

Created August 2016.

### NAME

Alinity i Anti-HBc II Controls (also referred to as Anti-HBc Ctrl)

### INTENDED USE

The Alinity i Anti-HBc II 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 antibody to hepatitis B core antigen (anti-HBc) in human serum and plasma. For additional information, refer to the Alinity i Anti-HBc II reagent package insert and the Alinity ci-series Operations Manual.

### CONTENTS

**CONTROL -** contains recalcified human plasma. **CONTROL +** contains recalcified human plasma and dye, and is reactive for anti-HBc. Preservatives: ProClin 950 and sodium azide.

The controls are at the following ranges:

| Control          | Quantity   | Color             | Anti-HBc      |              |
|------------------|------------|-------------------|---------------|--------------|
|                  |            |                   | TARGET (S/CO) | RANGE (S/CO) |
| <b>CONTROL -</b> | 1 x 8.0 mL | Natural           | -             | 0.00 - 0.80  |
| <b>CONTROL +</b> | 1 x 8.0 mL | Blue <sup>a</sup> | 2.73          | 1.50 - 3.96  |

<sup>a</sup> 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
- Control lot
- Reagent lot
- Calibrator lot
- Instrument

### 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.<sup>1-4</sup>
- The human-sourced material used in the Negative Control is nonreactive for anti-HBc, 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 is reactive for anti-HBc and nonreactive for HBsAg, anti-HIV-1/HIV-2, anti-HCV, and HIV-1 RNA or HIV-1 Ag.

The following warnings and precautions apply to:

**CONTROL -** and **CONTROL +**



**WARNING** Contains methylisothiazolone and sodium azide.

H317 May cause an allergic skin reaction.

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.

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.

Safety Data Sheets are available at [www.abbottdiagnostics.com](http://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.

### STORAGE

- Do not use past expiration date.

|                 | Storage Temperature | Maximum Storage Time  | Additional Storage Instructions                                 |
|-----------------|---------------------|-----------------------|---|
| <b>Unopened</b> | 2 to 8°C            | Until expiration date |   |
| <b>Opened</b>   | 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

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

Alinity is a trademark of Abbott Laboratories in various jurisdictions. All other trademarks are property of their respective owners.



Abbott GmbH & Co. KG  
Max-Planck-Ring 2  
65205 Wiesbaden  
Germany  
+49-6122-580



**Customer Service: Contact your local representative or find country-specific contact information on [www.abbottdiagnostics.com](http://www.abbottdiagnostics.com)**

Created August 2016.

©2016 Abbott Laboratories