ACCUCARE™

TOXOPLASMA IgG/IgM RAPID TEST

(Serum, Plasma or Whole blood)

For detection of Toxoplasma antibodies in Human Serum, Plasma or Whole Blood.
Only for *In Vitro* diagnostic use.

ORDER INFORMATION

REF	Cont.
TOXC 10	10 Test
TOXC 25	25 Test

CLINICAL SIGNIFICANCE

Toxoplasmosis is caused by infection with toxoplasma gondii, an eukaryotic pathogen-belongs to the group of sporozoes. The obligatoryintracellular living parasites is spread worldwide. Typical for sporocytes is the "flip-flop" between sexual (which only takes place in cats, the final host) and asexual reproduction. The infection is often highest in areas of the world that have hot, humid climates and lower altitudes. The mean source of infection is direct contact with cat faces or from eating undercooked meats. Toxoplasmosis is not passed from person to person, except in instances of mother to child (congenital) transmission and blood transfusion or organ transplantation. Toxoplasmosis generally presents with mild symptoms in immunocompetent individuals, but women newly infected with toxoplasmosis during pregnancy and anyone with a compromised immune system should be aware that toxoplasmosis can have severe consequences for them. Acute toxoplasmosis in pregnant women can result in miscarriage, poor growth, early delivery or stillbirth. IgG and IgM antibodies to Toxoplasma can be detected with 2-3 weeks after exposure. Positive, but the antibody level drops overtime.

PRINCIPLE

Toxoplasma IgG/IgM test device has 3 precoated lines on the surface of the membrane. The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. Anti-IgG and Anti-IgM antibodies coated on the test line 1 & 2 respectively. If sample contains antibody, reacts with gold conjugated nanoparticle and flow on the membrane. It will be captured by membrane coated antibodies depend on IgG or IgM type by developing purple color on test line.

KIT COMPONENTS

Test Cassette Device, sample Diluent buffer, Sample dropper and Instructions for Use

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

1. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
2. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
3. 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.
4. If specimens are to be shipped, they should be packed in compliance with federal regulations for the transportation of etiologic agents.

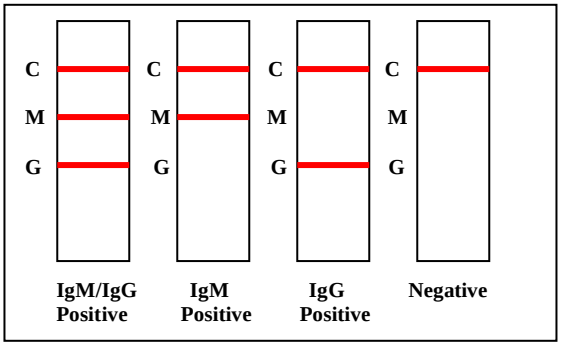
DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before 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. With a micropipette (not provided) or a disposable dropper, add about 10 µL of serum/ plasma or whole blood specimen into the sample well marked "S**".**
3. Add 3 drop of diluents buffer to the sample well.
4. As the test begins to work, you will see red color move across the result window in the center of the test device.
5. Interpret test results at 15-20 minutes. Caution: Do not read test results after 20 minutes. Reading too late can give false results.

Note: Do not interpret the result after 20 minutes.
When using finger prick or EDTA whole blood the appearance of C &T line can take up to 10 minutes to appear and wait till 20 minutes to interpret the results in this case.

INTERPRETATION OF RESULTS



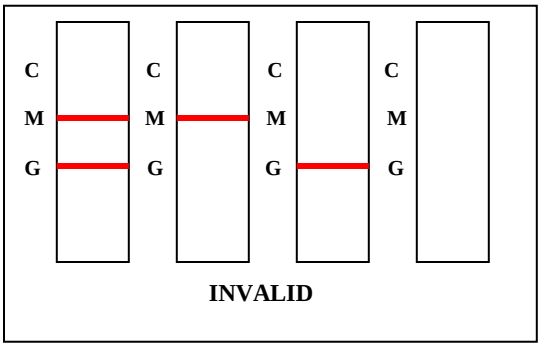
LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 ▪ Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com

1) IgG and IgM Positive
The control line (C), IgG (G) and IgM (M) lines are all visible on the test device. This is positive for both IgG and IgM antibodies. This is indicative of late primary or early secondary infection of Toxoplasma virus.

2) IgM Positive
The control line (C) and the IgM line (M) are visible on the test device. This is positive for IgM antibodies to Toxoplasma. This is an indication of a primary infection of Toxoplasma virus.

3) IgG Positive
The control line (C) and IgG line (G) are visible on the test device. This is positive for IgG antibodies to Toxoplasma virus. This is indicative of secondary or previous infection of Toxoplasma virus.

4) Negative
The control line is the only visible line on the test device. No IgG or IgM antibodies were detected. Retest in 3-5 days if Toxoplasma virus is suspected.



5) Invalid
The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

Limitations of the Test

1) The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to Toxoplasma virus in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2) The Toxoplasma IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to Toxoplasma virus in human serum or plasma. The intensity of the test band does not correlate with antibody titer of the specimen.
3) A negative result for an individual subject indicates absence of detectable Toxoplasma virus antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with Toxoplasma virus.

Internal Quality Control

The “Control Line” is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required

BIBLIOGRAPHY

1. Diagnosis of congenital toxoplasmosis: prenatal and neonatal evaluation of methods used in Toulouse university Hospital and incidence of congenital toxoplasmosis. Bessieres MH, Berrebi A, Cassaing S, Fillaux J Cambus JP, Berry A.
2. Dynamic Imaging of CD8(+) T cells and dentritic cells during infection with toxoplasma gondii, John B, Harris TH, Tait ED, Wilson EH, Gregg B.
3. Congenital toxoplasmosis: evaluation of serological methods for the detection of anti-Toxoplasma gondii IgM and IgA antibodies. Rodrigues IM, Castro AM, Gomes MB, Amaral WN. 2009 May: 104(3): 434-40.

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 ▪ Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com