Overview

Useful For
Determining whether a patient has had previous exposure to or recent infection with *Toxoplasma gondii*

Method Name
Multiplex Flow Immunoassay (MFI)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume: 0.5 mL

Forms
If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

Specimen Minimum Volume
0.4 mL

Reject Due To

<table>
<thead>
<tr>
<th></th>
<th>Mild OK; Gross reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemolysis</td>
<td></td>
</tr>
<tr>
<td>Lipemia</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Icterus</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Other</td>
<td>Heat-inactivated specimen</td>
</tr>
</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>14 days</td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>14 days</td>
</tr>
</tbody>
</table>

Clinical and Interpretive
Clinical Information

Toxoplasma gondii is an obligate intracellular protozoan parasite that is capable of infecting a variety of intermediate hosts including humans. Infected definitive hosts (cats) shed oocysts in feces that rapidly mature in the soil and become infectious.(1) Toxoplasmosis is acquired by humans through ingestion of food or water contaminated with cat feces or through eating undercooked meat containing viable oocysts. Vertical transmission of the parasite through the placenta can also occur, leading to congenital toxoplasmosis. Following primary infection, Toxoplasma gondii can remain latent for the life of the host; the risk for reactivation is highest among immunosuppressed individuals.

Seroprevalence studies performed in the United States indicate that approximately 9% to 11% of individuals between the ages of 6 and 49 have antibodies to Toxoplasma gondii.(2)

Infection of immunocompetent adults is typically asymptomatic. In symptomatic cases, patients most commonly present with lymphadenopathy and other nonspecific constitutional symptoms, making definitive diagnosis difficult to determine.

Severe-to-fatal infections can occur among patients with AIDS or individuals who are otherwise immunosuppressed. These infections are thought to be caused by reactivation of latent infections and commonly involved the central nervous system.(3)

Transplacental transmission of the parasites resulting in congenital toxoplasmosis can occur during the acute phase of acquired maternal infection. The risk of fetal infection is a function of the time at which acute maternal infection occurs during gestation.(4) The incidence of congenital toxoplasmosis increases as pregnancy progresses; conversely, the severity of congenital toxoplasmosis is greatest when maternal infection is acquired early during pregnancy. A majority of infants infected in utero are asymptomatic at birth, particularly if maternal infection occurs during the third trimester, with sequelae appearing later in life. Congenital toxoplasmosis results in severe generalized or neurologic disease in about 20% to 30% of the infants infected in utero; approximately 10% exhibit ocular involvement only and the remainder are asymptomatic at birth. Subclinical infection may result in premature delivery and subsequent neurologic, intellectual, and audiologic defects.

Reference Values

Toxoplasma ANTIBODY, IgG

Negative

Toxoplasma IgG

< or =9 IU/mL (Negative)

10-11 IU/mL (Equivocal)

> or =12 IU/mL (Positive)

Reference values apply to all ages.

Interpretation

A positive Toxoplasma IgG result is indicative of current or past infection with Toxoplasma gondii. A single positive Toxoplasma IgG result should not be used to diagnose recent infection.

Equivocal Toxoplasma IgG results may be due to very low levels of circulating IgG during the acute stage of infection. A second specimen should be submitted for testing if clinically indicated.
Individuals with negative *Toxoplasma* IgG results are presumed to not have had previous exposure to *Toxoplasma gondii*. However, negative results may be seen in cases of remote exposure with subsequent loss of detectable antibody.

Seroconversion from negative to positive IgG is indicative of *Toxoplasma gondii* infection subsequent to the first negative specimen.

Recent or acute infection with *Toxoplasma gondii* can be evaluated with the TOXMP / *Toxoplasma gondii* Antibody, IgM, Serum assay. A suspected diagnosis of acute toxoplasmosis should be confirmed by detection of *Toxoplasma gondii* DNA by PCR analysis of cerebrospinal fluid or amniotic fluid specimens (PTOX / *Toxoplasma gondii*, Molecular Detection, PCR).

For further confirmation of a diagnosis, the FDA issued a Public Health Advisory (7/25/1997) suggesting that sera found to be positive/equivocal for *Toxoplasma gondii* IgM antibody be sent to a *Toxoplasma* reference laboratory. Recommended laboratories included the CDC or Jack Remington MD, Palo Alto Medical Foundation, 860 Bryant St., Palo Alto, CA 94301.

**Cautions**

Sera drawn very early during the acute stage of infection may have *Toxoplasma* IgG levels below 9 IU/mL.

IgG is not useful for diagnosing infection in infants younger than 6 months of age. IgG antibodies in that age group usually are the result of passive transfer from the mother.

The *Toxoplasma* IgG assay should not be used alone to diagnose recent *Toxoplasma gondii* infection. Results should be considered in conjunction with clinical presentation, patient history, and other laboratory findings.

The performance characteristics of this assay have not been evaluated in immunocompromised individuals and have not been established for cord blood or for testing of neonates.

**Supportive Data**

To evaluate the accuracy of the BioPlex *Toxoplasma* IgG multiplex flow immunoassay, 600 prospective serum samples submitted for routine *Toxoplasma* IgG testing by the VIDAS enzyme-linked fluorescence immunoassay (ELFA; bioMerieux, Durham, NC) were also analyzed in a blinded fashion by the BioPlex assay within a 24 hour period. Samples with discordant results after initial testing were repeated by both assays during the same freeze/thaw cycle. Further resolution of discrepant results was performed by sending the samples to the Palo Alto Medical Foundation for testing. The results are summarized below:

<table>
<thead>
<tr>
<th>BioPlex <em>Toxoplasma</em> IgG</th>
<th>Toxoplasma IgG (VIDAS ELFA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>63</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
</tr>
<tr>
<td>Equivocal</td>
<td>0</td>
</tr>
</tbody>
</table>

Both of these serum samples were negative by the Sabin-Feldman dye test at the Palo Alto Medical Foundation *Toxoplasma* laboratory.

Sensitivity: 100% (63/63); 95% Confidence Interval (95% CI): 93.1% to 100%
Test Definition: TOXGP
Toxoplasma Ab, IgG, S

Specificity: 99.6% (528/530); 95% CI: 98.5% to 99.9%
Overall Percent Agreement: 98.7% (592/600); 95% CI: 97.3% to 99.4%

Clinical Reference

Performance

Method Description
The BioPlex 2200 Toxoplasma IgG assays uses multiplex flow immunoassay technology. Briefly, Toxoplasma antigen-coated fluorescent beads are mixed with an aliquot of patient sample and sample diluent and incubated at 37 degrees C. During this time IgG anti-Toxoplasma antibodies in the specimen will bind to the Toxoplasma antigen on the beads. After a wash cycle, a fluorescently-labeled antihuman IgG-antibody conjugate is added to the mixture and incubated at 37 degrees C. Following a wash step to remove unbound conjugate, the bead mixture is passed through a detector that identifies the bead based on dye fluorescence and determines the amount of antibody captured by the antigen based on fluorescence of the antihuman IgG conjugate. Raw data is calculated in relative fluorescence intensity and is converted to an antibody index for interpretation.

Three additional dyed beads, an internal standard bead, a serum verification bead, and a reagent black bead are present in each reaction mixture to verify detector response, the addition of serum to the reaction vessel and the absence of significant non-specific binding in serum, respectively.(Package insert: BioPlex 2200 System, ToRC IgG, Bio-Rad Laboratories, Clinical Diagnostics Group, Hercules, CA, March 2012)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Saturday; 9 a.m.

Analytic Time
Same day/1 day

Maximum Laboratory Time
3 days

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester
Fees and Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification

This test has been cleared or approved by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

86777

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOXGP</td>
<td>Toxoplasma Ab, IgG, S</td>
<td>In Process</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOXG</td>
<td>Toxoplasma Ab, IgG, S</td>
<td>40677-7</td>
</tr>
<tr>
<td>DEXG6</td>
<td>Toxoplasma IgG Value</td>
<td>8039-0</td>
</tr>
</tbody>
</table>