Louisiana Office of Public Health Laboratories	
Test Name	Syphilis (T. pallidum)
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	86780, (reflex) RPR 86592; if titered add 86593, (reflex) TP-PA 86780
Synonyms	Syph G/M, Syphilis, *Treponema pallidum*, Treponema, Syphilis IgG/IgM, RPR, TP-PA
Brief Description of Test	**Syphilis testing using the reverse testing algorithm.** Diasorin LIAISON™ Syphilis IgG/IgM uses chemiluminescent immunoassay (CLIA) for the qualitative determination of total antibodies directed against *Treponema pallidum* in human serum. The presence of antibodies to *Treponema pallidum* specific antigen, in conjunction with non-treponemal laboratory tests and clinical findings may aid in the diagnosis of syphilis infection. The Rapid Plasma Reagin (RPR) Automated Test System is a non-treponemal flocculation test that can qualitatively determine the presence of regain antibodies in human serum. It may be used to aid in the diagnosis of syphilis when used in conjunction with supplemental treponemal laboratory tests and other clinical information. The RPR is a reflex test that is performed when the Syphilis EIA is reactive or repeatedly equivocal. Serodia® TP-PA is a qualitative gelatin article agglutination assay intended to be used for the detection of *Treponema pallidum* antibodies in human serum as an aid in the diagnosis of syphilis. The TP-PA is a reflex test that is performed when the Syphilis EIA is reactive and the RPR is non-reactive.
Possible Results	**Diasorin Syphilis IgG/IgM** Nonreactive Repeatedly Equivocal Reactive **RPR** Nonreactive Reactive (with quantitation) **TP-PA** Non-Reactive Inconclusive

	Reactive
Reference Range	Nonreactive
Specimen Type	Serum
Specimen Container(s):	Blood Serum Collection Tube or Screw-cap aliquot tube
Minimum volume accepted:	Request 1 mL 220 µL serum for Diasorin Syphilis IgG (does not allow for repeat testing) 0.3 mL serum for RPR (does not allow for quantitation > 1:16) 50 µL serum for TP-PA (does not allow for repeat testing)
Collection Instructions	Specimen Container – 5-8 mL Serum Separator Tubes (SST) or Screw Cap Aliquot Label specimen with Patient Name and a 2nd unique identifier such as a chart number or medical record number. DOB is not considered unique. Complete a STD-HIV Lab Form to accompany the serum sample. Lab submission form must be thoroughly completed with patient's first and last name, 2nd patient identifier, gender, date of birth, date of collection, time of collection, test requested, and submitter's name, address, and contact number. Two unique identifiers **MUST** be recorded on the tube **AND** the Lab form. Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.
Storage and Transport Instructions	• -2-25°C for 7 days or • For shipments that are delivered >7 days from collection, specimens should be kept frozen (≤ -20°C). Do not freeze on the clot. Aliquot specimens.
Causes for Rejection	• Unspun • Short Draw/Overfill • Hemolyzed • Lipemic • Icteric • Received outside acceptable transport conditions • Incorrect source • Expired collection tubes
Limitations of the Procedure	**Syphilis IgG/IgM** This test allows screening for the presence of *Treponema pallidum* total antibodies. It detects both recent and past infections, but it cannot distinguish between different antibody classes. Detection of

	Treponema pallidum total antibodies may indicate recent, past or successfully treated syphilis: this test, therefore, cannot discriminate between active and treated disease and, as a consequence, may not be used for determining response to therapy. This test may produce positive results that score negative with non-treponemal tests (VDRL, RPR), because it detects *Treponema pallidum* antibodies that persist for life. RPR tests usually produce negative results in past infections, because they detect heterophilic antibodies that are present only in the early phase of infection. Bacterial contamination or heat inactivation of the specimens may affect the lab results. Diagnosis of syphilis should not be established on the basis of a single test result, but should be determined in conjunction with clinical findings and other diagnostic procedures as well as in association with medical judgement. Test results must be interpreted with caution in immunocompromised individuals since their antibody levels may be affected by this condition. **RPR** Test results are intended to aid in the diagnosis only. As with all serological tests for syphilis, results should always be interpreted in conjunction with additional treponemal serologic test results, the patient's clinical symptoms, medical history, and other clinical and/or laboratory findings to produce a diagnosis of syphilis by disease stage. A reactive test is not diagnostic of syphilis without additional serologic testing and a full clinical evaluation. Results in samples from immunosuppressed patients or from patients with disorders leading to immunosuppression should be interpreted with caution. With cardiolipin type antigens, biological false reactive results have been reported in diseases or conditions such as infectious mononucleosis, pregnancy, leprosy, malaria, intravenous blood users, autoimmune disease, lupus erythematosus, vaccinia, viral pneumonia, and people who have been recently immunized. Pinta, yaws, bejel and other treponemal diseases may produce reactive results with non-treponemal tests. Factors such as sample degradation, debris, and contaminants may result in false results. **TP-PA** The Serodia® TP-PA test is specific for detecting *Treponema pallidum* antibodies in serum. It does not detect *T. pallidum* directly. As will all serological tests for syphilis, interpretation of results obtained with this test must be used in conjunction with the patient's clinical symptoms, medical history and other clinical and/or laboratory findings to produce an overall clinical diagnosis. All treponemal tests tend to remain rective following treponemal infection; therefore, they should not be used to evaluate response to therapy. This test may be reactive in a small percentage (less than 1%) of normal or healthy persons; these flase-positive results are often transient, their cause unknown. False positive results may occur in association with other underlying illnesses and may be reactive in persons from areas where yaws or pinta was, or is, endemic. Samples from patients with HIV, Leprosy,

	Toxoplasmosis, H. pylori, or drug addiction may react, on occasion, with either the sensitized or the unsensitized particles, causing false-positive or Inconclusive results.
Interfering Substances	Hemolyzed, lipemic, or icteric specimens
References	Diasorin Syphilis package Insert RPR Package Insert Serodia® - TP-PA Package Insert
Additional Information	Samples that are repeatedly equivocal or reactive will be reflexed to RPR testing. TP-PA is automatically ordered on a sample when Syphilis IgG/IgM EIA assay is repeatedly equivocal or reactive and the RPR assay is nonreactive.
Release Date	11/5/2019

Warning: If you have printed a copy of this information please be advised that the Louisiana Office of Public Health Laboratories website and methods are updated on a regular basis. Please check the on-line version of this document to ensure you are relying on the most recent release.