Alinity i

Syphilis TP Controls

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Syphilis

REF 07P6010

G71146R02

C7P600

Read Highlighted Changes: Revised December 2017.

NAME

Alinity i Syphilis TP Controls (also referred to as Syphilis Ctrls)

INTENDED USE

The Alinity i Syphilis TP 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 *Treponema pallidum* (TP) in human serum and plasma.

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

CONTENTS

CONTROL – prepared with recalcified human plasma. CONTROL + prepared in recalcified human plasma (inactived); reactive for anti-TP. Preservatives: sodium azide and other antimicrobial agents.

The controls are at the following ranges:

Control	Quantity	Color	RANGE S/CO
CONTROL –	1 x 8.0 mL	Natural	≤ 0.40
CONTROL +	1 x 8.0 mL	Blue[a]	1.25 - 3.75

[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

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 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.[1-4]
- The human-sourced material used in the Negative Control is nonreactive for anti-TP, anti-HCV, HBsAg, HIV-1 RNA or HIV-1 Ag, and anti-HIV-1/HIV-2.
- The human-sourced material used in the Positive Control is reactive for anti-TP and nonreactive for anti-HCV, HBsAg, HIV-1 RNA or HIV-1 Ag, and anti-HIV-1/HIV-2.

The following warnings and precautions apply to: CONTROL – and CONTROL +	
Contains sodium azide.	
EUH032	Contact with acids liberates very toxic gas.
P501	Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at 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 (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. Store in an upright position. Return to refrigerated storage after use.

INSTRUMENT PROCEDURE

- To obtain the recommended volume requirements for the controls, hold the bottle vertically, and dispense 5 drops of the negative control and 5 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.

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

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