

## Probe Conditioning Solution

Read Highlighted Changes: Revised January 2018.

### NAME

Alinity i-series Probe Conditioning Solution (also referred to as Probe Cond)

### INTENDED USE

The Alinity i-series Probe Conditioning Solution is used as part of maintenance procedures. After the sample pipettor probe is cleaned, this solution is used to condition the probe to prevent the non-specific binding of analytes in the probe.

### CONTENTS / MATERIALS PROVIDED

Component	Quantity
Probe Conditioning Solution	2 x 31.8 mL

Probe Conditioning Solution contains recalcified human plasma.

Preservatives: Antimicrobial Agent and ProClin 300.

### MATERIALS REQUIRED BUT NOT PROVIDED

- 04R4701 Alinity Reagent Replacement Caps

### WARNINGS AND PRECAUTIONS

- IVD**
- For *In Vitro* Diagnostic Use
- Rx ONLY**
- 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 human-sourced material used in the Alinity i-series Probe Conditioning Solution is nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HCV, anti-HIV-1/HIV-2 and anti-HBs.

The following warnings and precautions apply to:	
Probe Conditioning Solution	
EUH208	Contains methylisothiazolones. May produce an allergic reaction.

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

- Alinity i-series Probe Conditioning Solution is ready-to-use.

### STORAGE

- Do not use past expiration date.
- The Alinity i-series Probe Conditioning Solution may be stored on the analyzer.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
<b>Unopened</b>	2 to 8°C	Until expiration date	Store in upright position.
<b>Onboard</b>	System Temperature	52 days (1248 hours)	
<b>Opened</b>	2 to 8°C	Until expiration date	Do not reuse original caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

- Alinity i-series Probe Conditioning Solution may be stored on or off the system. If removed from the system, store with new replacement caps in an upright position at 2 to 8°C. For cartridges stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

### INSTRUMENT PROCEDURE

- Load the Alinity i-series Probe Conditioning Solution cartridge prior to performing the maintenance procedure. For information on loading cartridges, refer to the Alinity ci-series Operations Manual, Section 5.
- For information on how to perform a maintenance or diagnostic procedure, refer to the Alinity ci-series Operations Manual, Section 9.

### INDICATIONS OF INSTABILITY OR DETERIORATION

Instability or deterioration should be suspected if there are visible signs of leakage.

### BIBLIOGRAPHY

- US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
- US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
- World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
- 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.

## Key to Symbols

### ISO 15223 Symbols

	Caution
	Consult instructions for use
	Manufacturer
	Sufficient for
	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
<b>SN</b>	Serial Number

### Other Symbols

<b>DISTRIBUTED IN THE USA BY</b>	Distributed in the USA by
<b>INFORMATION FOR USA ONLY</b>	Information needed for United States of America only
<b>PRODUCT OF GERMANY</b>	Product of Germany
<b>Rx ONLY</b>	For use by or on the order of a physician only (applicable to USA classification only).

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Abbott Ireland  
Diagnostics Division  
Finisklin Business Park  
Sligo  
Ireland  
+353-71-9171712



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Abbott Laboratories  
Abbott Park, IL 60064 USA

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