Sirin Diagnostics TOXO IgG/IgM Rapid Test Device (Whole Blood/Plasma/Serum)

INTENDED USE

The One Step TOXO IgG/IgM 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. Toxoplasma gondii is an obligate intracellular protozoan parasite with a worldwide distribution. Serological data indicates that approximately 30% of the population of most industrialized nations is chronically infected with the organism. A variety of serologic tests for antibodies to Toxoplasma gondii have been used as an aid in diagnosis of acute infection and to assess previous exposure to the organism. These tests are the Sabin-Feldman dye test, direct agglutination, indirect hemagglutination, latex agglutination, indirect immunofluorescence, and ELISA. Recently, lateral flow chromatographic immunoassay, such as The Toxo IgM/IgG Rapid Test (Whole Blood/Serum/Plasma) was introduced into the clinic for the serodiagnosis of Toxoplasma gondii infection. One step TOXO IgG/IgM Test is a simple, visual qualitative test that detects TOXO antibodies in human Whole Blood/serum/plasma. The test is based on immunochromatography and can give a result within 15 minutes.

PRINCIPLE

The One Step TOXO IgG/IgM 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 a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions
Disposable pipettes	For adding specimens use
Buffer	Phosphate buffered saline and preservative
Package insert	For operation instruction

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. Do not freeze. Do not use beyond the expiration date.

MATERIALS

Materials Provided

- Test devices
- Buffer
- Droppers
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Centrifuge
- Heparinized capillary tubes
- Timer

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.

SPECIMEN COLLECTION AND PREPARATION

1. The One Step Toxo IgG/IgM Test can be performed used on Whole Blood /Serum / Plasma.
2. To collect whole blood, serum or plasma specimens following regular clinical laboratory procedures.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room

temperature for prolonged periods. For long term storage, specimens should be kept below -20℃. Whole blood should be stored at 2-8℃ if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.

4. 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.

TEST PROCEDURE

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 drops of buffer (approximately 80μl) 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

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.

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

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.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance For IgM Test

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: 90.24% (81.16~99.33%); Relative Specificity: 100% (99.85~100%); Overall agreement: 98.34% (96.73~99.95%)

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: 96.36% (91.42~100%); Relative Specificity: 100% (99.85~100%); Overall agreement: 99.22% (98.13~100%)
*95%CI

LIMITATIONS

1. 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 One Step TOXO IgG/IgM Test 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.

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