Infection ichroma™ Toxo IgG/IgM

INTENDED USE

ichroma™ Toxo IgG/IgM is a fluorescence Immunoassay (FIA) for the qualitative determination of IgG/IgM antibodies against *Toxoplasma gondii* in human whole blood/serum/plasma. It is helpful as an aid in screening of *Toxoplasma Gondii* infection.

For *in vitro* diagnostic use only.

INTRODUCTION

Toxoplasma gondii is obligate intracellular parasite which causes the toxoplasmosis, a parasitic infection that can pass from the mother to the fetus through the placenta during pregnancy. Toxoplasmosis can result from swallowing parasites when handling feces from infected cats, drinking unpasteurized goat's milk, and most commonly eating contaminated meat.

Symptom of toxoplasmosis is categorized into three stages: acute, latent and cutaneous toxoplasmosis. In immunocompetent adults, most cases are asymptomatic but less show mild fever. While rare, central nervous system (CNS) infection or skin lesions may occur in the acquired tissue.

PRINCIPLE

This test uses a sandwich immunodetection method; the detector antibodies in buffer bind to antigens in the sample, forming antigen-antibody complexes, and migrate onto nitrocellulose matrix to be captured by the other immobilized-antibodies on test strip.

More antigens in the sample will form more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by instrument for ichroma test to show Toxoplasma IgG and IgM concentration in the sample. This signal then is interpreted by the reader to display the 'Positive'/ 'Negative' in the sample.

COMPONENTS

ichroma™ Toxo IgG/IgM consists of 'cartridges' 'detector tubes' and 'detector diluent'.

- The cartridge contains the membrane called a test strip which has anti-human IgM and anti-human IgG at each test line respectively, and chicken IgY at the control line. All cartridges are individually sealed in an aluminum foil pouch containing a desiccant, and they are further packaged in a box
- The detector tube has a granule containing Viral antigen fluorescence conjugates, anti-chicken IgY fluorescence conjugate, Bovine Serum Albumin (BSA) and sucrose as a stabilizer. All detector tubes are packed in a pouch.
- The detector diluent contains sodium chloride, Tween 20 as a detergent, sodium azide as a preservative in Tris buffer and it is pre-dispensed in a vial. The detector diluent is packed in a box.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow instructions and procedures described in this 'Instruction for use'.
- Lot numbers of all the test components (cartridge, detector tube, detector diluent and ID chip) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield incorrect test result(s).
- Do not reuse cartridge or detector tube. A cartridge should be used for testing one sample only. A detector tube should be used for processing of one sample only.
- The cartridge should remain sealed in its original pouch until just before use. Do not use cartridge, if pouch is damaged or has already been opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with local regulations. Sample with severe hemolysis and/or hyperlipidemia must not be used.
- The components contain NaN3 (sodium azide), may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure. Therefore, please avoid it contacts to eyes, skin, or clothing. If it happens, please wash with running water immediately.
- Allow cartridge, detector tube, detector diluent and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for ichroma™ tests may generate slight vibration during use.
- Used cartridges, detector tubes and detector diluent should be handled carefully and discarded by an appropriate method in accordance with the relevant local regulations.
- **ichroma™ Toxo IgG/IgM** will provide accurate and reliable results subject to the below conditions.
  - **ichroma™ Toxo IgG/IgM** should be used only in conjunction with instrument for ichroma™ tests.
  - Have to use recommended anticoagulant sample.

Recommended anticoagulant
Na-EDTA, K_2-EDTA, Na-Heparin, Li-Heparin, Sodium Citrate

STORAGE AND STABILITY

Storage condition			
Component	Storage Temperature	Shelf life	Note
Cartridge	2 - 30 °C	20 months	Disposable
Detector tube	2 - 30 °C	20 months	Disposable
Detector diluent	2 - 30 °C	20 months	Unopened
	2 - 30 °C	20 months	Opened

- After the cartridge pouch is opened, the test should be performed immediately.

LIMITATION OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result(s) due to the non-responsiveness of the antigen to the antibodies which is the most common if the epitope is masked by some unknown components, so therefore not being able to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may also cause false negative result as it makes the antigen unrecognizable by the antibodies.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician in conjunction with clinical symptoms and other relevant test results.

MATERIALS SUPPLIED

REF CFPC-112

Components of **ichroma™ Toxo IgG/IgM**

- Cartridge Box:
  - Cartridge 25
  - Detector tube 25
  - Detector diluent 1
  - ID chip 1
  - Instruction for use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ Toxo IgG/IgM.**

Please contact our sales division for more information.

- **ichroma™ II** REF FPRR021
- **ichroma™ III** REF FPRR037
- **Boditech Toxo IgG/IgM Control** REF CFPO-314
- **5 µL capillary tube (25ea)** REF CFPO-32
- **5 µL capillary tube (250ea)** REF CFPO-19

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ Toxo IgG/IgM** is human whole blood/serum/plasma.

- It is recommended to test the sample within 24 hours after collection.
- The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
- Samples may be stored for up to a week at 2-8 °C prior to being tested. If testing will be delayed more than a week, serum or plasma sample should be frozen at -20 °C.
- Serum or plasma sample stored frozen at -20 °C for 12 months showed no performance difference.
- However, the whole blood sample should not be kept in a freezer in any case.
- As a repeated freeze-thaw cycle may affect the test result, do not refreeze previously frozen samples

TEST SETUP

- Check the contents of **ichroma™ Toxo IgG/IgM**: Sealed cartridges, detector tubes, detector diluent, ID chip and Instruction for use.
- Ensure that the lot number of the cartridge matches that of the detector tube, detector diluent as well as an ID Chip.
- If the sealed cartridge, detector tube and detector diluent have been stored in a refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing
- Turn on the instrument for ichroma™ tests.
  (Please refer to the instrument for ichroma™ tests operation manual for the complete information and operating instructions).

TEST PROCEDURE

- **ichroma™ II**

<Multi mode>

① Transfer 150 µL of the detector diluent using a pipette to a detector tube containing granules. When the granule form is completely dissolved in the tube, it becomes detection buffer. (The detection buffer must be used immediately within 3 minutes.)

② Transfer sample 5 µL (human whole blood/serum/plasma/control) using a pipette or 5 µL capillary tube (sold separately) to a detector tube.

③ Close the lid of the detector tube and mix the sample thoroughly by shaking it about 10~20 times. (The Sample mixture must be used immediately within 3 minutes.)

④ Pipette out 75 µL of a sample mixture and load it into the sample well of the cartridge.

⑤ Leave the Cartridge at room temperature for 12 minutes before inserting the cartridge into the cartridge holder of ichroma™ II.

⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inaccurate test result.*

⑥ To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge especially for this purpose.

⑦ Tap the 'START' button on the instrument for ichroma™ tests to start the scanning process.

⑧ The instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.

⑨ Read the test result on the display screen of the instrument for ichroma™ tests

< Single mode>

① Transfer 150 µL of the detector diluent using a pipette to a detector tube containing granules. When the granule form is completely dissolved in the tube, it becomes detection buffer. (The detection buffer must be used within 3 minutes.)

② Transfer sample 5 µL (human whole blood/serum/plasma/control) using a pipette 5 µL capillary tube (sold separately) to a detector tube.

③ Close the lid of the detector tube and mix the sample thoroughly by shaking it about 10~20 times. (The sample mixture must be used within 3 minutes.)

④ Pipette out 75 µL of a sample mixture and load it into the sample well of the cartridge

⑤ Insert the cartridge into the holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge especially for this purpose.
⑥ Tap the 'START' button on the instrument for ichroma™ tests.
⑦ The Cartridge goes inside the Instrument for ichroma™ tests and will automatically start scanning the sample-loaded cartridge after 12 minutes.
⑧ Read the test result on the display screen of the instrument for ichroma™ tests.

▪ **ichroma™ III**

① The test procedure is same with "ichroma™ II single mode test ① – ④".
② Insert the sample-loaded cartridge into the ichroma™ III.
③ Tap the 'Start' button on the ichroma™ III.
④ The Cartridge goes inside and the ichroma™ III will automatically start scanning the sample-loaded cartridge after 12 minutes.
⑤ Read the test result on the display screen of the ichroma™ III.

INTERPRETATION OF TEST RESULT

- The instrument for ichroma™ tests calculates the test result automatically and displays Positive' / 'Negative' / 'Indeterminate'.
- Ancillary value is served in the form of an international unit (IU/mL) for IgG and a cut-off index (COI) for IgM.

Titer (IU/mL)	Result	Note
< 4	Negative for Toxo IgG	No need to retest
4 ≤ Titer < 8	Indeterminate	Need to retest
≥ 8	Positive for Toxo IgG	Need to confirmation test

Cut-off index (COI)	Result	Note
< 0.9	Negative for Toxo IgM	No need to retest
0.9 ≤ COI < 1.1	Indeterminate	Need to retest
≥ 1.1	Positive for Toxo IgM	Need to confirmation test

QUALITY CONTROL

- The Quality control tests should be used to confirm the reliability and the validity of **ichroma™ Toxo IgG/IgM**.
- The positive/negative controls are provided with the product for quality control.
- Quality control tests should be performed both to verify proper operation of instrument and to exclude any possible performance change in storage.
- For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.

PERFORMANCE CHARACTERISTICS

▪ **Analytical sensitivity**

Analytical sensitivity	Ig G (IU/mL)	Ig M (COI)
LOB	1.434	0.250
LOD	3.249	0.381

▪ **Analytical specificity**

- **Cross-reactivity**

Biomolecules listed in the following table were added to the test sample(s) at concentrations much higher than their normal physiological levels in the blood. ichroma™ Toxo IgG/IgM test results did not show any significant cross-reactivity with these biomolecules

Cross reactants	IgM		
	Number of samples	Negative	Positive
Anti-CMV	25	25	0
Anti-EBV	25	25	0
Anti-HAV	25	25	0
Anti-HCV	25	25	0
Anti-HBV	25	25	0
ANA	25	25	0
RF	25	25	0
Anti-Zika	20	20	0
Anti-Dengue	20	20	0
Cross reactants	**IgG**		
	Number of samples	Negative	Positive
Anti-CMV	25	25	0
Anti-EBV	25	25	0
Anti-HAV	25	25	0
Anti-HCV	25	25	0
Anti-HBV	25	25	0
ANA	25	25	0
RF	25	25	0
Anti-Zika	20	20	0
Anti-Dengue	20	20	0

- **Interference**

Interference materials listed in the following table were added to the test sample(s) the same as the below concentrations listed below. ichroma™ Toxo IgG/IgM test results did not show any significant interference with these materials.

No.	Interference materials	Conc.
1	Heparin	100,000 U/L
2	EDTA	5 μM
3	Sodium citrate	0.17 M
4	Bilirubin	500 μM
5	Hemoglobin	2 g/L
6	Triglycerides	1.5 g/L
7	Cholesterol	20 mM
8	Albumin	60 mg/mL

▪ **Precision**

- Between lots

One person tested three different lots of **ichroma™ Toxo IgG/IgM**, ten times at each concentration of the control standard.

- Between persons

Three different persons tested one lot of **ichroma™ Toxo IgG/IgM**, ten times at each concentration of the control standard.

- Between days

One person tested one lot of **ichroma™ Toxo IgG/IgM** during three days, ten times at each concentration of the control standard.

- Between sites

One person tested **ichroma™ Toxo IgG/IgM** at three different site, ten times at each concentration of the control standard.

ichroma™ Toxo IgG/IgM		Between Lot		Between person	
		Positive / No.	Positive rate (%)	Positive / No.	Positive rate (%)
Negative		0/30	0	0/30	0
IgM	Mid	30/30	100	30/30	100
	Low	30/30	100	30/30	100
IgG	Mid	30/30	100	30/30	100
	Low	30/30	100	30/30	100
ichroma™ Toxo IgG/IgM		Between day		Between site	
		Positive / No.	Positive rate (%)	Positive / No.	Positive rate (%)
Negative		0/30	0	0/30	0
IgM	Mid	30/30	100	30/30	100
	Low	30/30	100	30/30	100
IgG	Mid	30/30	100	30/30	100
	Low	30/30	100	30/30	100

- **Clinical performance evaluation**

ichroma™ Toxo IgG/IgM has demonstrated the flowing clinical performance results.

Toxo IgG		Comparator A		Total
		Pos.	Neg.	
ichroma™ Toxo IgG/IgM	Pos.	58	0	59
	Neg.	1	37	37
Total		59	37	96

- Clinical sensitivity (%) = 58/59 * 100 = 98%
- Clinical specificity (%) = 37/37 * 100 = 100%

Toxo IgM		Comparator A		Total
		Pos.	Neg.	
ichroma™ Toxo IgG/IgM	Pos.	28	2	30
	Neg.	2	67	69
Total		30	69	99

- Clinical sensitivity (%) = 28/30 * 100 = 93.3%
- Clinical specificity (%) = 67/69 * 100 = 97.1%

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Note: Please refer to the table below to identify various symbols.

	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse

For technical assistance; please contact:
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IVD