

## Total T<sub>3</sub> Manual Diluent

Read Highlighted Changes: Revised November 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 Total T<sub>3</sub> Manual Diluent (also referred to as Total T<sub>3</sub> Manual Diluent)

### INTENDED USE

The Alinity i Total T<sub>3</sub> Manual Diluent is used for manually diluting specimens for testing using the Alinity i Total T<sub>3</sub> Reagent Kit on the Alinity i analyzer.

For additional information, refer to the Alinity i Total T<sub>3</sub> reagent package insert and the Alinity ci-series Operations Manual.


### CONTENTS

REF	07P9440
MANUAL DILUENT	1 x 5 mL
MANUAL DILUENT	contains human serum. Preservative: sodium azide.

### PRECAUTIONS

- **IVD**
- For *In Vitro* Diagnostic Use
- **Rx ONLY**

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

The following warnings and precautions apply to: <b>MANUAL DILUENT</b>	
Contains sodium azide.	
EUH032	Contact with acids liberates very toxic gas.
P501	Dispose of contents / container in accordance with local regulations.

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](http://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.

### STORAGE

- Do not use past expiration date.

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

### INDICATIONS OF INSTABILITY OR DETERIORATION

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

### SAMPLE DILUTION PROCEDURES

Refer to the Sample Dilution Procedures section of the Alinity i Total T<sub>3</sub> reagent package insert.

### 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*. 6th ed. Washington, DC: US Government Printing Office; June 2020.
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>CONTAINS: AZIDE</b>	Contains Sodium Azide. Contact with acids liberates very toxic gas.
<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>MANUAL DILUENT</b>	Manual Diluent
<b>PRODUCT OF IRELAND</b>	Product of Ireland
<b>Rx ONLY</b>	For use by or on the order of a physician only (applicable to USA classification only).

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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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