Screening for Syphilis with a Treponemal Enzyme Immunoassay

After careful evaluation, PACLAB has made the decision to implement a new testing algorithm for syphilis.

- The Treponemal EIA immunoassay test will be the primary screen for syphilis.
- All reactive results by Treponemal Ab will reflex to RPR for confirmation (see algorithm).
- The new testing algorithm also applies to syphilis testing that is a part of our Obstetrics Panels.

Screening for syphilis by RPR will no longer be used. We are in the process of creating new requisitions to reflect this change. In the meantime, when you order the RPR using the old requisition, it will be change to the new testing technology (Treponemal EIA assay) when testing occurs.

This improvement in testing technology will also be reflected in our standard Obstetric Panel and any customized panel containing an RPR.

CLINICAL APPLICATION

Syphilis serologic tests fall into two categories—non-treponemal and treponemal.

- Reactive EIA results usually indicate a truly positive result but reflect the lifetime exposure of a patient to syphilis.
- Numerous conditions have been associated with false-positive non-treponemal test results.
- Numerous conditions have been associated with false-positive non-treponemal test results including other infections, pregnancy, connective tissue diseases, malignancy, and narcotic addiction.
- Because these are relatively common conditions, this lack of specificity may result in false-positive results that exceed the true positive non-treponemal test results among low-risk populations.

Treponemal

- Recently, many high-volume laboratories have converted to a treponemal test in an enzyme immunoassay (EIA) format to detect antibodies specific to T. pallidum to screen for syphilis, with confirmation of positive results with a non-treponemal test.
- Reactive EIA results usually indicate a truly positive result but reflect the lifetime exposure of a patient to syphilis, not necessarily active infection.
- Treponemal-based tests cannot differentiate past infection from current infection, thus the need for an algorithm that incorporates non-treponemal testing of EIA-positive samples.

It is important to note that a 2008 CDC evaluation of the new syphilis screening approach found that reversing the order of screen and confirmatory tests for syphilis resulted in detection of an additional 3% of positive samples that would not have been identified by the traditional testing algorithm.
CLINICAL BACKGROUND

Syphilis, an infectious disease that is acquired sexually or congenitally, is caused by the spirochete Treponema pallidum.

- The disease progresses through multiple clinical stages with characteristic features. If untreated, the disease may enter a latent phase for months, years or even decades.

- Despite efforts to reduce the incidence of syphilis, it re-emerged as a public health problem in 2001 and case rates have increased, primarily due to increased infections among men who have sex with men. Syphilis is also an increasing problem among heterosexuals. Cases of primary and secondary syphilis increased 18% between 2007 and 2008 in the United States. Laboratory testing for syphilis remains a fundamental component of prevention and control efforts.

CLINICAL MANAGEMENT

- The diagnosis of syphilis is almost exclusively limited to serologic testing.

- The development of detectable antibodies is dependent on the individual’s immune competency, the infectious dose, and the time interval between exposure and test screening.

- Syphilis is infamous for its protean presentations and the resultant challenges in clinical diagnosis. Laboratory diagnosis is equally challenging.

- Clinical judgment will be required to correlate the laboratory result with the individual patient findings.

SYPHILIS ALGORITHM

ORDERING & RESULTING SCHEMES

- Patients who screen negative by Treponemal Antibody by EIA will be reported as negative. No further testing will be performed.

- Patients who screen positive by Treponemal Antibody by EIA will reflex to RPR. If reactive, an RPR titer will also be performed and reported to aid in distinguishing between treated and untreated infections.

  When results are reactive to both treponemal and RPR tests, persons should be considered to have untreated syphilis unless it is ruled out by treatment history.

  Persons who were treated in the past are considered to have a new syphilis infection if quantitative RPR testing reveals a four-fold or greater increase in titer.

- Patients who screen reactive by Treponemal Antibody by EIA but non-reactive by RPR, will reflex to the TP-PA test.

  When results are reactive to the treponemal test but nonreactive to the RPR and TP-PA test, persons with a history of previous treatment will require no further management.

  If the result of TP-PA test is reactive, treatment of syphilis should be considered, unless previously treated.

TEST AND ORDER INFORMATION

For Test and Order Information, please consult the Test Directory at www.paclab.com or contact your local client services department or client representative.

SELECTED REFERENCES


