Toxo IgG/IgM cassette

RUO

CONTENTS	
REF	4216240 Toxo IgG/IgM 40 Tests
For professional use only	

Toxo IgG/IgM

A rapid one step test for the simultaneous detection and differentiation of IgG and IgM anti-Toxoplasma gondii (T. gondii) in human serum, plasma or whole blood.

ONE STEP

PRINCIPLE

The LINEAR Toxo IgG/IgM cassette is intended to be used as a screening test of infection with T. gondii. Any reactive specimen with the Toxo IgG/IgM must be confirmed with alternative testing method(s) and clinical findings.
Toxo IgG/IgM cassette 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 (M and G bands) and a control band (C band). The M band is pre-coated with monoclonal anti-human IgM for detection of IgM anti-*T. gondii* antibody, G band is pre-coated with reagents for detection of IgG anti-*T.gondii* antibody, and the C band is pre-coated with a control line antibody.
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 M 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 G line, indicating a *T. gondii* IgG positive or reactive test result.
Absence of any T lines (M and G) 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 the control line antibodies gold conjugate regardless of color development on any of the T lines. Otherwise, the test result is invalid and the specimen must be retested with another device.

PACKAGING CONTENTS

REF 4216240 40 Toxo IgG/IgM Combo Rapid Test
40 Plastic droppers
1 Sample diluent (5 mL)

STORAGE AND STABILITY

Store at 2-30ºC. 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 the kit or expose the kit over 30°C**. Do not uses beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma

1. Collect blood specimen into collection tube (EDTA, citrate or heparin, respectively in Vacutainer® by veinpuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.

Serum

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately.
Store specimens at 2°C-8°C for up to 5 days. The specimens should be frozen at -20°C for longer storage.
Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Blood

Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use hemolized blood for testing.
Whole blood specimens should be stored in refrigeration (2°C - 8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

MATERIAL REQUIRED

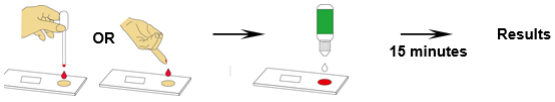
- Timer

PROCEDURE

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

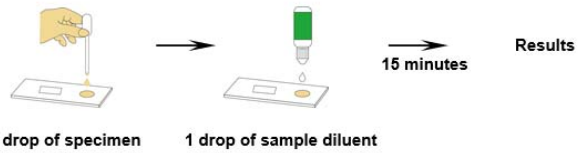
1. Remove the test device from the sealed pouch and use it as soon as possible. Place the test device on a clean, flat surface.
2. Be sure to label the device with specimen's ID number.
3. **For whole blood test**

– Apply 1 drop of whole blood (about 40-50 µL) into the sample well.
– Then add 1 drop (about 35-50 µL) of Sample Diluent immediately.



4. **For serum or plasma test**

– Fill the plastic dropper with the specimen.
– Holding the dropper vertically, dispense 1 drop (about 30-45 µL) of specimen into the sample well making sure that there are no air bubbles.
– Then add 1 drop (about 35-50 µL) of Sample Diluent immediately.

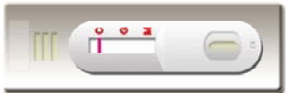


5. Set up timer.
6. Result should be read in 15 minutes. Positive results may be visible in as soon as 1 minute.

Do not read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE RESULT:** If only the C line is present, the absence of any burgundy color in both the test lines (M and G) indicates that no anti-*T. gondii* antibodies are detected in the specimen. The result is negative or non-reactive



LINEAR CHEMICALS S.L. Joaquim Costa 18 2ª planta. 08390 Montgat, Barcelona, SPAIN
Telf. (+34) 934 694 990 Fax. (+34) 934 693 435. website www.linear.es

2. POSITIVE RESULT:

2.1. In addition to the presence of the C line, if only the M line is developed, the test indicates the presence of IgM anti-*T. gondii* in the specimen. The result is positive or reactive.

2.2. In addition to the presence of the C line, if only the G line is developed, the test indicates the presence of IgG anti-T. gondii in the specimen. The result is positive or reactive.

2.3. In addition to the presence of the C line, if both the M and the G lines are developed, the test indicates the presence of both IgG and IgM anti-T. gondii in the specimen. The result is also positive or reactive.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. INVALID: If no C line is developed, the assay is invalid regardless of any burgundy color in the test bands as indicated below. Repeat the assay with a new device.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

CLINICAL SIGNIFICANCE

T. gondii is an obligate intracellular protozoan parasite with a worldwide distribution[1,2]. Serological data indicates that approximately 30% of the population of most industrialized nations is chronically infected with the organism[3].

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 ELISA4-7. 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.

ANALYTICAL PERFORMANCE

1. Clinical Performance For IgM Test

A total of 202 samples from susceptible subjects were tested by the Linear Toxo IgG/IgM and by a commercial IgM EIA kit. Comparison of the results for all subjects is shown in the following table.

	Toxo IgG/IgM cassette		
IgM EIA	**Positive**	**Negative**	**Total**
Positive	2	0	2
Negative	2	198	200
Total	4	198	202

Relative Sensitivity: 100% , Relative Specificity: 99.0%,
Overall Agreement: 99.0%

2. Clinical Performance For IgG Test

A total of 224 samples from susceptible subjects were tested by the Linear Toxo IgG/IgM and by a commercial IgG EIA kit. Comparison of the results is shown in the following table.

	Toxo IgG/IgM Rapid Test		
IgG EIA	**Positive**	**Negative**	**Total**
Positive	22	2	24
Negative	3	197	200
Total	25	199	224

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

LIMITATIONS OF TEST

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to T. gondii in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Linear Toxo IgG/IgM is limited to the qualitative detection of antibodies to T. gondii in human serum or plasma. The intensity of the test line does not have a linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti-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 anti-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 titers of heterophile antibodies or rheumatoid factor may affect expected results.
6. If the symptoms persist when the result from Linear Toxo IgG/IgM Rapid Test is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PRECAUTIONS

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 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. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.

REFERENCES

1. Krick JA and Remington JS: Toxoplasmosis in the adult: An overview. New Eng. J. Med. 1978, 298:550-553
2. Anderson SE and Remington JS: The diagnosis of Toxoplasmosis. So. Med. J. 1975, 68:1433-1443
3. Wilson CB, Remington JS, Stagno S, and Reynolds DW: Development of adverse sequelae in children born with subclinical congenital Toxoplasma infection. Pediatrics 1980, 66:767-774
4. Berrebi A; Kobuch WE; Bessieres MH; Bloom MC; Rolland M; Sarramon MF; Roques C;: Termination of pregnancy for maternal toxoplasmosis. Lancet 1994, 344: 36-9
5. Fraser KB, Shirodaira PV, and Stanford CF: Fluorescent staining and human IgM Br. Med. J. 1971, 3:707
6. Pyndiah N, Krech U, Price P and Wilhelm J: Simplified chromatographic separation of immunoglobulin M from G and its application to Toxoplasma indirect immunofluorescence. J. Clin. Micro.1979, 9:170-174
7. Montoya JG, Rosso F. Diagnosis and management of toxoplasmosis. Clin Perinatol. 2005, 32(3):705-26

O4216240 ing -3/1604

LINEAR CHEMICALS S.L. Joaquim Costa 18 2ª planta. 08390 Montgat, Barcelona, SPAIN
Telf. (+34) 934 694 990 Fax. (+34) 934 693 435. website www.linear.es