

Syphilis Serology Methodology and Test Menu Changes

Effective June 3, 2019 syphilis testing at South Bend Medical Foundation will be performed using the BioPlex 2200 Syphilis Total & RPR Assay, a multiplex flow immunoassay for the qualitative detection of total (IgG/IgM) antibodies to *Treponema pallidum* and non-treponemal reagin antibodies in human serum. This new automated dual treponemal/non-treponemal test streamlines laboratory workflow while offering improved sensitivity and specificity over previous methods.

The Syphilis Total Antibody assay is reported as Nonreactive, Equivocal, or Reactive. A nonreactive result does not exclude the possibility of exposure to or infection with *T. pallidum*. Antibodies may be at low or undetectable levels in incubating or early primary disease and in some clinical conditions. Detection of treponemal antibodies may indicate recent, past or successfully treated syphilis infections and therefore cannot be used to differentiate between active and cured cases. A patient with a Syphilis Total reactive result will usually remain reactive for life, and therefore antibody index values cannot be used to monitor response to therapy.

The RPR assay is reported as Nonreactive or Reactive. False positive results may be seen in patients with Systemic Lupus Erythematosus, pregnancy, malaria, autoimmune disease, viral pneumonia, intravenous drug use, or recent immunization (e.g. smallpox vaccination).

Syphilis Total & RPR test results should be considered with other laboratory results and the clinical presentation of the patient. Results should be interpreted by a physician. Results obtained from immunocompromised individuals should be interpreted with caution.

Summary of Changes

Test	Previous Method	New Method
<i>T. pallidum</i> (syphilis) Antibody	BioPlex 2200 Syphilis IgG	BioPlex 2200 Syphilis Total & RPR
RPR, Qualitative	Sure-Vue RPR	
RPR Titration	Sure-Vue RPR	No changes
<i>T. pallidum</i> Ab, confirmatory	Fujirebio TP-PA	

Specimen Information

Specimen:	Serum
Container:	Gold top (SST) or Red top (Serum) tube
Requested Volume:	1 mL
Minimum Volume:	0.5 mL
Collect:	Standard phlebotomy procedure. Mix by inverting tube 5 times.
Specimen Processing:	Allow specimen to clot completely at room temperature. Centrifuge and separate serum from cells ASAP or within 2 hours of collection. SST: Transport properly centrifuged gel-barrier tube specimen in the original collection tube. Red top: Transfer serum to a plastic transport tube.
Storage/Transport Temp:	Refrigerated.
Rejection Criteria:	Contaminated, heat-inactivated, hemolyzed, icteric, or lipemic specimens.
Stability:	Refrigerated: 5 days Frozen: Greater than 5 days (avoid repeated freeze/thaw cycles)

SOUTH BEND MEDICAL FOUNDATION

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Joyce L. Simpson, M.D. • Medical Director

Revised Test Menu:

Traditional Syphilis Serology Testing Algorithm:

Rapid Plasma Reagin (RPR) Screen with Reflex to Syphilis Total Antibody and RPR Titer, Serum

Order NEW Test# **28445** CPT: 0065U OR 0064U

- If RPR is Nonreactive, no further testing is performed and CPT 0065U is billed.
- If RPR is Reactive, then Syphilis Total Antibody is added and CPT 0064U is billed.

If RPR and Syphilis Total Antibody are both reactive, then RPR titration (CPT 86593) is added.

Reverse Syphilis Serology Testing Algorithm:

Syphilis Total Antibody with Reflex to RPR and TP-PA, Serum

Order NEW Test# **28439** CPT: 86780 OR 0064U

- If Syphilis Total Antibody is Nonreactive or Equivocal, no further testing is performed and CPT 86780 is billed.
- If Syphilis Total Antibody is Reactive, then qualitative RPR is added and CPT 0064U is billed.

If RPR is Reactive, then RPR titration (CPT 86593) is added.

If RPR is Nonreactive, then *T. pallidum* Antibody by TP-PA (CPT 86780-59) is added.

Monitoring Test for Patients Previously Diagnosed with Syphilis:

Rapid Plasma Reagin (RPR) with Reflex to RPR Titer, Serum (Response to Therapy)

Order NEW Test# **28446** CPT: 0065U

If RPR is Nonreactive, no further testing is performed.

If RPR is Reactive, then RPR titration (CPT 86593) is added.

Order Sets:

Obstetric Panel with Reflex

Order NEW Test# **35851** CPT: 80055

Panel Components:

- CBC with Automated Differential
- Hepatitis B Virus Surface Antigen, with Reflex to HBsAg Neutralization
- Rubella Antibody, IgG
- Rapid Plasma Reagin (RPR) Screen with Reflex to Syphilis Total Antibody and RPR Titer, Serum
- HDN Antibody Screen with Reflex to Antibody ID and Titer(s)
- ABO Blood Group and Rh Type

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Obstetric Panel (Includes HIV Ag/Ab) with Reflex

Order NEW Test# **35852** CPT: 80081

Panel Components:

- CBC with Automated Differential
- Hepatitis B Virus Surface Antigen, with Reflex to HBsAg Neutralization
- HIV Antigen-Antibody Combo with Reflex to HIV-1/HIV-2 Ab Differentiation
- Rubella Antibody, IgG
- Rapid Plasma Reagin (RPR) Screen with Reflex to Syphilis Total Antibody and RPR Titer, Serum
- HDN Antibody Screen with Reflex to Antibody ID and Titer(s)
- ABO Blood Group and Rh Type

Discontinued Tests:

- SBMF# 35849 Obstetric Panel (Includes HIV Ag/Ab) with Syphilis Screen by Immunoassay with Reflex to RPR and TP-PA
- SBMF# 35850 Obstetric Panel (Includes HIV Ag/Ab) with Syphilis Screen by RPR with Reflex to TP-PA
- SBMF# 35839 Obstetric Panel with Syphilis Screen by Immunoassay with Reflex to RPR and TP-PA
- SBMF# 35842 Obstetric Panel with Syphilis Screen by RPR with Reflex to TP-PA
- SBMF# 28058 Rapid Plasma Reagin (RPR) with Reflex to Titer
- SBMF# 28068 Rapid Plasma Reagin (RPR) with Reflex to Titer and TP-PA
- SBMF# 44405 Treponema pallidum Antibody, IgG by ELISA
- SBMF# 28059 Treponema pallidum Antibody, IgG by MFI with Reflex to RPR and TP-PA, Serum
- SBMF# 47012 VDRL with Reflex to Titer, Serum

SBMF online Test Directory

Questions: Please contact **CLIENT SERVICES 800-950-7263**

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