Infection

ichroma™ CMV IgG

INTENDED USE

ichroma™ CMV IgG is a fluorescence immunoassay (FIA) for the qualitative determination of IgG antibodies against Cytomegalovirus (CMV) in human whole blood/serum/plasma. It is helpful as an aid in screening of CMV infection.

For *in vitro* diagnostic use only.

INTRODUCTION

Cytomegalovirus (CMV) is a human herpes virus and is the most common congenital viral infection.

CMV is easily transmitted through bodily fluids such as urine, saliva, blood, and can pass from mother to the fetus through the placenta during pregnancy.

CMV infection is usually asymptomatic, but can cause serious symptoms in fetuses, organ transplant patients, cancer patients, and HIV patients.

PRINCIPLE

The test uses a sandwich immunodetection method.

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

More antibodies in the sample will form more antigen-antibody complexes which lead to stronger fluorescence signal by detector antigens, which is processed by the instrument for ichroma™ tests to show CMV IgG concentration and 'Positive' / 'Negative' in the sample.

COMPONENTS

ichroma™ CMV IgG consists of 'cartridges', 'detector tubes' and 'detector diluent'.

- The cartridge contains the membrane called a test strip which has anti-human IgG 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 viral antigen fluorescence conjugate and anti-chicken IgY fluorescence conjugate. All detector tubes are packed in a pouch.
- The detector diluent contains sodium azide as a preservative and Tween 20 as a detergent 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 cartridges 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 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™ CMV IgG** will provide accurate and reliable results subject to the below conditions.
  - **ichroma™ CMV IgG** should be used only in conjunction with the instrument for ichroma™ tests.
  - Have to use recommended anticoagulant.

Recommended anticoagulant
K_2 EDTA, K_3 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.

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
		12 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 antibodies to the antigens 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 antigens. The instability or degradation of the antibodies with time and/or temperature may also cause false negative result as it makes the antibodies unrecognizable by the antigens.
- 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-144

Components of **ichroma™ CMV IgG**

- 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™ CMV IgG.**

Please contact our sales division for more information.

- Instrument 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™ CMV IgG** 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 (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 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:
  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™ CMV IgG**: 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, the detector diluent as well as the ID chip.
- If the sealed cartridge, the detector tube and the 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) Take 150 µL of 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. Do not

exceed 30 seconds.)
2) Take 5 µL of sample (whole blood/serum/ plasma) using a pipette or 5 µL capillary tube (sold separately) and dispense it to the 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. Do not exceed 30 seconds.)
4) Take 75 µL of the sample mixture and dispense it into the sample well of the cartridge.
5) 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.*
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 test mode

1) The test procedure is same with the 'Multi test mode 1) – 4)'.
2) Insert the sample-loaded 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) 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 AU/mL for IgG.

Titer (AU/mL)	Result	Note
< 4	Negative for CMV IgG	No need to retest
4 ≤ Titer < 6	Indeterminate	Need to retest
≥ 6	Positive for CMV IgG	Need to confirmation test

■ Values between 4 and 6 need to retest. If the same result is shown after retest, a new sample should be collected after 10 to 15 days.

PERFORMANCE CHARACTERISTICS

■ **Analytical sensitivity**

- Limit of Blank (LoB) 0.97 AU/mL
- Limit of Detection (LoD) 2.12 AU/mL

■ **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™ CMV IgG** test results did not show any significant cross-reactivity with these biomolecules.

Cross reactants	IgG		
	Number of samples	Negative	Positive
Rubella	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
Interferents listed in the following table were added to the test sample at the concentration mentioned below. **ichroma™ CMV IgG** test results did not show any significant interference with these materials.

No.	Interferents	Concentration
1	Li-Heparin	100,000 U/L
2	Sodium Heparin	100,000 U/L
3	K_2 EDTA	5 µmol/L
4	K_3 EDTA	5 µmol/L
5	Sodium citrate	0.327 mol/L
6	Hemoglobin	10 g/L
7	BSA	60 g/L
8	Bilirubin	0.684 mmol/L
9	Triglycerides	15 g/L
10	Cholesterol	20 mmol/L

■ **Precision**

- Single-site study
Repeatability (within-run precision)
within-laboratory precision (Total precision)
Lot to lot precision
3 Lots of **ichroma™ CMV IgG** were tested for 20 days. Each standard material was tested 2 times per day. For each test, each material was duplicated.
- Multi-site study
Reproducibility
1 Lot of **ichroma™ CMV IgG** was tested for 5 days in 3 different sites (1 person per 1 site, 1 instrument per 1 site). Each standard material was tested 1 time per and 5 replicates per day.

CMV IgG [AU/mL]	Repeatability		Total precision (within-lab precision)	
	Pos# /Tot#	Positive rate(%)	Pos# /Tot#	Positive rate(%)
Cal 1	0/40	0	0/80	0
Cal 2	40/40	100	80/80	100
Cal 3	40/40	100	80/80	100

CMV IgG [AU/mL]	Lot to lot precision		Reproducibility	
	Pos# /Tot#	Positive rate(%)	Pos# /Tot#	Positive rate(%)
Cal 1	0/240	0	0/75	0
Cal 2	240/240	100	75/75	100
Cal 3	240/240	100	75/75	100

■ **Clinical performance evaluation**
ichroma™ CMV IgG has demonstrated the flowing clinical performance results.

CMV IgG		Comparator A		Total
		Pos.	Neg.	
ichroma™ CMV IgG	Pos.	66	1	67
	Neg.	3	34	37
Total		69	35	104

- Percent positive agreement (PPA) (%) = 66/69 * 100 = 95.7%
- Percent negative agreement (PNA) (%) = 34/35 * 100 = 97.1%
- Total agreement (%) = (66+34)/104 * 100 = 96.2%

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

Σ	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