantity	Color	RANGE (S/CO)
CONTROL –	1 x 8.0 mL	Natural	≤ 0.56
CONTROL +	1 x 8.0 mL	Blue[a]	1.03 - 3.53

[a] Dye: Acid Blue No. 9

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

STANDARDIZATION

The Alinity i HAVAb IgG Positive Control is standardized to the WHO 2nd International Standard for Anti-Hepatitis A, Immunoglobulin, Human (NIBSC Code 97/646).

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 this product, human specimens, and all consumables contaminated with potentially infectious materials be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.[1-4]
- The human plasma used in the Negative Control is nonreactive for anti-HAV, HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HIV-1/HIV-2, and anti-HCV.
- The human plasma used in the Positive Control is reactive for IgG anti-HAV and nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HIV-1/HIV-2, and anti-HCV.

The following warnings and precautions apply to: CONTROL – / CONTROL +

WARNING	Contains methylisothiazolones and sodium azide.
H317	May cause an allergic skin reaction.
H402*	Harmful to aquatic life.
H412	Harmful to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

* Not applicable where regulation EC 1272/2008 (CLP) has been implemented.

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Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott 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.

INSTRUMENT PROCEDURE

- To obtain the recommended volume requirements for the controls, hold the bottle vertically, and dispense 4 drops of the negative control and 4 drops of the positive control 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

ISO 15223 Symbols

	Caution
	Consult instructions for use
	Manufacturer
	Temperature limitation
	Use by/Expiration date
CONTROL –	Negative Control
CONTROL +	Positive Control
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	List Number

Other Symbols

CN	Control Number
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
PRODUCT OF GERMANY	Product of Germany
RANGE	Range

Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden
Germany
+49-6122-580

CE
0123

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

For customers in the European Union: if, in the course of using this device, you have reason to believe that a serious incident has occurred, report it to the manufacturer and to your national authority.

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