



#### 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 the 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 2 granules 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 'Instructions for use'.
- Use only fresh samples and avoid direct sunlight.
- 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 tubes. 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.
- If test components and/or sample are stored in refrigerator, then 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, detector diluent, capillary tube and pipette tips should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- The detector tube and the detector diluent contain sodium azide (NaN<sub>3</sub>), and it may cause certain health issues like convulsions, low blood pressure, low heart rate, loss of consciousness, lung injury and respiratory failure. Avoid contact with skin, eyes, and clothing. In case of contact, rinse immediately with running water.
- **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 the instrument for ichroma™ tests.
  - Have to use recommended anticoagulant.

#### Recommended anticoagulant

Na EDTA, K<sub>2</sub> EDTA, Sodium Heparin,  
Lithium Heparin, Sodium Citrate

- The capillary tube should be used when the following conditions are met.
  - The capillary tube provided with the kit is recommended to obtain correct test result.
  - Whole blood should be immediately tested after collection.
  - Excess whole blood around the capillary tube should be wiped off.
  - In order to avoid cross-contamination, please do not reuse capillary tube for multiple samples.

## 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          | 2 - 30 °C           | 20 months  | Unopened   |
| diluent           | 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 antigens 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 antigens with time and/or temperature may also cause false negative result as it makes the antigens unrecognizable by the antibodies.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- 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
  - Instructions for use 1

## MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

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

Please contact our sales division for more information.

- Instrument for **ichroma™** tests
  - 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. when collected sample is stored at room temperature.

- The samples (serum, plasma) should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
- The samples (whole blood, serum, plasma) may be stored for a week at 2-8 °C prior to being tested. If testing will be delayed more than a week, samples (serum, plasma) should be frozen at -20 °C.
- The samples (serum, plasma) 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.
- Whole blood sample can be collected using a capillary tube according to below:
  - Wear disposable gloves and the protective equipment for safety.
  - Open the zipper bag which has capillary tubes.
  - Take out the capillary tube and check for damaged or contamination.
  - Hold the handle of the capillary tube and touch the surface of blood with the capillary tube.
  - Fill it with blood completely.  
(Make sure that no air bubbles are present in the capillary tube. Do not get blood on the surface of the capillary tube. If the blood gets on the surface of the capillary tube, remove it gently with gauze.)

## TEST SETUP

- Check the contents of **ichroma™ Toxo IgG/IgM**: Sealed cartridges, detector tubes, a detector diluent, ID chip and Instructions 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.
- Insert the ID chip into the 'ID chip port'.
- Please refer to the instrument for ichroma™ tests operation manual for the complete information and operating instructions.**

## TEST PROCEDURE

### ► **ichroma™ II**

#### **Multi test mode**

- Select the sample type (whole blood or serum/plasma) on the screen.
  - If using control as the sample, select the 'serum/plasma'.
- Take 150 µL of detector diluent using a pipette and dispense it to the detector tube containing 2 granules. When the granules are completely dissolved in the tube, they become the detection buffer.  
(The detection buffer must be used within 3 minutes.)
- Take 5 µL of sample (whole blood/serum/plasma/control) using a pipette and dispense it to the detector tube.
  - If the test use whole blood, transfer the blood (collected in a capillary tube) to a detector tube.

- 4) 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.)
- 5) Take 75 µL of the sample mixture and dispense it into the sample well of the cartridge.
- 6) 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.

- 7) 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.
- 8) Press the 'Select' or tap the 'Start' button on the instrument for ichroma™ tests to start the scanning process.
- 9) The instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
- 10) Read the test result on the display screen of the instrument for ichroma™ tests.

#### Single test mode

- 1) The test procedure is same with the 'ichroma™ II test procedure 1) – 5)'.
- 2) 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.
- 3) Tap the 'Start' button on the instrument for ichroma™ tests.
- 4) The Cartridge goes inside the Instrument for ichroma™ tests and will automatically start scanning the sample-loaded cartridge after 12 minutes.
- 5) Read the test result on the display screen of the instrument for ichroma™ tests.

#### ► ichroma™ III

- 1) Select the sample type (whole blood or serum/etc.) on the screen. Press the key button to change the desired sample type.  
※ If using control as the sample, select the 'serum/etc.'.
- 2) The test procedure is same with the 'ichroma™ II test procedure 2) – 5)'.
- 3) Insert the sample-loaded cartridge into the holder of the ichroma™ III. 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.
- 4) Tap the 'Start' button on the ichroma™ III to start the scanning process.
- 5) The cartridge goes inside and ichroma™ III will automatically start scanning the sample-loaded cartridge after 12 minutes.
- 6) 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

- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with ichroma™ Toxo IgG/IgM. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.  
(Please refer to the instructions for use of control material.)

#### PERFORMANCE CHARACTERISTICS

##### Analytical sensitivity

| Analytical sensitivity | IgG (IU/mL) | IgM (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         | Number of samples | IgM      |          |
|-------------------------|-------------------|----------|----------|
|                         |                   | Negative | Positive |
| Anti-CMV                | 20                | 20       | 0        |
| Anti-EBV                | 20                | 20       | 0        |
| Anti-HIV                | 20                | 20       | 0        |
| Anti-HCV                | 20                | 20       | 0        |
| Anti-HAV                | 20                | 20       | 0        |
| Anti-HBV                | 20                | 20       | 0        |
| Anti-HSV                | 20                | 20       | 0        |
| Anti-Rubella            | 20                | 20       | 0        |
| Anti-Treponema pallidum | 20                | 20       | 0        |
| Anti-Chlamydia          | 5                 | 5        | 0        |
| Anti-Gonorrhea          | 5                 | 5        | 0        |
| Anti-Malaria            | 5                 | 5        | 0        |

|                         |                   |          |          |
|-------------------------|-------------------|----------|----------|
| RF                      | 20                | 20       | 0        |
| ANA                     | 5                 | 5        | 0        |
| Cross reactants         | IgG               |          |          |
|                         | Number of samples | Negative | Positive |
| Anti-CMV                | 20                | 20       | 0        |
| Anti-EBV                | 20                | 20       | 0        |
| Anti-HIV                | 20                | 20       | 0        |
| Anti-HCV                | 20                | 20       | 0        |
| Anti-HBV                | 20                | 20       | 0        |
| Anti-HSV                | 20                | 20       | 0        |
| Anti-Rubella            | 20                | 20       |          |
| Anti-Treponema pallidum | 20                | 20       | 0        |
| Anti-Chlamydia          | 5                 | 5        | 0        |
| Anti-Gonorrhea          | 5                 | 5        | 0        |
| Anti-Malaria            | 5                 | 5        | 0        |
| RF                      | 20                | 20       | 0        |
| ANA                     | 5                 | 5        | 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.

| Interferents   | Concentration |
|----------------|---------------|
| Heparin        | 100,000 U/L   |
| EDTA           | 5 µM          |
| Sodium citrate | 0.17 M        |
| Bilirubin      | 500 µM        |
| Hemoglobin     | 2 g/L         |
| Triglycerides  | 1.5 g/L       |
| Cholesterol    | 20 mM         |
| 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™<br>Toxo<br>IgG/IgM | Between Lot       |                      | Between person    |                      |
|-----------------------------|-------------------|----------------------|-------------------|----------------------|
|                             | Positive /<br>No. | Positive<br>rate (%) | Positive /<br>No. | Positive<br>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™<br>Toxo            | Between day       |                      | Between site      |                      |
|                             | Positive /        | Positive             | Positive /        | Positive             |

| IgG/IgM  | No.       | rate (%) | No.   | 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™     | Pos. 58      | 0    | 59    |
| Toxo IgG/IgM | 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™     | Pos. 28      | 2    | 30    |
| Toxo IgG/IgM | 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                               |
|  | Batch code                                |
|  | Catalog number                            |
|  | Caution                                   |
|  | Manufacturer                              |
|  | <i>In vitro</i> diagnostic medical device |
|  | Temperature limit                         |
|  | Do not reuse                              |

For technical assistance; please contact:

**Boditech Med Inc.'s Technical Sales**

Tel: +(82) -33-243-1400

E-mail: sales@boditech.co.kr



**Boditech Med Inc.**

43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, 24398, Republic of Korea

Tel: +(82) -33-243-1400

Fax: +(82) -33-243-9373

www.boditech.co.kr

