ACCUCARE®

ONE STEP TOXOPLASMA IgG/IgM RAPID TEST

(Whole Blood/Serum/Plasma)

One step rapid Card Test for qualitative detection of IgG/IgM antibodies to Toxoplasma in human Whole Blood/Serum/Plasma

Store at 2-30°C. DO NOT FREEZE.
For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
10 Tests	TOXC 10
25 Tests	TOXC 25

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

ACCUCARE® ONE STEP TOXOPLASMA IgG/IgM RAPID TEST has 3 pre-coated 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 G & M 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.

CONTENTS

Test Device
Assay Buffer
Instruction for Use (IFU)
Disposable 10 µl Dropper
Desiccant

STORAGE & STABILITY

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

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

LIMITATIONS

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 ACCUCARE® ONE STEP 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.

SPECIMEN COLLECTION & PREPARATION

1. The ACCUCARE® ONE STEP TOXOPLASMA IgG/IgM RAPID TEST can be performed using either Whole Blood or serum or plasma.
2. If you want to use Serum or Plasma than separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. 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.
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.
5. If specimens are to be shipped, it should be packed in compliance with federal regulations for transportation of etiologic agents.

PROCEDURE

1. Allow test device, Assay buffer and specimen equilibrate to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and flat surface. Carefully dispense 1 drop (10 µl) of Whole Blood/Serum/Plasma into the sample well (S) using the sample dropper provided.
4. Add 3 drops (appx. 75 µl) of buffer from the dropper bottle to the sample well (S) of the device and start the timer. Avoid trapping air bubbles in the sample well (S).
5. Read the results at 20 minutes. Do not interpret the results after 20 minutes.

NOTE: 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.

ISO 13485:2016

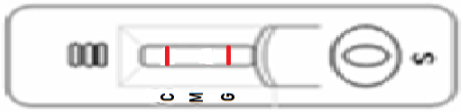
CE

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

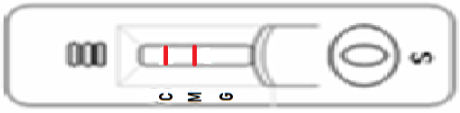
INTERPRETATION OF RESULTS

1. POSITIVE

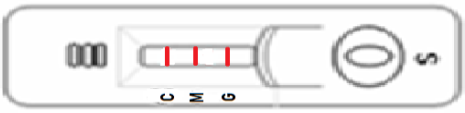
- If two color lines appear, one at control region 'C' and other at test region 'G', it indicates the secondary or previous infection of Toxoplasma virus.



- If two color lines appear, one at control region 'C' and other at test region 'M', it indicates the primary infection of Toxoplasma virus.

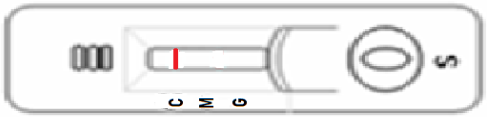


- If three color lines appear, one at control line 'C', one at test region 'G' and one at test line 'M', it indicates the late primary or early secondary infection of Toxoplasma virus.



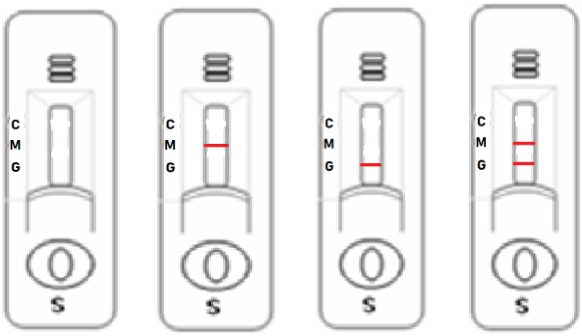
2. NEGATIVE

If only one color band appear at control line 'C' as the specimen is Negative for Toxoplasma.



3. INVALID

If no color band appear, at control line 'C' within the stipulated time then result is invalid. Repeat the test using a fresh Test Device.



PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP TOXOPLASMA IgG/IgM RAPID TEST has been evaluated with positive and negative samples and data are as below:

Specimen	Positive	Negative	Sensitivity
IgG Positive	19	1	95.0 %
IgM Positive	19	1	95.0 %

Specimen	Positive	Negative	Sensitivity
Negative	10	90	90.00%

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.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
IVD	For *in vitro* Diagnostic use only		Keep Dry
Σ	Tests per Kit		Do Not Use if Damaged

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Website : www.labcarediagnostics.com