Test Definition: TXM

Toxoplasma gondii Antibody, IgM, Serum

Overview

Useful For

Detecting recent infection with *Toxoplasma gondii*

Highlights

Detection of IgM-class antibodies to *Toxoplasma gondii* may be useful as a screen for recent infection with *T gondii*.

Per the US Food and Drug Administration, IgM-positive results by a screening assay should be confirmed, for example, by a *Toxoplasma* reference laboratory.

A single negative result by this assay does not rule-out toxoplasmosis as the specimen may have been collected too early following infection, prior to development of detectable antibodies.

Method Name

Multiplex Flow Immunoassay (MFI)

NY State Available

No

Specimen

Specimen Type

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: 1 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume

0.8 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	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 6.7% of individuals between the ages of 12 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

Negative

Reference values apply to all ages.

Interpretation

Active toxoplasmosis is suggested by the presence of IgM-class antibodies, but elevated anti-IgM titers may be absent in patients who are immunocompromised. In addition, elevated IgM can persist from an acute infection that may have occurred as long ago as 1 year. A suspected diagnosis of acute toxoplasmosis should be confirmed by detection of *Toxoplasma gondii* DNA by polymerase chain reaction analysis of cerebrospinal fluid or amniotic fluid specimens (PTOX / *Toxoplasma gondii*, Molecular Detection, PCR, Varies).

For confirmation of toxoplasmosis, the US Food and Drug Administration issued a Public Health Advisory (07/25/1997) that recommends sera found to be positive for *Toxoplasma gondii* IgM antibodies should be sent to a *Toxoplasma* reference laboratory.

A single negative result should not be used to rule out toxoplasmosis, and repeat testing is recommended for patients at high risk for infection.

Cautions

Diagnosis of recent infection by *Toxoplasma gondii* can only be established on the basis of a combination of clinical and serological data.

The result of a single serum sample does not constitute sufficient proof for diagnosis of recent infection.

If a serum specimen was collected too soon after infection, IgM antibodies to *Toxoplasma gondii* may be absent. If this is suspected, a second serum specimen should be collected 2 to 3 weeks later, and the test repeated.

Results should be interpreted with caution in patients who are either HIV-positive, receiving immunosuppressive therapy, or have other disorders leading to immunosuppression.

Heterophile antibodies in the patient specimens may interfere with the assay performance.

The performance of the assay has not been established for cord blood testing.

As with any low prevalence analyte, there is the increased possibility that a positive result may actually be false, reducing the assay's positive predictive value. Per the Public Health Advisory (7/25/1997), the US Food and Drug Administration suggests that sera found to be positive for *Toxoplasma gondii* IgM antibodies should be submitted to a *Toxoplasma* reference laboratory.

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, Rivera HN, Price C, Wilkins PP. *Toxoplasma gondii* seroprevalence in the United States 2009-2010 and comparison with the past two decades. Am J Trop Med Hyg. 2014;90(6):1135-1139
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 gondii* IgM assay 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 IgM anti-*Toxoplasma* antibodies in the specimen will bind to the *Toxoplasma* antigen on the beads. After a wash cycle, a fluorescently labeled antihuman-IgM 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-IgM conjugate. Raw data is calculated in relative fluorescence intensity and is converted to an antibody index for interpretation. Antibody index (AI) values of 0.8 and below are considered negative. AI values of 0.9 and 1.0 are equivocal. AI values of 1.1 and above are considered positive. 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 IgM, Bio-Rad Laboratories, Clinical Diagnostics Group, Hercules, CA 8/2017)

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

Test Definition: TXM

Toxoplasma gondii Antibody, IgM, Serum

86778

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
TXM	Toxoplasma Ab, IgM, S	40678-5

Result ID	Test Result Name	Result LOINC® Value
TXM	Toxoplasma Ab, IgM, S	40678-5