

## HBsAg Next Qualitative Controls

Created January 2019.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

### NAME

Alinity i HBsAg Next Qualitative Controls (also referred to as HBsAgNx Ctrl)

### INTENDED USE

The HBsAg Next Qualitative Controls are for the estimation of test precision and the detection of systematic analytical deviations of the Alinity i system when used for the qualitative detection and for the confirmation of the presence of hepatitis B surface antigen (HBsAg) in human serum and plasma.

For additional information, refer to the HBsAg Next Qualitative and HBsAg Next Confirmatory reagent package inserts and the Alinity ci-series Operations Manual.

### CONTENTS

The **CONTROL -** contains recalcified human plasma. Preservatives: ProClin 950 and sodium azide.

The **CONTROL +** contains inactivated purified human HBsAg (subtype ad/ ay) in phosphate buffer with a protein (bovine) stabilizer. Preservatives: ProClin 300 and ProClin 950.

The controls are at the following targets and ranges:

#### Alinity i HBsAg Next Qualitative (01R64)

Control	Quantity	HBsAg	
		TARGET (S/CO)	RANGE (S/CO)
<b>CONTROL -</b>	1 x 8.0 mL	-	≤ 0.85
<b>CONTROL +</b>	1 x 8.0 mL	3.20	1.60 - 4.80

#### Alinity i HBsAg Next Confirmatory (01R65)

Quantity	HBsAg C2			% NEUTRALIZATION
	TARGET	RANGE		
	(S/CO)*	(S/CO)*		
<b>CONTROL +</b>	1 x 8.0 mL	2.90	1.45 - 4.35	≥ 50%

\* A target and a range are not defined for C1 S/CO.

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 this product 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 Negative Control contains human plasma that is nonreactive for HBsAg, HIV-1 Ag or HIV-1 RNA, anti-HIV-1/HIV-2, anti-HCV, and anti-HBs.
- The purified HBsAg (inactivated) used in the Positive Control was derived from human donor units tested and found to be nonreactive for HIV-1 Ag or HIV-1 RNA, anti-HIV-1/HIV-2 and anti-HCV.

The following warnings and precautions apply to: <b>CONTROL -</b>	
<b>WARNING</b>	Contains methylisothiazolones and sodium azide.
H317	May cause an allergic skin reaction.
EUH032	Contact with acids liberates very toxic gas.
<b>Prevention</b>	
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.
<b>Response</b>	
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.
<b>Disposal</b>	
P501	Dispose of contents / container in accordance with local regulations.

The following warnings and precautions apply to: <b>CONTROL</b> +	
	
<b>WARNING</b>	Contains methylisothiazolones.
H317	May cause an allergic skin reaction.
<b>Prevention</b>	
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.
<b>Response</b>	
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.
<b>Disposal</b>	
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

- For information on configuring the positive control for the Alinity i HBsAg Next Confirmatory assay refer to the Alinity i HBsAg Next Confirmatory reagent package insert.
- To obtain the required volume of controls for the Alinity i HBsAg Next Qualitative assay, hold the control bottles vertically and dispense 6 drops of each control into each respective sample cup.
- To obtain the required volume of controls for the Alinity i HBsAg Next Confirmatory assay, hold the positive control bottle vertically and dispense 10 drops of Positive Control **only** (for two replicates, one for C1 and one for C2) into a sample cup.
- 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
<b>IVD</b>	<i>In Vitro</i> Diagnostic Medical Device
<b>LOT</b>	Lot Number
<b>REF</b>	List Number

Other Symbols	
<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>NEUTRALIZATION</b>	Neutralization
<b>PRODUCT OF IRELAND</b>	Product of Ireland
<b>RANGE</b>	Range
<b>TARGET</b>	Target

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