

July 2010

Dear Client:

Effective August 17, 2010, PAML and partners will adopt a new algorithm for syphilis testing that uses Treponemal Antibody by EIA as the primary screen for syphilis.

The rapid plasma reagin (RPR) test has been the primary screening test for syphilis for decades. This test lacks specificity, providing false-positive results in a number of common clinical conditions (e.g., infections, pregnancy, connective diseases, malignancy, and narcotic addiction). This lack of specificity has been addressed by the requirement for confirmatory testing with a Treponemal antibody test. A recent CDC evaluation of a syphilis screening approach based on screening with a treponemal antibody test (2008) demonstrated the detection of an additional 3% of positive samples, which would not have been identified by the traditional RPR testing algorithm. Since the treponemal antibody test detects any past exposure to *Treponemal pallidum*, to evaluate whether the patient has active disease, all positive Treponemal antibodies will reflex to RPR. To assess disease activity, all positive RPRs will reflex to an RPR titer. The differences between the current and the planned testing algorithms are summarized below:

<b>Screening test</b>	<b>Screening test characteristics</b>	<b>Confirmatory testing</b>
RPR	Good sensitivity; poor specificity	Identify false positives from screening
Treponemal Antibody	Sensitivity and specificity: excellent. Does not distinguish between active disease and past infection	Assess disease activity

We are in the process of creating and distributing new requisitions, which reflect these changes. Following August 17, 2010, requests for RPR on an old requisition will be automatically converted to the new Treponemal antibody assay. Physicians who wish to monitor patient response to antibiotic therapy should order an RPR titer. For more information about this new approach to syphilis screening, please contact your local representative.

Sincerely,

Joseph Schappert, M.D.  
Chief Medical Officer

Ann Robinson, Ph.D.  
Director, Microbiology and Virology

**CEO \ President**

Thomas O. Tiffany  
Ph.D., DABCC, FACB

**Medical Director**

Joseph Schappert, M.D.

**Chief Science and Technical Officer**

L. M. Killingsworth  
Ph.D., DABCC

**Technical Site Director**

Bill Remillard  
BS, MT(ASCP)

**Technical Directors**

Julie Biggerstaff  
Ph.D., FACMG

David Michaelsen, MS, RP

Marcy Hoffmann, Ph.D.

Danbin Xu, M.D.,  
Ph.D., FACMG

Reza Saleki, Ph.D., FACMG

Karim Ouahchi, M.D.,  
FACMG

William A. Dittman Jr., M.D.

Carmen L. Wiley  
Ph.D., DABCC

Ann Robinson  
Ph.D., DABMM