Toxo IgG/IgM Device (2–30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADTOX3	20 Tests

Intended Use:
The Toxo IgG/IgM Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to *Toxoplasma gondii* (Toxo) in serum or plasma.

Summary:
T. gondii is an obligate intracellular protozoan parasite with a worldwide distribution. Serological data indicates that approximately 30% of the population of most developed nations is chronically infected with the organism. Previous serologic antibody tests to *T gondii* for acute and chronic infection include the Sabin-Feldman dye test, direct agglutination, indirect haemagglutination, indirect immunofluorescence and ELISA. The Toxo IgG/IgM Rapid Test Device is designed as a screening test and for serodiagnosis of *T gondii* infection in the clinic with minimal equipment required.

Test Principle:
In the test anti-human IgG antibody and anti-human IgM antibody are immobilized on the membrane in the two test regions. During the test, serum or plasma added to the sample well reacts with T gondii antigen coated particles on the test strip. The reaction mixture migrates up the membrane by capillary action and reacts with the anti-human-IgG and -IgM antibodies in respective test regions. The development of a coloured line in one or both of the test regions indicates a positive result, no coloured line in either test region indicates a negative result. To serve as a procedural control, a coloured line should always appear in the control line region indicating that proper volume of sample has been added and membrane wicking has occurred.

Reagents:
The test device contains mouse anti-human IgG, mouse anti-human IgM and recombinant *T gondii* antigen. A goat anti-mouse IgG is coated in the control line region.

Materials Provided
Test devices in individually sealed pouches
Disposable pipettes
Buffer
Instructions for Use

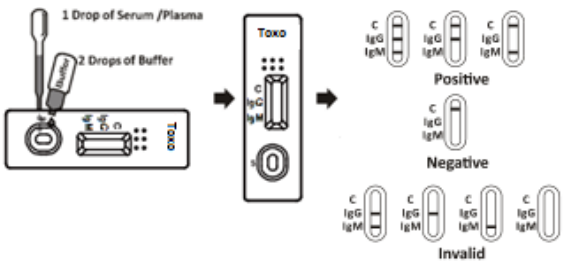
Materials not provided: Micropipette, timer, specimen collection container, centrifuge

Precautions:
1. For professional in vitro diagnostic use only. Do not use after the expiry date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.

Reagent Preparation and Stability:
Store as packaged at room temperature or refrigerated (2-30°C). The test is stable till the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiry date.

Specimen Collection and Storage:
1. The Toxo IgG/IgM Rapid Test Device can be performed using serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear, non-haemolysed samples.
3. Testing should be performed immediately after sample collection. Do not leave the samples at room temperature for prolonged periods. Serum and plasma samples may be stored at 2-8°C for up to 3 days. For long term storage, samples should be kept below -20°C.
4. Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.

Assay Procedure:
Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.
1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed within one hour of opening the pouch.
2. Holding the dropper vertically draw up the sample up to the fill line in the dropper and then dispense one drop (approximately 20 µl) into the sample well of the test device. Add 2 drops (approximately 80µl) of buffer to the sample well of the device and start the timer.
3. Wait for the coloured lines to appear. Read the result in 15 minutes, do not interpret the result after 20 minutes.



Interpretation of Results:

POSITIVE: Two or three coloured bands appear. One band appears in the control region (C) and another one or two bands appear in the IgG and/or IgM test regions.
IgM Positive: One band appears in the control region (C) and another appears in the IgM test region (IgM).
IgG Positive: One band appears in the control region (C) and another appears in the IgG test region (IgG).

NOTE: The intensity of the colour in the IgG and IgM test regions will vary depending on the concentration of Toxo IgG and/or IgM present in the sample. Therefore, any shade of colour in the test regions should be considered positive.

Quality Controls:
- An internal procedural control is included in the test. A coloured band appearing in the control region (C) is considered a positive procedural control, confirming sufficient sample volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test:
1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of Toxo IgG and/or IgM in serum or plasma from individual subjects. Failure to follow the procedures may give inaccurate results.
2. The Toxo IgG/IgM Rapid Test Device is limited to the qualitative detection of Toxo IgG and/or IgM in human serum or plasma. The intensity of the test band does not not give any indication of the antibody titre in the sample.
3. A negative result for an individual subject indicates absence of detectable antibodies to Toxo. 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 concentration of Toxo IgG or IgM present in the sample is below the detection limits of the assay, or the antibodies are not present during the stage of disease in which the 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 not be used as the sole criteria for diagnosis but be interpreted in conjunction with other diagnostic procedures and clinical findings.

Performance Characteristics:

Sensitivity and Specificity

Method		T gondii IgM ELISA		Total Results
Toxo IgG/IgM Rapid Test Device	Result	Positive	Negative	
	Positive	28	5	33
	Negative	2	345	347
Total Results		30	350	380

Relative Sensitivity: 93.3% (95%CI*: 77.2 – 99.2%) *Confidence Intervals
Relative Specificity: 98.6% (95%CI*: 96.7 – 99.5%)
Accuracy: 98.2% (95%CI*: 96.2 % – 99.3%)

Method		T gondii IgG ELISA		Total Results
Toxo IgG/IgM Rapid Test Device	Result	Positive	Negative	
	Positive	29	6	35
	Negative	1	344	345
Total Results		30	350	380

Relative Sensitivity: 96.7% (95%CI*: 82.8 – 99.9%) *Confidence Intervals
Relative Specificity: 98.3% (95%CI*: 96.3 – 99.4%)
Accuracy: 98.2% (95%CI*: 96.2 % – 99.3%)

Intra-Assay
Within-run precision was determined using 10 replicates of three samples, a negative, a low positive and a high positive. The samples were correctly identified >99 % of the time.

Inter-Assay
Between-run precision was determined by running 10 separate assays on 10 different days on the same three samples, a negative, a low positive and a high positive. Three different lots of the Toxo IgG/IgM Rapid Test Device (Serum/Plasma) were tested using these samples. The specimens were correctly identified > 99 % of the time.

Cross-Reactivity
The Toxo IgG/IgM Rapid Test Device has been tested using HBsAg, HBsAb, HBeAg, HBeAg, HBcAb, anti-HAV IgM, anti-HAV IgG, anti-HCV IgG, anti-HIV IgG, anti-RF IgG, anti-Syphilis IgG, anti-H Pylori IgG, anti-CMV IgG, anti-CMV IgM, anti-Rubella IgG, anti-Rubella IgM, anti-HSV1 IgG and IgM and anti-HSV 2 IgG and IgM positive samples and the results showed no cross-reactivity.

Interfering Substances
The following compounds have been tested using the Toxo IgG/IgM Rapid Test Device and no interference was observed.

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: 2 g/dl	Phenylpropanolamine: 20 mg/dl	Glucose 20 mg/dl
Bilirubin 1000 mg/dl	Salicylic Acid: 20 mg/dl	Phenothiazine: 20 mg/dl

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V4: rev Oct 2018

References:

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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. Berebi A, Kobuch WE, Bessieres MH, Bloom MC, Rolland M, SarramonMF, Roques C and Fournie A. Termination of pregnancy for maternal Toxoplasmosis. Lancet. 1994; 344: 36-39.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

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