Infection

ichroma™ Rubella IgM

INTENDED USE

ichroma™ Rubella IgM is a fluorescence Immunoassay (FIA) for the qualitative determination of IgM antibodies against Rubella virus in human whole blood/serum/plasma. It is useful as an aid in the determination of immune status to rubella.

For *in vitro* diagnostic use only.

INTRODUCTION

Rubella is an infectious viral disease caused by the rubella virus. About half of the people pass by without knowing if they are infected because the symptoms are not so serious, but if they are infected during pregnancy, miscarriage, or congenital rubella syndrome (CRS) may appear.

The main symptom of rubella is a rash, which begins in the face and spreads throughout the body. lymphadenitis is also common, and fever, sore throat, and fatigue can also occur. Symptoms of congenital rubella syndrome include eye disorders such as cataracts, hearing disorders, and heart and brain diseases.

PRINCIPLE

This test uses a sandwich immunodetection method.

The detector antibody in buffer bind to antigens in the sample, forming antigen-antibody complexes, and migrate onto nitrocellulose matrix to be captured by the recombinant antigens 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 Rubella IgM concentration and 'Positive' / 'Negative' in the sample.

COMPONENTS

ichroma™ Rubella IgM consists of 'cartridges' 'detector tubes' and 'detector diluent'.

- The cartridge contains the membrane called a test strip which has Rubella Ag at the test line 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 anti-human IgM fluorescence conjugates and anti-chicken IgY fluorescence conjugate. 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-Cl 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 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.
- 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 the relevant local regulations.
- The detector diluent contains sodium azide (NaN_3), 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™ Rubella IgM** will provide accurate and reliable results subject to the below conditions.
  - **ichroma™ Rubella IgM** should be used only in conjunction with instrument for ichroma™ tests.
  - Have to use recommended anticoagulant.

Recommended anticoagulant
K_2 EDTA, Sodium Heparin, Lithium Heparin, Sodium Citrate

- **The capillary tube should be used when the following conditions are met.**
  - 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 re-use capillary tube for multiple samples.

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.

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	12 months	Opened

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

MATERIALS SUPPLIED

REF CFPC-145

Components of **ichroma™ Rubella 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 from **ichroma™ Rubella IgM.**

Please contact our sales division for more information.

- Instruments for ichroma™ tests
  - **ichroma™ II** REF FPRR021
  - **ichroma™ III** REF FPRR037
- **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™ Rubella 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 up to 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 10 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:
  ① Wear disposable gloves and protective equipment for safety.
  ② Open the zipper bag which has capillary tubes.
  ③ Take out the capillary tube and check for damage or contamination.
  ④ Hold the handle of the capillary tube and touch the surface of blood with the capillary tube.
  ⑤ 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™ Rubella IgM**: Sealed cartridges, detector tubes, a detector diluent, an ID chip and an instructions for use.
- Ensure that the lot number of the cartridge matches that of the detector tube, detector diluent as well as the 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

1) Select the sample type (whole blood or serum/plasma) on the screen.
2) Take 150 µL of the detector diluent using a pipette and dispense it to the detector tube containing a granule. When the granule form is completely dissolved in the tube, it becomes detection buffer.
(The detection buffer must be used immediately within 30 seconds.)
3) Take 5 µL of sample (human whole blood/serum/plasma) using a pipette or 5 µL capillary tube (sold separately) and dispense it to the 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 immediately. Do not exceed 30 seconds.)
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.
⚠ *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) 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 'Multi test mode 1) – 5)'.
2) Insert the sample-loaded cartridges 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) The test procedure is same with the 'Single test mode'.

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 a cut-off index (COI) for IgM.

Cut-off index (COI)	Result	Note
< 0.9	Negative for Rubella IgM	No need to retest
0.9 ≤ COI < 1.1	Indeterminate	Need to retest
≥ 1.1	Positive for Rubella 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 be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with **ichroma™ Rubella 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 specificity**

- **Cross-reactivity**

ichroma™ Rubella IgM test results did not show any significant cross-reactivity with these clinical samples.

Clinical samples (Positive)	IgM		
	Number of samples	Negative	Positive
CMV	25	25	0
EBV	25	25	0
HAV	25	25	0
HCV	25	25	0
HBV	25	25	0
ANA	25	25	0
RF	25	25	0
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™ Rubella IgM test results did not show any significant interference with these materials.

No.	Interferents	Concentration
1	Sodium Heparin	100,000 U/L
2	Lithium Heparin	100,000 U/L
3	K_2 EDTA	2 mg/mL 5 μM
4	Sodium citrate	0.34 M
5	Bilirubin (unconjugated)	833 μM
6	Hemoglobin	10 g/L
7	Triglycerides	15 g/L
8	Cholesterol	7.7 mg/mL 20 mM
9	BSA	60 mg/mL

- **Precision**

- **Single-site study**

Repeatability (within-run precision)
within-laboratory precision (Total precision)
Lot to lot precision

3 Lots of **ichroma™ Rubella IgM** were tested for 21 days. Each standard material was tested 2 times per day. For each test, each material was duplicated.

- **Multi-site study**

Between persons

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

Between sites

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

- Between reader

One person tested one lot of **ichroma™ Rubella IgM** using three readers, ten times at each concentration of the control standard.

Rubella IgM [COI]	Repeatability		Total precision (Within-laboratory precision)	
	Positive/ Total	Positive rate (%)	Positive/ Total	Positive rate (%)
Cal. 1	0/42	0	0/84	0
Cal. 2	42/42	100	84/84	100

Cal. 3	42/42	100	84/84	100
Rubella IgM [COI]	Lot to lot precision		Between-person	
	Positive/ Total	Positive rate (%)	Positive/ Total	Positive rate (%)
Cal. 1	0/252	0	0/30	0
Cal. 2	252/252	100	30/30	100
Cal. 3	252/252	100	30/30	100
Rubella IgM [COI]	Between-site		Between-reader	
	Positive/ Total	Positive rate (%)	Positive/ Total	Positive rate (%)
Cal. 1	0/30	0	0/30	0
Cal. 2	30/30	100	30/30	100
Cal. 3	30/30	100	30/30	100

- **Clinical performance evaluation**
  ichroma™ Rubella IgM has demonstrated the following clinical performance results.

Rubella IgM		Comparator A		Total
		Neg.	Pos.	
ichroma™	Neg.	67	2	69
Rubella IgM	Pos.	3	32	35
Total		70	34	104

- Percent positive agreement (PPA) (%)
  = 32/34 * 100 = 94.1 %
- Percent negative agreement (PNA) (%)
  = 67/70 * 100 = 95.7 %
- Total agreement (%) = (32+67)/104 * 100 = 95.2 %

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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
	In vitro diagnostic medical device
	Temperature limit
	Do not reuse

For technical assistance, please contact:
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