# Test Definition: PTOX

Toxoplasma gondii, Molecular Detection, PCR, Varies

## Overview

### Useful For

Supporting the diagnosis of acute cerebral, ocular, disseminated, or congenital toxoplasmosis

This test **should not be used** to screen healthy patients.

### Testing Algorithm

For information see Meningitis/Encephalitis Panel Algorithm.

### Special Instructions

- Meningitis/Encephalitis Panel Algorithm

### Method Name

Polymerase Chain Reaction (PCR)/DNA Probe Hybridization

### NY State Available

Yes

## Specimen

### Specimen Type

Varies

### Necessary Information

**Specimen source is required.**

### Specimen Required

**Submit only 1 of the following specimens:**

**Specimen Type:** Amniotic fluid
**Container/Tube:** Sterile container
**Specimen Volume:** 0.5 mL
**Collection Instructions: Do not centrifuge.**

**Specimen Type:** Spinal fluid
**Supplies:** Sarstedt Aliquot Tube, 5 mL (T914)
**Container/Tube:**
**Preferred:** 12 x 75-mm screw cap vial
**Acceptable:** Sterile vial

**Specimen Volume:** 0.5 mL
**Collection Instructions: Do not centrifuge.**

**Specimen Type:** Fresh tissue
**Supplies:** M4-RT (T605)
**Container/Tube:**
**Preferred:** Multi-microbe medium (eg, M4-RT)
**Acceptable:** Sterile container with 1 to 2 mL of sterile saline
**Specimen Volume:** Entire collection
**Collection Instructions:** Submit only fresh tissue in a sterile container containing 1 mL to 2 mL of sterile saline or multi-microbe medium (M4-RT, M4, or M5)

**Specimen Type:** Ocular fluid
**Supplies:** Sarstedt Aliquot Tube 5 mL (T914)
**Collection Container:** 12 x 75-mm screw cap vial **(swabs are NOT acceptable)**
**Specimen Volume:** 0.3 mL
**Collection Instructions:**
1. Aliquot collected fluid into screw-cap vial. **Do not submit ocular fluid in syringe.**
2. **Do not centrifuge or dilute the specimen.**

### Forms

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

### Specimen Minimum Volume

Amniotic fluid, Ocular fluid, Spinal fluid: 0.3 mL; Tissue: 2 x 2 mm biopsy

### Reject Due To

| | |
|---|---|
| Heat-inactivated specimen | Reject |
| Paraffin blocks | Reject |
| Swab received | Reject |

### Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---|---|---|---|
| Varies | 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, and these rapidly mature in the soil and become infectious.(1) Toxoplasmosis is acquired by humans through ingestion of food or water contaminated with cat feces containing oocysts or through eating undercooked meat containing viable tissue cysts. 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 and other individuals with profound immune compromise. These infections are usually due to reactivation of latent infections and commonly involve the central nervous system.(4,5)

Transplacental transmission of the parasites resulting in congenital toxoplasmosis most often occurs during primary maternal infection and rarely after reactivation in an immunocompromised pregnant woman. 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.

Serology is the traditional method for diagnosing toxoplasmosis and ascertaining the previous exposure history of the host. However, serology may be unreliable or challenging to interpret in immunocompromised patients and in suspected intrauterine infection. Detection of *T gondii* DNA by polymerase chain reaction has proven to be a rapid and reliable alternative or supportive method for the diagnosis of toxoplasmosis.

### 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 and is not for screening healthy patients. Depending on the population, varying percentages of patients may be found to be positive.

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

Analytical Sensitivity/Limit of Detection:
The limit of detection for this assay is less than 5000 copies/mL in spinal fluid, tissue, ocular fluid, and amniotic fluid.

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
7 days

### 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.

### 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 |
|---|---|---|

| | | |
|---|---|---|
| PTOX | Toxoplasma gondii PCR | 29904-0 |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| SRC74 | Specimen Source | 31208-2 |
| 81795 | Toxoplasma gondii PCR | 29904-0 |