

ASSAY INFORMATION:

Effective November 3, 2009, the Chemistry Laboratory will begin performing a *Treponema* assay as initial screening for syphilis. The assay will be performed on the DiaSorin Liaison, which utilizes a sandwich chemiluminescence immunoassay for the qualitative determination of total antibodies directed against *Treponema pallidum* in serum. If you have any questions regarding this change in testing, please contact Dr. Greg Sharp in the laboratory (847-5115) or by email (greg.sharp@vtmednet.org).

METHOD:

The DiaSorin Liaison *Treponema* assay is a one-step sandwich chemiluminescence immunoassay. *Treponema pallidum* antibodies present in the patient sample bind to magnetic particles coated with recombinant *Treponema pallidum* antigens as well as the isoluminol-antigen conjugate (recombinant *Treponema pallidum* antigen conjugated to isoluminol). A wash cycle removes unbound material. Starter reagents are added to induce a flash chemiluminescent reaction. The light signal, and hence the isoluminol-antigen conjugate, is measured by a photomultiplier as relative light units and is indicative of *Treponema pallidum* total antibody concentration.

CLINICAL APPLICATION:

Syphilis is a disease, generally sexually transmitted, caused by an infection with the spirochete *Treponema pallidum*. The natural course of syphilis is divided into three phases. After an incubation period of about three weeks, a skin lesion (chancre) appears and is often associated with regional lymphadenopathy (primary phase). The disease progresses into the secondary phase, which is disseminated and accompanied by general mucocutaneous lesions and lymphadenopathy. If syphilis is allowed to progress into the late phases of the disease, a subclinical infection (latent syphilis) can only be detected by serological tests.

Reversal of the traditional syphilis screening sequence from initial testing with a nontreponemal test such as RPR, followed by a treponemal assay when positive, to initial testing with a treponemal assay, followed by a RPR when positive, was suggested by the CDC a few years ago.

Treponemal assays detect antibodies specific to *Treponema pallidum*. A reactive treponemal result indicates that treponemal infection has occurred at some point in the past but can not differentiate between treated and untreated infections. Treponemal assays can produce reactive results for life even after treatment for syphilis.

Nontreponemal assays such as the RPR detect antibodies to cardiolipin and are not specific for treponemal infection. Nontreponemal assays are more likely than treponemal assays to produce nonreactive results after treatment.

When results are reactive by both the treponemal and RPR tests, persons should be considered to have untreated syphilis unless it is ruled out by treatment history. When results are reactive by the treponemal assay but nonreactive by RPR, samples will be sent to the State Laboratory for a FTA (fluorescent treponemal antibody) assay.

FLETCHER ALLEN HEALTH CARE

PATHOLOGY & LABORATORY MEDICINE

TEST UPDATE: SYPHILIS SEROLOGY

ASSAY LIMITATIONS:

- This assay screens for the presence of *Treponema pallidum* total antibodies. It detects both recent and past infections, but it can't differentiate between antibody classes.
- Detection of *Treponema pallidum* total antibodies may indicate recent, past or successfully treated syphilis. Therefore, this assay can not discriminate between active and treated disease.
- The Liaison Treponema assay may produce reactive results than are nonreactive by RPR because it detects *Treponema pallidum* antibodies that persist for life. RPR tests usually produce negative results in the absence of recent infection because they detect heterophilic antibodies that are present in only the early phase of infection.
- Grossly hemolyzed, icteric or lipemic samples are not acceptable for analysis.

ORDERING INFORMATION:

Test Name: Syphilis Serology

Test Code: SYPH

CPT Code: 86592

Sample Requirements: Collect 2.5 mL of blood in either a SST or Red Top Tube.
Submit 0.8 mL of serum refrigerated.
The minimum volume is 0.5 mL.

Test Note: Samples that are reactive by the Treponema assay will reflex an RPR. If the RPR is negative the sample will be sent to the State Laboratory for a FTA assay. You have the option to decline reflex testing if you believe it is not medically necessary.

Expected value: Non reactive

Test Schedule: Monday-Friday

Analytical Time: Same Day

Price: Contact laboratory Customer Service for pricing information (847-5121 or 1-800-991-2799)

Effective Date: November 3, 2009

References:

Liaison Treponema Assay product insert, DiaSorin Inc., February, 2009.

Morbidity and Mortality Weekly Report 57(32);872-875, August 15, 2008.