Test Definition: TOXB

Toxoplasma gondii, Molecular Detection, PCR, Blood

Overview

Useful For
Supporting the diagnosis of active toxoplasmosis, particularly in immunocompromised individuals

Method Name
Polymerase Chain Reaction (PCR)/DNA Probe Hybridization

NY State Available
Yes

Specimen

Specimen Type
Whole Blood EDTA

Specimen Required
Container/Tube: Lavender top (EDTA)
Specimen Volume: 1 mL
Collection Instructions: Send whole blood specimen in original tube. **Do not aliquot**.

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

Specimen Minimum Volume
0.3 mL

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Whole Blood EDTA	Refrigerated (preferred)	7 days	
	Frozen	7 days	

Clinical & Interpretive

Clinical Information

Toxoplasma gondii is an obligate intracellular protozoan parasite that can infect 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 immunosuppressed individuals.

Seroprevalence studies performed in the United States indicate that approximately 9% to 11% of individuals between the ages of 6 and 49 years have antibodies to *T gondii*.(2,3)

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.(4,5)

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.(6,7) 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. Most 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.

Detection of *T gondii* DNA by polymerase chain reaction (PCR) has proven to be a rapid and reliable alternative or supportive method for the diagnosis of toxoplasmosis. When performed on blood, it may detect circulating parasite DNA and thus confirm or support the results of serologic testing. PCR testing on peripheral blood has been used successfully to detect cases of ocular toxoplasmosis (2) as well as invasive disease in allogeneic stem cell recipients.(4,6) However, blood may not be a sensitive specimen for detecting organ specific disease (eg, ocular or cerebral toxoplasmosis). In this case, other specimens (eg, ocular fluid, spinal fluid, fresh tissue) should be considered (order PTOX / *Toxoplasma gondii,* Molecular Detection, PCR, Varies).

Reference Values

Negative

Interpretation

A positive result indicates presence of DNA from *Toxoplasma gondii*.

Negative results indicate absence of detectable DNA, but do not exclude the presence of organism or active or recent

disease.

Cautions

This assay is designed for use in patients with a clinical history and symptoms consistent with toxoplasmosis. This test should not be used to screen healthy patients.

Blood may not be a sensitive specimen for detecting organ specific disease (eg, ocular or cerebral toxoplasmosis). In this case, other specimens (eg, ocular fluid, spinal fluid, fresh tissue) should be considered.

Results should be interpreted with consideration of clinical and laboratory findings. A negative result does not indicate absence of disease. Reliable results depend on adequate specimen collection and the absence of inhibiting substances.

Supportive Data

Accuracy/Diagnostic Sensitivity and Specificity:
Accuracy was determined using a combination of spiking and clinical specimens for each source accepted for testing. Accuracy ranges from 97% to 100%.

Analytical Sensitivity/Limit of Detection:
The limit of detection for this assay is less than 5000 copies/mL

Analytical Specificity:
No polymerase chain reaction signal was obtained from extracts of 20 bacterial, parasitic, and viral isolates from similar organisms and from organisms commonly found in the specimen types tested.

Precision:
Intra-assay precision and interassay precision are 100%.

Reference Range:
The reference range is "Negative" for this assay.

Reportable Range:
This is a qualitative assay and results are reported as "Negative" or "Positive."

Clinical Reference

1. Robert-Gangneux F, Darde ML. Epidemiology of and diagnostic strategies for toxoplasmosis. Clin Microbiol Rev. 2012;25(2):264-296
2. Mattos CC, Meira CS, Ferreira AI, et al. Contribution of laboratory methods in diagnosing clinically suspected ocular toxoplasmosis in Brazilian patients. Diagn Microbiol Infect Dis. 2011;70(3):362-366
3. Jones JL, Kruszon-Moran D, Elder S, et al. Toxoplasma gondii infection in the United States, 2011-2014. Am J Trop Med Hyg. 2018;98(2):551-557. doi:10.4269/ajtmh.17-0677
4. Martino R, Bretagne S, Einsele H, et al. Early detection of Toxoplasma infection by molecular monitoring of Toxoplasma gondii in peripheral blood samples after allogeneic stem cell transplantation. Clin Infect Dis. 2005;40(1):67-78
5. Elsheikha HM, Marra CM, Zhu XQ. Epidemiology, pathophysiology, diagnosis, and management of cerebral toxoplasmosis. Clin Microbiol Rev. 2020;34(1):e00115-19

6. Fricker-Hidalgo H, Bulabois CE, Brenier-Pinchart MP, et al. Diagnosis of toxoplasmosis after allogeneic stem cell transplantation: results of DNA detection and serological techniques. Clin Infect Dis. 2009;48(2):e9-e15
7. Maldonado YA, Read JS. Committee on infectious diseases. Diagnosis, treatment, and prevention of congenital toxoplasmosis in the United States. Pediatrics. 2017;139(2):e20163860. doi:10.1542/peds.2016-3860

Performance

Method Description

DNA from clinical specimens is extracted using the Roche MagNA Pure system. *Toxoplasma gondii* DNA is then detected by using real-time polymerase chain reaction (PCR) to amplify the target sequence. The LightCycler amplifies and monitors fluorescent development of target nucleic acid after each cycle. The continuous monitoring is derived from the fluorescence resonance energy transfer (FRET) principle: a hybridization probe with a donor fluorophore on the 3' end is excited by an external light source and emits light that is absorbed by a second hybridization probe with an acceptor fluorophore at the 5' end. The acceptor fluorophore emits light of a different wavelength that can be measured with a signal that is proportional to the amount of specific PCR product. Melting temperature analysis is used following amplification for sensitive and specific detection of amplified target DNA.(Cockerill FR, Uhl FR: Applications and challenges of real-time PCR for the clinical microbiology laboratory. In: Reischl U, Wittwer C, Cockerill F, eds. Rapid Cycle Real-Time PCR, 2002; Nolte FS. Target amplification techniques. In: Carroll KC, Pfaller MA, Landry ML, et al, eds. Manual of Clinical Microbiology. 12th ed. ASM Press; 2019)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

1 to 4 days

Specimen Retention Time

1 week

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

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.

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Test Classification

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

87798

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
TOXB	Toxoplasma gondii PCR, B	16279-2

Result ID	Test Result Name	Result LOINC® Value
62977	Toxoplasma gondii PCR, B	16279-2