Test Definition: TXPM

Toxoplasma gondii Antibody, IgM, Serum

Overview

Useful For

Qualitative detection of IgM antibodies to *Toxoplasma gondii* in serum

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 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

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

Yes

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

Forms

If not ordering electronically, complete, print, and send an Infectious Disease Serology Test Request (T916) with the specimen.

Specimen Minimum Volume

0.7 mL

Reject Due To

Gross hemolysis	Reject

Gross lipemia	Reject
Gross icterus	Reject
Additives (eg, biocides, antioxidants)	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	21 days	
	Ambient	72 hours	
	Frozen	90 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. 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 US indicate approximately 6.7% of individuals aged 12 to 49 years have antibodies to *T gondii*.

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 that are otherwise immunosuppressed. These infections are thought to be caused by reactivation of latent infections and commonly involve the central nervous system.

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. 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. Many 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

Negative:

No IgM to *Toxoplasma gondii* detected. False-negative results may occur in immunocompromised patients or if testing was performed within 1 to 2 weeks of initial exposure and repeat testing may be helpful.

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

Borderline:

Repeat testing on a new sample collected in 2 to 3 weeks is recommended to assess for seroconversion. Further confirmatory testing may be necessary at a Toxoplasma reference laboratory in borderline results persist following repeat testing.

Positive:

Toxoplasma gondii IgM antibodies detected. Specimens with positive results should be confirmed by a laboratory with expertise in the diagnosis of toxoplasmosis.

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 *T gondii* IgM antibodies should be sent to a *Toxoplasma* reference laboratory.

Cautions

Diagnosis of recent or active infection by *Toxoplasma gondii* can only be established based on a combination of clinical and serological data. The result of a single serum sample does not constitute sufficient proof for diagnosis of recent infection. Elevated IgM can persist from an acute infection that may have occurred as long ago as 1 year.

To differentiate between a recently acquired and past infection in patients who are IgM and IgG positive for *Toxoplasma* antibodies, *Toxoplasma* IgG avidity testing should be considered. A high avidity index for IgG antibodies indicates that the infection occurred at least 4 months ago. No clinical interpretation can be deduced from a low avidity result.

A negative *Toxoplasma* IgM result in combination with a positive IgG result does not completely rule out the possibility of an acute infection with *Toxoplasma.*

Elevated anti-IgM titers may be absent in patients who are immunocompromised. Results should be interpreted with caution in patients who are either HIV-positive, receiving immunosuppressive therapy, or have other disorders leading to immunosuppression.

A suspected diagnosis of central nervous system or congenital toxoplasmosis should be confirmed by detection of *T gondii* DNA by polymerase chain reaction analysis of cerebrospinal fluid or amniotic fluid specimens, respectively, (PTOX / *Toxoplasma gondii*, Molecular Detection, PCR, Varies).

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

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.

Specimens should not be collected from patients receiving therapy with high biotin doses (ie. >5 mg/day) until at least 8 hours following the last biotin administration.

As with any low prevalence analyte, there is the increased possibility that a positive result may 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 *T gondii* IgM antibodies should be submitted to a Toxoplasma reference laboratory.

The anti-Toxoplasma IgM results in a given specimen, as determined by assays from different manufacturers, can vary due to differences in assay and reagent methods. Results from assays of other manufacturers cannot be used interchangeably.

Clinical Reference

Matta SK, Rinkenberger N, Dunay IR, Sibley LD. Toxoplasma gondii infection and its implications within the central nervous system. Nat Rev Microbiol. 2021;19(7):467-480. doi:10.1038/s41579-021-00518-7

Performance

Method Description

The electrochemiluminescence immunoassay for the in vitro qualitative determination of IgM antibodies to *Toxoplasma gondii* in human serum is a micro-capture test principle. During the first incubation, 6 mcL of sample are automatically prediluted 1:20 with Diluent Universal. *Toxoplasma gondii* specific recombinant antigen labeled with a ruthenium complexa) is added. Anti-Toxo IgM antibodies present in the sample react with the ruthenium-labeled *Toxoplasma gondii* -specific recombinant antigen. In the second incubation, biotinylated monoclonal h-IgM-specific antibodies and streptavidin-coated microparticles are added. The complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell II M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. Results are determined automatically by the software by comparing the electrochemiluminescence signal obtained from the reaction product of the sample with the signal of the cutoff value previously obtained by calibration.(Package insert: Elecsys Toxo IgM, Roche Diagnostics GmbH, 01/2024)

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 Laboratories - Rochester Superior Drive

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

86778

LOINC® Information

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

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