Test Definition: TOXGP

Toxoplasma gondii Antibody, IgG, Serum

Overview

Useful For

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

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

Method Name

Multiplex Flow Immunoassay (MFI)

NY State Available

No

Specimen

Specimen Type

Serum

Ordering Guidance

IgG antibodies in patients younger than 6 months of age are typically the result of passive transfer from the mother. To assess possible *Toxoplasma gondii* infection in patients younger than 6 months, order TXM / *Toxoplasma gondii* Antibody, IgM, Serum.

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume

0.4 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Heat-inactivated specimen	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Frozen	14 days	

Clinical & Interpretive

Clinical Information

Toxoplasma gondii is an obligate intracellular protozoan parasite 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, *T gondii* can remain latent for the life of the host; the risk for reactivation is highest among individuals who are immunosuppressed.

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

Infection of immunocompetent adults is typically asymptomatic. In symptomatic cases, patients most frequently 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 involve 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 *T 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 *T gondii* infection subsequent to the first negative specimen.

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

For additional confirmation of a diagnosis, the US Food and Drug Administration issued a Public Health Advisory (07/25/1997) suggesting that sera found to be positive/equivocal for *T gondii* IgM antibody be sent to a *Toxoplasma* reference laboratory.

Cautions

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

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, 100 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. The results are summarized below:

	***Toxoplasma* IgG (VIDAS ELFA)**		
BioPlex		Positive	Negative

***Toxoplasma* IgG**	Positive	33	0
	Negative	0	67

Sensitivity: 100% (33/33); 95% Confidence Interval (95% CI): 87.6%-100%
Specificity: 100% (67/67); 95% CI: 93.5%-100%
Overall Percent Agreement: 100% (100/100); 95% CI: 95.6%-100%

Clinical Reference

1. Tenter AM, Heckeroth AR, Weiss LM. *Toxoplasma gondii*: from animals to humans. Int J Parasitol. 2000;30(12-13):1217-1258
2. Jones JL, Kruszon-Moran D, Sanders-Lewis K, Wilson M. *Toxoplasma gondii* infection in the United States, 1999-2004, decline from the prior decade. Am J Trop Med Hyg. 2007;77(3):405-410
3. Luft BJ, Remington JS. Toxoplasmic encephalitis in AIDS. Clin Infect Dis. 1992;15(2):211-222
4. Wong SY, Remington JS. Toxoplasmosis in pregnancy. Clin Infect Dis. 1994;18(6):853-861
5. Wang ZD, Liu HH, Ma ZX, et al. *Toxoplasma gondii* infection in immunocompromised patients: A systematic review and meta-analysis. Front Microbiol. 2017;8:389

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 nonspecific binding in serum, respectively.(Package insert: BioPlex 2200 System, ToRC IgG, Bio-Rad Laboratories, Clinical Diagnostics Group, Hercules, CA)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

Same day/1 to 3 days

Specimen Retention Time

14 days

Performing Laboratory Location

Mayo Clinic Jacksonville Clinical Lab

Fees & 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 account representative. For assistance, contact Customer Service.

Test Classification

This test has been cleared, approved, or is exempt by the US 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

Test ID	Test Order Name	Order LOINC® Value
TOXGP	Toxoplasma Ab, IgG, S	40677-7

Result ID	Test Result Name	Result LOINC® Value
TOXG	Toxoplasma Ab, IgG, S	40677-7
DEXG6	Toxoplasma IgG Value	8039-0