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DIAGNOSTICS

ARCHITECT SYPHILIS TP

BACKGROUND

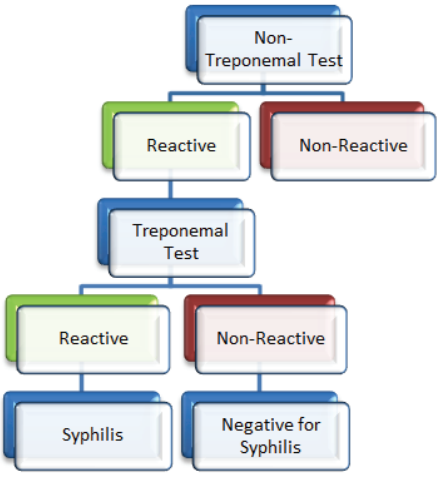
- Syphilis is a treatable infection caused by the bacteria Treponema pallidum (TP) that is most often spread by sexual contact; however, if left untreated the disease can spread and cause considerable organ damage[1]
- The number of primary and secondary syphilis cases in the US increased 66.7% from 2011 to 2015[1]
- Treponemal tests are required to screen and diagnose a syphilis infection[2]
- Two different algorithms, which combine a treponemal with a nontreponemal test, are used to aid in the diagnosis of syphilis. In recent years, the reverse algorithm has become increasingly utilized compared to the traditional algorithm due to reduced screening labor costs and improved clinical performance[3,4]

VALUE TO YOUR LAB

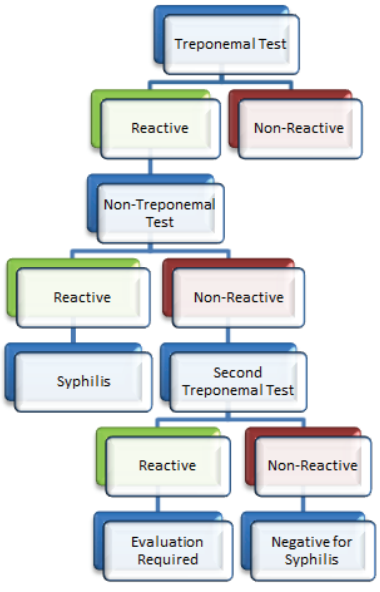
The ARCHITECT Syphilis TP assay is a qualitative test for the detection of antibodies (IgG and IgM) directed against TP to aid in the diagnosis of syphilis infection:[3-7]

- Automated Treponemal test that can significantly decrease manual RPR testing labor costs
- Provides objective interpretation of results that can be interfaced with LIS
- Utilizes three recombinant antigens (Tp15, Tp17, and Tp47) on microparticle for improved syphilis detection
- Reverse algorithm can decrease the number of false positives resulting in improved specificity and is also more sensitive than the traditional algorithm for detecting cases of primary and latent syphilis infections

TRADITIONAL ALGORITHM[3]



REVERSE ALGORITHM[3]



INTENDED USE AND IMPORTANT SAFETY INFORMATION

For *In Vitro* Diagnostics Use

Intended Use: The ARCHITECT Syphilis TP assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of antibodies (IgG and IgM) directed against Treponema pallidum (TP) in human serum and plasma. The ARCHITECT Syphilis TP assay is intended to be used as an initial diagnostic test or in conjunction with a nontreponemal laboratory test and clinical findings to aid in the diagnosis of syphilis infection.

See Important Safety Information on Reverse

SPECIFICATIONS[5-7]

METHOD & FORMAT	Two-step chemiluminescent microparticle immunoassay (CMIA)
THROUGHPUT / TIME TO FIRST RESULT	Up to 200 tests per hour / 29 minutes
REAGENT ON-BOARD / CALIBRATION STABILITY	30 days / 30 days
INTERPRETATION OF RESULTS	Reactive for treponemal antibodies: ≥1.00 Nonreactive for treponemal antibodies: <1.00
SAMPLE VOLUME	Single test – 150 µL Each additional test – 30 µL
SAMPLE TYPE	Human serum and plasma

ORDERING INFORMATION

PRODUCT DESCRIPTION	LIST NUMBER	CONFIGURATION
Reagent (tests): 100 500	 8D06-31 8D06-41	Each test kit contains: 1 bottle each (microparticles, conjugate, and diluent)
Calibrator	8D06-04	1 Calibrator
Control	8D06-13	Negative and Positive

AVAILABILITY ON SYSTEM
ARCHITECT *i*1000SR, *i*2000, *i*2000SR

REFERENCES:

1. Center for Disease Control and Prevention. Syphilis. https://www.cdc.gov/std/stats15/syphilis.htm. Accessed: 10 Feb 2017.
2. Lab Tests Online. Syphilis Tests. https://labtestsonline.org/understanding/analytes/syphilis/tab/test. Accessed: 10 Feb 2017.
3. Theel Elli. Serologic Testing for Syphilis. Mayo Clinic Comparison of the Traditional and Reverse Screening Algorithms. http://www.arlingtonscientific.com/assets/mayo-serologic-testing-for-syphilis.pdf. Accessed: 10 Feb 2017.
4. Journal of Clinical Microbiology. Point-Counterpoint: It Is Time To Use Treponema-Specific Antibody Screening Tests for Diagnosis of Syphilis. http://jcm.asm.org/content/50/1/2.full. Accessed: 10 Feb 2017.
5. ARCHITECT Syphilis Package Insert G5-6810/R01.
6. ARCHITECT Operations Manual 96211-116.
7. Data on file at Abbott.

INTENDED USE AND IMPORTANT SAFETY INFORMATION (continued)

Warning: The ARCHITECT Syphilis TP assay is not intended for use in screening blood, plasma, or tissue donors. The effectiveness of the ARCHITECT Syphilis TP assay for use in screening blood, plasma, or tissue donors has not been established.

Important Safety Information: Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in the package insert. This product contains sodium azide. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.

Caution: United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to, by, or on the order of a physician. This product contains human-sourced and/or potentially infectious components and must be handled in accordance with the OSHA Standard on Bloodborne Pathogens.

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