ARCHITECT
Syphilis TP Controls

REF 8D06-13

en

Syphilis TP
8D06
G5-6811 / R03
C8D0Z0

Revised June 2016.

INTENDED USE

The ARCHITECT Syphilis TP Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT iSystem when used for the qualitative detection of antibody to *Treponema pallidum* (TP) in human serum and plasma. Refer to the ARCHITECT Syphilis TP reagent package insert for additional information.

CONTENTS

2 Bottles (8.0 mL each) of ARCHITECT Syphilis TP Controls: Negative Control and Positive Control prepared in recalcified human plasma. The Positive Control (inactivated) is reactive for anti-TP. Preservatives: sodium azide and other antimicrobial agents.

Control	Color	Control Range S/CO
CONTROL –	Natural	≤ 0.40
CONTROL +	Blue*	1.25 - 3.75

* Dye: Acid Blue No. 9

PRECAUTIONS

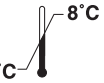
- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY
- **CAUTION:** This product contains human-sourced and/or potentially infectious components. Refer to the **CONTENTS** section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious. It is recommended that 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.[1-4]
- The human plasma 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 plasma 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 – / 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 ARCHITECT System Operations Manual, Section 8.

STORAGE

- Controls are stable until the expiration date when stored and handled as directed.
- Do not use past expiration date.
- Controls must be stored at 2-8°C in an upright position and may be used immediately after removal from 2-8°C storage.
- 

PREPARATION FOR USE

Controls may be used immediately after removal from 2-8°C storage.

Prior to use, mix by gentle inversion (5-10 times).

After each use, tightly close the caps and return the controls to 2-8°C storage.

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.

Key to Symbols

	Caution
	Consult instructions for use
	Manufacturer
	Temperature limitation
	Use by/Expiration date
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
CONTROL –	Negative Control
CONTROL +	Positive Control
DISTRIBUTED IN THE USA BY	Distributed in the USA by
INFORMATION FOR USA ONLY	Information needed for United States of America only
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
PRODUCT OF GERMANY	Product of Germany
RANGE	Range
REF	List Number
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).

ARCHITECT is a trademark of Abbott Laboratories in various jurisdictions.

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