Spectrum For Diagnostic Industries

Toxo IgM/IgG Rapid Test Cassette (Serum/Plasma/Whole blood)

REF: 518 30 030 30 test

INTENDED USE

The Toxo IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of IgG and IgM anti-Toxoplasma gondii (T. gondii) in human serum ,plasma or whole blood. This kit is intended to be used as a screening test and as an aid in the diagnosis of infection with T. gondii. Any reactive specimen with the Toxo IgG/IgM Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY

T. 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 serological 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. 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 IgG/IgM Rapid Test has been introduced to the clinic for the instant detection of T. gondii infection.

TEST PRINCIPLE

The Toxo IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant T. gondii antigens conjugated with colloidal gold (T. gondii conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (IgM and IgG bands) and a control band (C band). The IgM band is pre-coated with monoclonal anti-human IgM for detection of IgM anti-T. gondii antibody, IgG band is pre-coated with reagents for detection of IgG anti-T.gondii antibody, 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. IgM anti-T. gondii if present in the specimen will bind to the T. gondii conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody forming a burgundy colored IgM line, indicating a T. gondii IgM positive or reactive test result.

IgG anti-T. gondii if present in the specimen will bind to the T. gondii conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane forming a burgundy colored IgG line, indicating a T. gondii IgG positive or reactive test result.

Absence of any Test bands (IgM and IgG) suggests a negative or non-reactive result. The test contains an internal control (C band) which should exhibit a burgundy colored line of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of color development on any of the Test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

The test contains mouse anti-human IgM, mouse anti-human IgG and Toxoplasma T.gondii antigen. A goat antibody is employed in the control line system.

1. Test Cassettes.
2. Buffer
3. Droppers
4. Package inserts.

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Centrifuge

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolized blood for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the negative and positive control in the same manner as patient specimens.
11. The test results should be read within 15 minutes after a specimen is applied to the sample well or sample pad of the device. Reading the results after 15 minutes may give erroneous results.
12. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTION

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. Do not freeze the kit. Do not expose the kit over 30°C. The positive and negative controls should be kept at 2°C-8°C or the temperature indicated. If stored at 2°C-8°C, ensure that the test device is brought to 15°C-30°C before opening. The test device is stable through the expiration date printed on the sealed pouch.

SPECIMEN COLLECTION AND PREPARATION

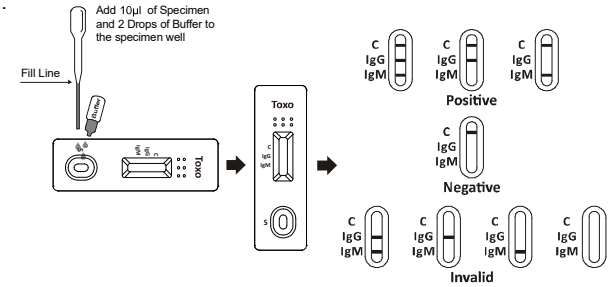
- The Toxo IgG/IgM Rapid Test Cassette (Whole Blood) can be performed using whole blood.
- Both Finger stick Whole Blood and Venipuncture Whole Blood can be used.
- **To collect Finger stick Whole Blood specimens:**
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger
- 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.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. Whole blood collected by finger stick 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 for more than three times.

TEST PROCEDURE

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

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.

2. Place the cassette on a clean and level surface. Hold the dropper vertically, draw the specimen (serum/plasma/whole blood) up to the Fill Line as shown in illustration below (approximately 10 µl). Transfer the specimen to the specimen well, then add 2 drops of buffer (approximately 80 µl) and start the timer. See the illustration below
3. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two or three lines appear. One colored line should always appear in the control line region (C) and another one or two apparent colored line(s) should be in the test line region(s) (IgM and/or IgG).IgM

Positive: Along with line in Control region (C), a line appears in IgM region. It indicates a positive Test result for antibodies to Toxoplasma

IgG Positive: Along with line in Control region (C), a line appears in IgG region. It indicates a positive Test result for antibodies to Toxoplasma

***NOTE:** The intensity of the color in the test line regions (IgM and IgG) may vary depending on the concentration of Toxoplasma antibodies present in the specimen. Therefore, any shade of color in the test line region (IgM and/or IgG) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line regions (IgM and IgG).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

1. Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding the specimen and the sample diluent. If the C line does not develop, review the whole procedure and repeat the test with a new device.

2. External Control: Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:

a. New operator uses the kit, prior to performing the testing of specimens.
b. A new lot of test kits is used.
c. A new shipment of kits is used.
d. The temperature used during storage of the kits fall outside of 2-30°C.
e. The temperature of the test area falls outside of 15-30°C.
f. To verify a higher than expected frequency of positive or negative results.
g. To investigate the cause of repeated invalid results.

LIMITATIONS OF TEST

1. 1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to T.gondii in whole blood, serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Toxo IgG/IgM Rapid Test Cassette is limited to the qualitative detection of the antibodies to *T.gondii* in human whole blood, serum or plasma. The intensity of the test band does not linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable T. gondii antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with T. gondii.
4. A negative result can occur if the quantity of the T. gondii antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

Expected Values

The Toxo IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial Toxo IgG/IgM ELISA test. The correlation between these two systems is over 97%

PERFORMANCE CHARACTERISTICS

1. Clinical Performance For IgM Test

A total of 302 samples from susceptible subjects were tested by Toxo IgG/IgM Rapid Test and by a commercial IgM EIA kit. Comparison of the results for all subjects is shown in the following table.

Toxo IgG/IgM Rapid Test			
IgM EIA	Positive	Negative	Total
Positive	2	0	2
Negative	2	298	300
Total	4	298	302

Relative Sensitivity: 100%
Relative Specificity: 99.3%
Overall Agreement: 99.3%

2. Clinical Performance For IgG Test

A total of 324 samples from susceptible subjects were tested by the Toxo IgG/IgM Rapid Test and by a commercial IgG EIA kit. Comparison of the results for all subjects is shown in the following table.

Toxo IgG/IgM Rapid Test			
IgG EIA	Positive	Negative	Total
Positive	22	2	24
Negative	3	297	300
Total	25	299	324

Relative Sensitivity: 91.6%
Relative Specificity: 99.0%
Overall Agreement: 98.5%

REFERENCES

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