TOXO IgG/IgM Rapid Test Package Insert

Cat: ITO-422 **Specimens:** Whole Blood/Serum/Plasma
Version:03 **Effective Date:** 2024-07

For professional *in vitro* diagnostic use only.

INTENDED USE

The TOXO IgG/IgM Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to *Toxoplasma gondii* in Whole Blood /Serum / Plasma to aid in the diagnosis of TOXO infection

INTRODUCTION

T. gondii is an obligate intracellular protozoan parasite with a worldwide distribution ([1, 2]). Serological data indicate that approximately 30% of the population of most industrialized nations is chronically infected with the organism ([3]). When a seronegative woman becomes infected with T. gondii during pregnancy, the organism is often transmitted across the placenta to the fetus ([1, 4]). The severity of the infection in the fetus varies with the trimester during which the infection was acquired. Infection during pregnancy may lead to spontaneous abortion, stillbirth or overt diseases in the neonate. Approximately 75% of congenitally infected newborns are symptomatic. However, nearly all children born with subclinical toxoplasmosis will develop adverse ocular or neurologic sequelae later in life ([4, 7]). Approximately 80-85% develops chorioretinitis and some may also experience blindness or mental retardation.

A variety of serologic tests for antibodies to T. gondii have been used as an aid in diagnosis of acute infection and to assess previous exposure to the organism. The more widely used tests include the Sabin-Feldman dye test, direct agglutination, indirect hemagglutination, latex agglutination, indirect immunofluorescence, and ELISA ([5, 6]).

PRINCIPLE

The TOXO IgG/IgM Rapid Test is a qualitative membrane strip based immunoassay for the detection of TOXO antibodies (IgG and IgM) in Whole Blood /Serum / Plasma. The test device consists of: 1) a burgundy colored conjugate pad containing TOXO recombinant envelope antigens conjugated with Colloid gold (TOXO conjugates) and rabbit IgG-gold conjugates,2) a nitrocellulose membrane strip containing two test bands (T1 and T2 bands) and a control band (C band). The T1 band is pre-coated with the antibody for the detection of IgM anti-TOXO, T2 band is coated with antibody for the detection of IgG anti-TOXO, and the C band is pre-coated with goat anti rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgG anti-TOXO, if present in the specimen, will bind to the TOXO conjugates. The immunocomplex is then captured by the reagent pre-coated on the T2 band, forming a burgundy colored T2 band, indicating a TOXO IgG positive test result and suggesting a recent or repeat infection. IgM anti-TOXO if present in the specimen will bind to the TOXO conjugates. The immunocomplex is then captured by the reagent coated on the T1 band, forming a burgundy colored T1 band, indicating a TOXO IgM positive test result and suggesting a fresh infection. Absence of any T bands (T1 and T2) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the T bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

KIT COMPONENTS

Individually packed test devices	Each device contains colored conjugates and reactive reagents pre-spreaded at the corresponding regions
Droppers	For adding specimens use
Buffer	Phosphate buffered saline and preservative
Package insert	For operation instruction

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Follow standard biosafety guidelines for handling and disposal of potential infective material.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The TOXO IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect Fingerstick Whole Blood specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingersitck Whole Blood specimen to the test device by using a capillary tube or hanging drop.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test devices
- Buffer
- Droppers
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Centrifuge
- Lancets (for fingerstick whole blood only)
- Timer
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or controls to reach room temperature 15-30℃ (59-86°F) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface.
3. Hold the dropper vertically and transfer 1 drop of specimen (approximately 10µl) to the specimen well(S) of the test device, then add 2-3 drops of buffer (approximately 80µl-120µl) and start the timer. See illustration below.
4. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.

Notes:

Applying sufficient amount of specimen is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of buffer to the specimen well.

INTERPRETATION OF RESULTS

POSITIVE RESULT:



IgM Positive:* The colored line in the control line region (C) appears and a colored line appears in test line region 1 (T1). The result is positive for Toxo virus specific-IgM antibodies and is indicative of primary Toxo infection.



IgG Positive:* The colored line in the control line region (C) appears and a colored line appears in test line region 2 (T2). The result is positive for Toxo virus specific-IgG and is probably indicative of secondary Toxo infection.



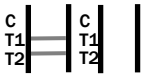
IgG and IgM Positive:* The colored line in the control line region (C) appears and two colored lines should appear in test line regions 1 and 2 (T1 and T2). The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary Toxo infection.

NEGATIVE RESULT:



The colored line in the control line region (C) appears. No line appears in test line regions 1 or 2 (T1 or T2).

INVALID RESULT:



Control line (C) falls to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level cannot be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The TOXO IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of TOXO antibodies in Whole Blood /Serum / Plasma specimens only. Neither the quantitative value nor the rate of increase in TOXO antibodies can be determined by this qualitative test.
2. The TOXO IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) will only indicate the presence of TOXO antibodies in the specimen and should not be used as the sole criteria for the diagnosis of TOXO infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of TOXO infection.

EXPECTIED VALUES

The TOXO IgG/IgM Test has been compared with a reference ELISA, demonstrating an overall TOXO IgM Rapid Test accuracy of 98.3%,demonstrating an overall TOXO IgG Rapid Test accuracy of 99.2%.

PERFORMANCE CHARACTERISTICS

1. <u>Clinical Performance For IgM Test</u>

41 positive samples from patients and 200 negative samples collected from health people were tested by the TOXO IgG/IgM Rapid Test.

	TOXO IgG/IgM Rapid Test		
ELISA	**Positive**	**Negative**	**Total**
Positive	37	4	41
Negative	0	200	200
Total	37	204	241

Relative Sensitivity: 90.2% (76.87~97.28%);
Relative Specificity: >99.9% (98.17~100.0%);

Overall agreement: 98.3% (95.81~99.55%)

2. Clinical Performance For IgG Test

55 positive samples from patients and 200 negative samples collected from health people were tested by the TOXO IgG/IgM Rapid Test.

	TOXO IgG/IgM Rapid Test		
ELISA	**Positive**	**Negative**	**Total**
Positive	53	2	55
Negative	0	200	200
Total	53	202	255

Relative Sensitivity: 96.4% (87.47~99.56%);
Relative Specificity: >99.9% (98.17~100%);
Overall agreement: 99.2% (97.2~99.9%) *95%CI

PRECISION

Intra-Assay

Within-run precision has been determined by using replicates of 10 tests for each of three lots using TOXO IgG/IgM specimen levels at negative, low positive sample and medium positive sample. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same five specimens: negative, low positive sample and medium positive sample of TOXO IgG/IgM. Three different lots of the TOXO IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

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