



ichroma™ IGRA-TB 25

INTENDED USE

ichroma™ IGRA-TB 25 is a qualitative fluorescence immunoassay (FIA) for detection of IFN-γ (Interferon gamma) released in response to *in vitro* stimulation by *Mycobacterium tuberculosis* specific antigen in human whole blood. It is useful as an aid in management and monitoring of Tuberculosis infection.

For *in vitro* diagnostic use only.

INTRODUCTION

Tuberculosis (TB) is a chronic disease that is infected by *Mycobacterium tuberculosis* and is one of the most serious epidemics in the world, along with HIV and malaria. It is categorized into two phases, active TB and Latent TB in clinical point of view. It is crucial to detect Latent TB since about 10% of it give rise to active disease in immunocompromised patients. Diagnosis of Latent TB, however, is not easy because it is normal in the *mycobacterium* culture test and chest X-ray examination. To diagnose the Latent TB, the IFN-γ release assays (IGRAs), *in vitro* blood tests of cell-mediated immune response that measure T-cell released IFN-γ following stimulation by antigens specific to the *M. tuberculosis* (ESAT-6 and CFP-10), have been used.

ichroma™ IGRA-TB 25 is the first lateral flow system of IGRA assays, which means that it is more simple and rapid test ever. It is useful as an aid in excluding the tuberculosis diseases.

PRINCIPLE

The 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 streptavidin on a 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™ tests to show Latent TB infection 'Positive', 'Negative' in the sample

COMPONENTS

ichroma™ IGRA-TB 25 consists of 'cartridges', 'detector tubes', and 'detector diluent'.

- The cartridge contains the membrane called a test strip which has streptavidin 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 2 granules containing anti-IFN-γ fluorescence conjugate, anti-IFN-γ biotin conjugate, anti-chicken IgY fluorescence conjugate. All detector tubes are packed in a box.

- The detector diluent contains tween 20 as a detergent and sodium azide in Tris-HCl, 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 the 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.
- The lot number of the IGRA-TB tube is managed separately.
- 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 the 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 and pipette tips should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- No Biotin interference was observed in **ichroma™ IGRA-TB 25** when biotin concentration in the sample was below 200 ng/mL. If a patient has been taking biotin at dosage of more than 0.03 mg a day, it is recommended to test again 24 hours after discontinuation of biotin intake.
- **ichroma™ IGRA-TB 25** will provide accurate and reliable results subject to the below conditions.
 - **ichroma™ IGRA-TB 25** should be used only in conjunction with instrument for ichroma™ tests.
 - Have to use recommended anticoagulant.

Recommended anticoagulant

Lithium Heparin

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
		20 months	Opened

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

MATERIALS SUPPLIED

REF CFPC-86-1

Components of **ichroma™ IGRA-TB 25**

- Cartridge Box:
 - Cartridge 150
 - Detector tube 150
 - Detector diluent 6
 - ID chip 1
 - Instructions for use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately with **ichroma™ IGRA-TB 25**.

Please contact our sales division for more information.

- Instrument for ichroma™ tests
 - **ichroma™ II** **REF** FPRR021
 - **ichroma™ III** **REF** FPRR037
 - **ichroma™ M2** **REF** FPRR031
- **Boditech IGRA-TB Control** **REF** CFPO-294
- **ichroma™ IGRA-TB tube** **REF** CFPO-206

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ IGRA-TB 25** is Lithium heparin plasma.

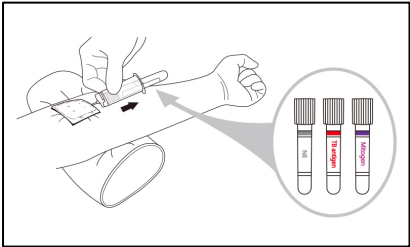
- For each patient, collect 1 mL of blood by venipuncture directly into each of the **ichroma™ IGRA-TB Tube**.
 - The black line on the side of the tube indicates the range from 0.8 to 1.2 mL if the blood level in the tube deviates off the indicated range, a new blood sample must be taken.
- Collect 1 mL of blood in the order of the ichroma™ IGRA-

TB Nil tube (gray), TB antigen tube (red) and Mitogen tube (purple) and invert 10 times gently so that the additive and blood are well mixed.

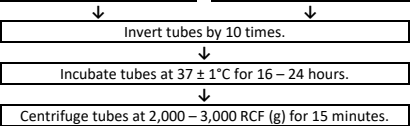
- Invert well to ensure that the inner wall of the tube is completely coated with blood.
- If inverted too vigorously, hemolysis and gel division may occur, which may cause abnormal results.
- Fill in the information of the patient whose blood has been collected on the label.
- After blood collection, it must be transferred to an incubator (37 ± 1°C) immediately or within 16 hours.
 - Prior to incubation, maintain and transport the tubes at room temperature (22 ± 5°C).
 - If not incubated immediately but within 16 hours after collection, invert the tube 10 times gently again before incubation.
- Incubate the tube by placing vertically within 16 hours of sample collection at 37 ± 1°C for 16-24 hours.

※ **If the above method is not followed, there may be errors in the results.**

- After incubation, centrifuge the blood collection tube at 2,000 ~ 3,000 RCF (g) for 15 minutes.
 - After incubation, the centrifugation should be immediately performed to obtain plasma.
- Sample storage;
 - The centrifuged tube can be stored for up to 1 week at 2°C to 8°C before the extraction of plasma and if harvested, should be stored at below -20°C for 1 month.
 - As a repeated freeze-thaw cycle may affect the test result, do not refreeze previously frozen samples.
 - Samples containing precipitates must be clarified by centrifugation before analysis.



Drawing into ichroma™ IGRA-TB Tube	Drawing into Lithium Heparin Tube
Collect 1mL of blood into each of ichroma™ IGRA-TB Tubes. (Nil ▶ TB antigen ▶ Mitogen)	Collect 4mL of blood into Li-Heparin coated tubes and distribute it into each of ichroma™ IGRA-TB Tube (Nil ▶ TB antigen ▶ Mitogen)



TEST SETUP

- Check the contents of **ichroma™ IGRA-TB 25**: Sealed cartridges, detector tubes, detector diluents, an ID chip and an instructions for use.
- Ensure that the lot number of the cartridge matches that of the detector tubes, the detector diluent as well as an 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 complete information and operating instructions.**

TEST PROCEDURE

▶ ichroma™ II

Multi test mode

- 1) After turning on the instrument, enter the multi test mode and select the sample type (Serum / Plasma / etc.)
- 2) Enter the patient ID (PID), gender, and age.

Patient ID	Age	Gender	Type	Item	Result
tester	24	Male	Sp/Plac	IGRA-TB	Positive
2			Sp/Plac		
3			Sp/Plac		
4			Sp/Plac		
5			Sp/Plac		

※ If the PID was not entered in step 2), after performing up to step 8), enter the PID in the IGRA-TB specific test mode pop-up and touch the 'Start' button to perform the measurement. If the PID is not entered, the test cannot be started.

- 3) Label the 3 cartridges along with test sequence, Nil, TB antigen, and Mitogen.
ex) N for Nil, A for TB antigen, M for Mitogen
- 4) Take 100 μ L of the detector diluent using a pipette and dispense it to the detector tube containing 2 granules. 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.)

- 5) Take 50 μ L of sample (lithium heparin plasma/control) using a pipette to the detector tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately. Do not exceed 30 seconds.)
- 6) Take 100 μ L of the sample mixture and dispense it into the sample well of the cartridge.
(① Nil, ② TB antigen and ③ Mitogen samples are loaded sequentially.)
- 7) Leave the cartridge at room temperature for 15 minutes.
- 8) Insert Nil tube sample-loaded cartridge into the cartridge holder of the ichroma™ II first and touch the "Start" button. Make sure the pop-up display of IGRA-TB-specific test mode, and then touch the "Start" button again.
- 9) Confirm the value of Nil tube-test (IU/mL) and then insert TB antigen tube sample-loaded cartridge into the holder. Touch the "Start" on the IGRA-TB mode.

- 10) Confirm the value (IU/mL) and then insert Mitogen tube sample-loaded cartridge into the holder finally. Touch the "Start" on the IGRA-TB mode. Ensure proper orientation and sequence of the cartridge before pushing it all the way inside the cartridge holder.

※ If re-testing of any of the three tubes is required, follow the procedure below. If re-testing is not required, proceed to step 11).

※ Re-testing must be performed within 24 hours only for samples in which an error (invalid) occurred. After 24 hours, the samples will be removed from the re-test list.

- ① Touch the 'Retest' check box.

- ② When the IGRA-TB Selection Dialog window appears, select the appropriate option under Selection and press the 'OK' button."

- ③ The selected test result in the Selection Dialog is loaded into the IGRA-TB mode, and the test is started after the test result is displayed."

- 11) Make sure "Final result" on the screen and the printed result. If you want to other IGRA-TB tests, touch the "Finish" to back into Multi mode.

- 12) Repeat steps 2) to 11) to carry out the new IGRA-TB test.
13) If you want to know detailed information of the test on the screen, check the History menu (Home → Review → Patient result).

► ichroma™ III IGRA-TB mode

- After turning on the instrument, touch 'Settings' at the top of the display and then touch 'Measure' and 'IGRA-TB Mode ON'.
- Touch 'IGRA START' on the 'Test Cartridge' tab in display to start IGRA-TB mode.

- Enter the PID, gender, and age in IGRA-TB mode, and proceed with the test according to the test procedure below.

※ If the PID is not entered, the test cannot be started.

- This step is same with ichroma™ II test procedure from 3) to 5).
- Take 100 μ L of Nil sample mixture using a pipette and dispense it in the sample well on the cartridge.
- Insert Nil tube sample-loaded cartridge into the cartridge holder of ichroma™ III first and touch the "Start" button. Make sure the pop-up display of IGRA-TB specific test mode.

- 7) Repeat step 3) – 5) ichroma™ II test procedure. Using a pipette, take 100 µL of TB antigen sample mixture and dispense it in the sample well on the cartridge.
- 8) Insert TB antigen tube sample-loaded cartridge into the cartridge holder of ichroma™ III first and touch the "Start" button. Make sure the pop-up display of IGRA-TB specific test mode.
- 9) Repeat step 3) – 5) ichroma™ II test procedure. Using a pipette, take 100 µL of Mitogen sample mixture and dispense it in the sample well on the cartridge.
- 10) Insert Mitogen tube sample-loaded cartridge into the cartridge holder of ichroma™ III first and touch the "Start" button. Make sure the pop-up display of IGRA-TB specific test mode.
(① Nil, ② TB antigen, ③ Mitogen samples are loaded sequentially.)
- 11) Make sure "Final result" on the screen and the printed result. If you want to other IGRA-TB tests, touch the "New IGRA-TB" to proceed new IGRA-TB test.
※ If you want to re-test among 3 tubes, touch the "Retest" button to choose the test result needs re-test. And insert the cartridge and touch the "Start".
※ Re-testing must be performed within 24 hours only for samples in which an error (invalid) occurred. After 24 hours, the samples will be removed from the re-test list.
- 12) Insert new Nil tube sample-loaded cartridge into the holder and touch the "Start" to the carry out new IGRA-TB test.
- 13) If you want to know detailed information of the test on the screen, double touch each result and make sure the details.

► ichroma™ M2

Read now mode

- 1) Check the display "Read Now" on the ichroma™ M2 screen and set the tube type (Nil, TB antigen, Mitogen).
- 2) The test procedure is same with "ichroma™ II test procedure 3) – 6)."
- 3) Leave the cartridge at room temperature for 15 minutes.
⚠ Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inaccurate test result.
- 4) 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.
- 5) ichroma™ M2 will start the test automatically after inserting.
- 6) The instrument for ichroma™ tests will start scanning the sample loaded cartridge immediately.
- 7) Read the test result on the display screen of the instrument for ichroma™ tests.

Walk away mode

- 1) Check the display "Walk Away" on the ichroma™ M2

- screen and set the tube type (Nil, TB antigen, Mitogen).
- 2) The test procedure is same with "ichroma™ II test procedure 3) – 6)."
- 3) 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.
- 4) ichroma™ M2 will start the test tested automatically after inserting.
- 5) The cartridge goes inside the instrument for ichroma™ tests and will automatically start scanning the sample-loaded cartridge after 15 minutes.
- 6) Read the test result on the display screen of the instrument for ichroma™ tests.

INTERPRETATION OF TEST RESULT

- The instrument for ichroma™ tests automatically calculates the test result and displays the IGRA-TB concentration (IU/mL) in the sample along with a qualitative result of 'Positive' or 'Negative'.

Nil (IU/mL)	TB Antigen minus Nil (IU/mL)	Mitogen minus Nil (IU/mL)	ichroma™ IGRA-TB 25	Report / Interpretation
<0.35	≥0.35 and <25% of Nil value	≥0.5	Negative	M. Tuberculosis infection NOT likely
≤8.0	≥0.35 and ≥25% of Nil value	Any	Positive	M. Tuberculosis infection likely
<0.35	<0.35	<0.5	Indeterminate	Results are indeterminate for TB-Antigen responsiveness
≥0.35 and <25% of Nil value	<0.5			
>8.0	Any	Any		

- Display of the ichroma™ result is shown on the pop-up screen of IGRA-TB immediately.
- The results are also shown on the screen of the 'Multi-mode' as above described.

Example for result (ichroma™ II)

IGRA-TB mode

Result: Neg.

Nov-12-2025 / 11:31:59

✓	Patient ID	Age	Gender	Type	Item	Result
1	tester	-	-	S/Plate	IGRA-TB	Negative
2				S/Plate		
3				S/Plate		
4				S/Plate		
5				S/Plate		

Navigation: Home, Delete, Print, Start

Pos.

IGRA-TB mode

Nov-12-2025 / 11:31:59

IGRA-TB

PID: tester

☐ NIL

☐ TB antigen

☒ Mitogen

5.00 IU/mL

7.00 IU/mL

5.00 IU/mL

Final result: **Positive**

Retest: ☐ (NEW TEST)

Start

Finish

Multi-mode

Nov-12-2025 / 11:31:59

Patient ID	Age	Gender	Type	Item	Result
1	-	-	S/Spec	IGRA-TB	Positive
2	-	-	S/Spec	-	-
3	-	-	S/Spec	-	-
4	-	-	S/Spec	-	-
5	-	-	S/Spec	-	-

Home

Delete

Print

Start

Indeterminate

IGRA-TB mode

Nov-12-2025 / 11:31:59

IGRA-TB

PID: tester

☐ NIL

☐ TB antigen

☒ Mitogen

5.00 IU/mL

7.00 IU/mL

5.00 IU/mL

Final result: **Indeterminate**

Retest: ☐ (NEW TEST)

Start

Finish

Multi-mode

Nov-12-2025 / 11:31:59

Patient ID	Age	Gender	Type	Item	Result
1	-	-	S/Spec	IGRA-TB	Indeterminate
2	-	-	S/Spec	-	-
3	-	-	S/Spec	-	-
4	-	-	S/Spec	-	-
5	-	-	S/Spec	-	-

Home

Delete

Print

Start

Invalid

IGRA-TB mode

Nov-12-2025 / 11:31:59

IGRA-TB

PID: tester

☐ NIL

☐ TB antigen

☒ Mitogen

5.00 IU/mL

7.00 IU/mL

Invalid-36

Final result: **Invalid**

Retest: ☐ (NEW TEST)

Start

Finish

Multi-mode

Nov-12-2025 / 11:31:59

Patient ID	Age	Gender	Type	Item	Result
1	-	-	S/Spec	IGRA-TB	Invalid-36
2	-	-	S/Spec	-	-
3	-	-	S/Spec	-	-
4	-	-	S/Spec	-	-
5	-	-	S/Spec	-	-

Home

Delete

Print

Start

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™ IGRA-TB 25**. 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**

Limit of Blank (LoB)	0.03 IU/mL
Limit of Detection (LoD)	0.05 IU/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™ IGRA-TB 25** test results did not show any significant cross-reactivity with these biomolecules.

Cross-reactants	Conc.
Tumor Necrosis Factor-α (TNF-α)	100 ng/mL
Tumor Necrosis Factor-β (TNF- β)	100 ng/mL
Interleukin-2 (IL-2)	100 ng/mL
Interleukin-4 (IL-4)	100 ng/mL
Interleukin-6 (IL-6)	100 ng/mL
Interleukin-10 (IL-10)	100 ng/mL
Interleukin-17 (IL-17)	100 ng/mL
Interleukin-23 (IL-23)	100 ng/mL
Interleukin-27 (IL-27)	100 ng/mL
 - Interference
Interferents listed in the following table were added to the test sample at the concentration mentioned below. **ichroma™ IGRA-TB 25** test results did not show any significant interference with these materials.

Interferents	Conc.
Li-Heparin	100,000 U/L
Bilirubin	400 μM
Hemoglobin	2 mg/mL
Triglycerides	1.5 mg/mL
Cholesterol	7.7 mg/mL
BSA	60 mg/mL

Form-GE02-15 (Rev. 04)

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■ Precision

Single-site study

ichroma™ IGRA-TB 25 were tested with the 3 different Lots by the same person at the same site in duplicate 2 times a day for 20 days.

Between person

Three different people test the standard materials 2 times for 5 days.

Between site

At three different sites each, the standard materials are tested 2 times for 5 days.

Between reader

Three different readers test the standard materials 2 times for 5 days.

Single-site study				
Standard material	Single-site study		Between person	
	Positive No./ Total No.	Positive rate	Positive No./ Total No.	Positive rate
Neg.	0 / 240	0%	0 / 30	0%
Low Pos.	240 / 240	100%	30 / 30	100%
Mid Pos.	240 / 240	100%	30 / 30	100%
Standard material	Between site		Between reader	
	Positive No./ Total No.	Positive rate	Positive No./ Total No.	Positive rate
Neg.	0 / 30	0%	0 / 30	0%
Low Pos.	30 / 30	100%	30 / 30	100%
Mid Pos.	30 / 30	100%	30 / 30	100%

■ Clinical performance

		Comparator A		Total
		Pos.	Neg.	
ichroma™	Pos.	102	6	108
IGRA-TB 25	Neg.	23	232	255
Total		125	238	363
Positive Percentage Agreement (PPA)		81.6% (95% C.I 73.9 ~ 87.4%)		
Negative Percentage Agreement (NPA)		97.5% (95% C.I 94.6 ~ 98.8%)		
Overall Percentage Agreement (OPA)		92.0% (95% C.I 88.8 ~ 94.4%)		
* Cohen's kappa (K)		0.817 (95% C.I 0.754 ~ 0.881) [very good agreement]		

*<Analysis of kappa statistics>

- 0.000 ~ 0.200: poor agreement
- 0.201 ~ 0.400: fair agreement
- 0.401 ~ 0.600: moderate agreement
- 0.601 ~ 0.800: good agreement
- 0.801 ~ 1.000: very good agreement

REFERENCES

1. Mahomed, H., et al. "Comparison of Mantoux skin test with three generations of a whole blood IFN-γ assay for tuberculosis infection." The International Journal of Tuberculosis and Lung Disease 10.3 (2006): 310-316.
2. ECDC. 2011. Use of interferon-gamma release assays in support of TB diagnosis

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
	Authorized representative of the European Community
	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

For technical assistance, please contact:

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