Toxo IgG / IgM Rapid Test

TEST KIT DESCRIPTION

The Biopanda Toxo IgG/IgM Rapid Test detects and differentiates between anti-T. *gondii* IgG and anti-T. *gondii* IgM antibodies in whole blood, serum, or plasma samples. This test applies lateral flow immuno-chromatography and is a tool to assist in the diagnosis of infection with T. *gondii*.

BACKGROUND

T. gondii is an obligate intracellular protozoan parasite with 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 serologic 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[4-7]. Recently, lateral flow chromatographic immunoassay, such as The Biopanda Toxo IgG/IgM Rapid Test was introduced into the market for the serodiagnosis of *T. gondii* infection.

PRINCIPLE

The Biopanda Toxo IgG/IgM Rapid Test is a qualitative, lateral flow immunoassay for the detection of IgG and IgM antibodies to Toxoplasma in whole blood, serum or plasma specimens. In this test, mouse anti-human IgG and mouse anti-human IgM are coated in the test line regions of the test. During testing, the specimen reacts with *T.gondii* antigen coated particles in the test strip. The mixture then migrates laterally on the membrane by capillary action and reacts with the mouse anti-human IgG and mouse anti-human IgM on the membrane in the test line region respectively. The presence of a coloured line in the test line region indicates a positive result for *T.gondii* infection, while its absence indicates a negative result for that infection.

To serve as a procedural control, a coloured line will always appear in the respective control line regions of all the two strips indicating that proper volume of specimen has been added and membrane wicking has occurred.

KIT CONTENTS

- 10 x foil wrapped cassettes and desiccant.
- 10 x pipettes
- 1 x buffer tube
- 1 x product insert

STORAGE AND STABILITY

Store the kit between 2-30°C and ensure the kits are not frozen or stored in direct sunlight. The test is valid until the expiration date printed on the foil wrapping.

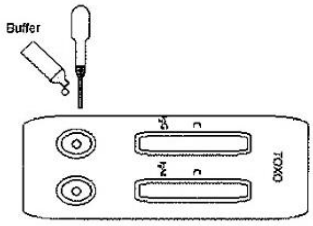
PRECAUTIONS

Follow these instructions for the best results:

- The Biopanda Toxo IgG/IgM Rapid Test can be performed using whole blood.
- Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
- To collect **Fingerstick 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 fingerstick 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.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

TEST PROCEDURE

1. Ensure specimen and test kits are brought to room temperature before testing.
2. Remove the test cassette from the sealed pouch and use it within one hour. Best results will be obtained if the assay is performed as soon as possible.
3. Place the test cassette on a clean and level surface. Hold the dropper vertically; draw the specimen about **1 cm above** the upper end of the nozzle as shown in illustration below. Transfer 1 full drop (**approx. 20 µl**) of specimen to each sample well, then add 2 drops of buffer (approximately 80 µl) to each sample well and start the timer. See the illustration below.
4. Wait for the coloured line(s) to appear. The result should be read at 15 minutes. Do not interpret results after 20 minutes.



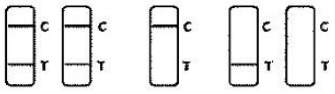
TEST RESULTS

POSITIVE:* Two coloured lines appear. One coloured line should always appear in the control line region (C) and another line should be in the test line region.

***NOTE:** The intensity of the colour in the test line regions may vary depending on the concentration of *T. gondii* IgG or IgM antibodies present in the specimen. Therefore, any shade of colour in the test line region should be considered positive.

NEGATIVE: One coloured line appears in the control line region (C). No line appears in the test line regions.

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.



HOW TO INTERPRET RESULTS

IgM	IgG	Possible Interpretation
Negative	Positive	Past infection
Negative	Negative	No infection or very early infection; no previous exposure
Positive	Negative	Early infection; in a newborn, indicates congenital infection
Positive	Positive	Current infection; chronic infection; could indicate re-activation; IgM may be positive for several months after the infection resolves

QUALITY CONTROL

Internal procedural controls are included in the test. A coloured line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

swiss pharm

Biopanda Reagents

CE

LIMITATIONS OF THE TEST PROCEDURE

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 Biopanda TOXO IgG/IgM Rapid Test 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 give linear correlation with the antibody titre 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 titre 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 Biopanda TOXO IgG/IgM Rapid Test has been compared with a leading commercial TOXO IgG/IgM ELISA test. The correlation between these two systems is over 98.2%

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

A clinical evaluation was conducted comparing the results obtained using the Biopanda TOXO IgG/IgM Rapid Test to TOXO IgG/IgM ELISA Testing. The study included 450 IgG specimens and 450 IgM specimens. For the IgG specimen both assays identified 394 negative and 48 positive results, about the IgM specimen both assays identified 395 negative and 47 positive results.

IgG Reults

Method		ELISA		Total Results
Biopanda Toxo IgG/IgM Rapid Test for IgG	Results	Positive	Negative	
	Positive	48	6	51
	Negative	2	394	396
Total Results		50	400	450

Relative Sensitivity: 96.0% (95%CI*: 86.3%-99.5%) *Confidence Interval
Relative Specificity: 98.5% (95%CI*: 96.8%-99.4%)
Accuracy: 98.2% (95%CI*: 96.5%-99.2%)

IgM Results

Method		ELISA		Total Results
Biopanda Toxo IgG/IgM Rapid Test for IgM	Results	Positive	Negative	
	Positive	47	5	52
	Negative	3	395	398
Total Results		50	400	450

Relative Sensitivity: 94.0% (95%CI*: 83.5%-98.7%) *Confidence Interval
Relative Specificity: 98.8% (95%CI*: 97.1%-99.6%)
Accuracy: 98.2% (95%CI*: 96.5%-99.2%)

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens: a negative, a low positive, and a high positive. The negative, low positive, and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same three specimens: a negative, a low positive, and a high positive. Three different lots of the Biopanda TOXO IgG/IgM Rapid Test have been tested over a 10 day period using negative, low positive, and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Biopanda TOXO IgG/IgM Rapid Test has been tested for HBsAg, HBsAb, HbeAg, HBeAb, HBcAb, HCV,HIV, Syphilis, *H. Pylori*, HSV 1/2, CMV and Rubella positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to TOXO negative and positive specimens.

Acetaminophen: 20 mg/dL Caffeine: 20 mg/dL EDTA: 20 mg/dl
Acetylsalicylic Acid: 20 mg/dL Gentisic Acid: 20 mg/dL Ethanol: 10%
Ascorbic Acid: 2g/dL Phenylpropanolamine: 20mg/dl Glucose: 20mg/dl
Bilirubin: 1g/dL Salicylic Acid: 20mg/dl, Phenothiazine: 20mg/dl
None of the substances at the concentration tested interfered in the assay.

BIBLIOGRAPHY

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; Fournie A: 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.

Thank you for purchasing Biopanda's Toxo IgG/IgM Rapid Test kit. Please read this manual carefully before operating to ensure proper use.

Biopanda Reagents Ltd.

Unit 14 Carrowreagh Business Park
Carrowreagh Road
Belfast, BT16 1QQ
United Kingdom
Tel: +44 (0) 28 95438774
Fax: + 44 (0) 28 90486696
E-mail: info@biopanda.co.uk
Website: www.biopanda.co.uk

(Revised 30/05/17)