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Treponema Confirmatory Testing for Diagnosing Syphilis Infection
Testing Algorithm for Diagnostic Syphilis Testing

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Mnemonics:	RPR	Not individually orderable
Test Name:	RPR Screen	Treponema Ab
Test Number:	3000100	3001500
Specimen:	1 mL **SERUM ONLY**, 2-8^{0}C up to 5 days	1 mL **SERUM ONLY**, 2-8^{0}C up to 7 days, -20^{0}C or colder up to 6 months
Notes:	1. If RPR screen is reactive, a RPR quantitation and Treponema Ab are reflexively added. 2. Reactive results are reported to the PA State Department of Health. 3. FTA-ABS will remain orderable as an individual test, if needed.	

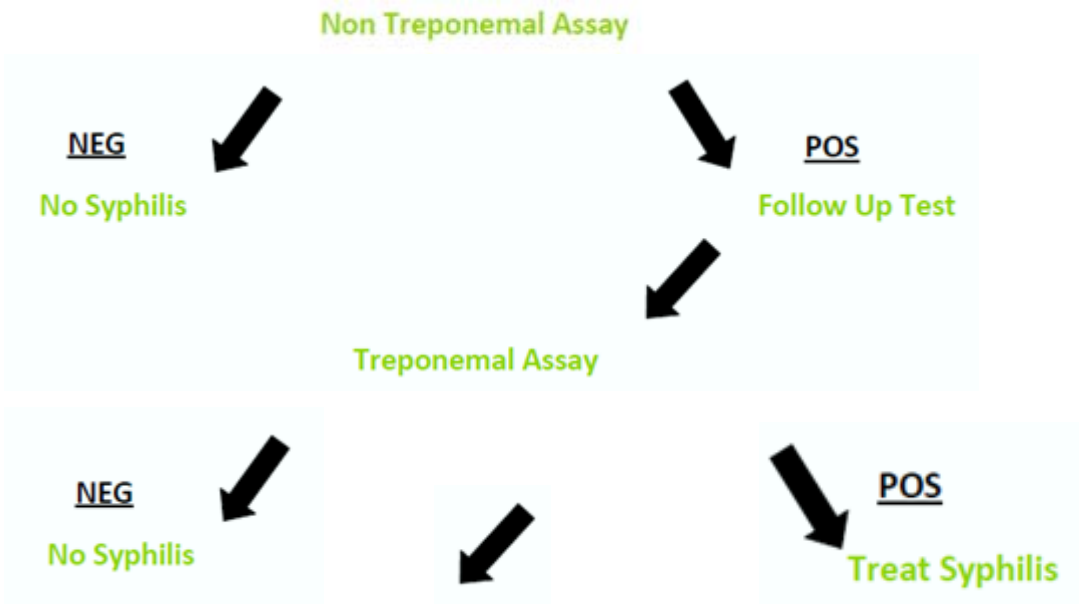
Effective Date: Target implementation May 1, 2014.

Performed: Twice weekly

Reference Range: Negative

Introduction:

Two types of serologic tests, Nontreponemal and Treponemal, are used for the presumptive diagnosis of Syphilis. Nontreponemal tests (such as RPR) detect active infection. These tests use antibodies directed against lipoidal antigens (damaged host cells or possibly from treponemes). Treponemal tests (FTA-ABS, *T. pallidum* ELISA, and chemiluminescence methods) detect the antibody response to *T. pallidum* in samples at any stage of infection. CDC standard treatment guidelines state that the use of only one type of serologic test is insufficient for diagnosis because false positive nontreponemal test results are sometimes associated with various medical conditions unrelated to syphilis. CPAL will use the recommended CDC screening algorithm in which the non-treponemal RPR assay will be used for the initial screening step, and samples with positive results will be confirmed reflexively with a treponemal chemiluminescence assay.



The Liaison chemiluminescent immunoassay (CLIA) Treponema Assay was designed as a confirmatory assay and has the following benefits over the FTA-ABS confirmatory assay:

- The assay is based upon the *T. pallidum* recombinant N17 antigen which is the most reactive antigen for IgG and IgM antibodies to *T. pallidum*.
- IgG and IgM detection improves sensitivity in primary syphilis cases as compared with IgG only assays.
- Use of recombinant antigens reduce the risk of cross-reactivity.
- Detection of syphilis regardless of the stage and treatment status of the patient. Primary, Secondary, Latent, Tertiary, and Congenital stages are detectable.

Results Interpretation:

Result	Interpretive Comment
Negative	Current infection unlikely. Biological false positive may be due to other medical conditions.
Equivocal	Qualitative interpretation could not be determined. Recommend resubmission of a sample for RPR testing no less than one week later.
Positive	Presumptive evidence of current infection (or inadequately treated infection, persistent infection, reinfection, or biological false positive if prior history).

Validation Data:

Within run reproducibility was performed using 20 replicates of a positive patient pool and 20 replicates of a negative patient pool replicates, with 100% agreement.

Between run reproducibility, carryover, and method comparison studies were performed concurrently using 20 known positive and 20 known negative patient samples. All studies showed 100% agreement with expected values.

Manufacturer's claims for assay performance as a confirmatory test:

In a study of 204 RPR/VDRL positive samples collected from the Northeastern and Southeastern regions of the United States, Liaison Treponema assay showed initial positive agreement of 99.5% and negative agreement of 100% versus an FDA-cleared Syphilis-G ELISA. Following resolution of discordant results, positive agreement was 100%.

LIS Changes:

The following changes are required in order to report Treponema Ab results:

- Reactive RPRs will no longer reflex to FTA-ABS.
- Treponema Ab will reflex for reactive RPRs.
- New test map details were sent to LIS contacts on 3/18/2014.

Note:

- Donor Testing is not currently affected by this change.
- FTA-ABS will remain available as an orderable test, if needed.
- Acceptable specimen type: SERUM ONLY.

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For questions about this and other information, call Central Pennsylvania Alliance Laboratory at 1-888-480-1422.