LAB4400 Syphilis *Treponema pallidum* Total Antibody with Reflex

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BMC

Specimen Type
Serum

Preferred Container
Gold or Red top

Minimum Volume to Submit for Testing
2 mL Serum
Separate tube is required to perform the test and subsequent reflex testing based on the reverse sequence algorithm for diagnosis of syphilis.

Storage Requirements
Primary specimen tubes should be centrifuged within 2 hours of collection followed by transfer of the serum to a labeled plastic, aliquot tube.
See Causes of Rejection for temperature requirements.

Transportation Needs
Deliver specimen to laboratory within 1 hour of collection if unspun.
If not possible see "Storage Requirements".

Causes for Rejection
Mislabeled or unlabeled specimen
Less than 50% draw for vacutainer tubes
Spun or Unspun sample > 7 days refrigerated
Spun or Unspun sample > 3 days at room temperature
Hemolysis > 500 mg/dL HgB
Lipemia > 3000 mg/dL Trig
Bilirubin > 20 mg/dL Bili
Total Protein > 12 g/dL
EDTA, Heparin, NaF, Citrate, Oxalate

Reference Values

Diagnostic considerations should be based on treponemal and nontreponemal testing as described in the Centers for Disease Control and Prevention (CDC) Sexually Transmitted Diseases Treatment Guidelines, 2015.3. The testing and reporting protocol for Syphilis TP Total Antibody is as follows:		
Value S/CO	**Reported as:**	**Interpretation**
<1.00	Non-Reactive	A nonreactive result does not exclude the possibility of exposure to or infection with syphilis, nor rule out incubating or early primary infection

≥1.00	Reactive	A reactive result for treponemal antibodies is not diagnostic of syphilis without additional serologic testing and a clinical evaluation. Specimen is reflexed to second tier (RPR) testing.

Interpretation Table					
Patient history	**Test and Result**			**Interpretation**	**Follow-up**
	TP Ab	**RPR**	**TP-PA**		
Unknown history of syphilis	Non-reactive	N/A	N/A	No serologic evidence of syphilis	None, unless clinically indicated (i.e., early syphilis)
	Reactive	Reactive	N/A	Untreated or recently treated syphilis	See CDC treatment guidelines
	Reactive	Non- reactive	Non- reactive	Probable false-positive screening test	No follow-up testing, unless clinically indicated
	Reactive	Non- reactive	Reactive	Possible syphilis (i.e., early or latent) or previously treated syphilis	Historical and clinical evaluation required
Known history of syphilis	Reactive	Non- reactive	Reactive or N/A	Past, successfully treated syphilis	Prior syphilis confirm treatment history

TP Ab, Treponemal Antibody; N/A, not applicable; RPR, rapid plasma reagin; TP-PA, Treponema pallidum particle agglutination.

Reflex Testing

A **confirmatory RPR (Rapid Plasma Reagin)** (OCH Lab test, LAB494) is required for every Reactive result, and will be auto-reflexed. When an RPR screen is Negative, the specimen will be sent to the reference laboratory for confirmatory testing **TP-PA** (LAB3599). If needed, the laboratory will contact patient for redraw.

Limitations

In accordance with CDC guidelines, Syphilis TP testing should not be performed on infants aged < 30 days. Order an RPR (LAB494) and batch to OCH if needed.
False reactive results can be expected with any test kit based on specificity of the test kit, specimen integrity and the characteristics of the local population being screened
A nonreactive treponemal test result does not exclude the possibility of exposure to or infection with syphilis.
A reactive test result for treponemal antibodies is not diagnostic of syphilis without additional serologic testing and a full clinical evaluation.
This test cannot distinguish between active and treated infection
Assay interference due to circulating antibodies against yaws, pinta, and bejel has not been evaluated. Cross-reactivity with these treponemal disease conditions is to be expected.

Available STAT

No

Methodology
Chemiluminescent Microparticle Immunoassay

CPT Code
86780, if reflexed add 86592 and/or 86780