ichroma™ IGRA-TB

Latent Tuberculosis
made simple
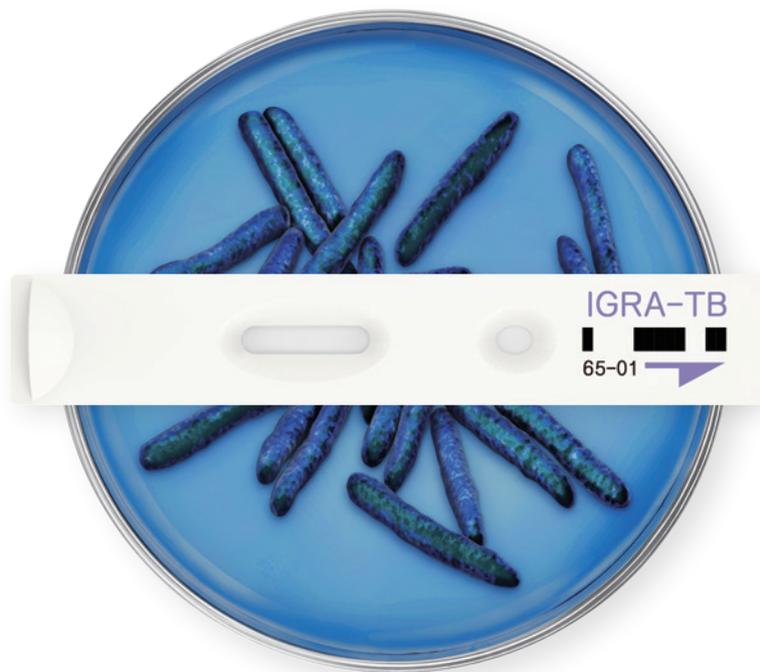
A Solution That Offers the Easiest, Fastest, and Most Convenient Way to Assist in the Diagnosis of Latent Tuberculosis Infection

Scan this QR Code to watch our video
for the ichroma™ IGRA-TB
Or go to: https://bit.ly/49MG1w9

To end Active TB,
Diagnosis of Latent TB is the **Key**

Continuing the Fight:
Tuberculosis and Global Health [1]

about
2 billion
is infected with
Mycobacterium tuberculosis
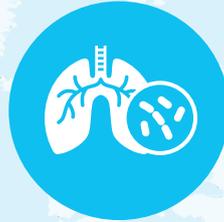
Over
### 10 million
continue to fall ill with
TB every year

Over
1.3 million
die due to
tuberculosis

A huge number of LTBI is continue to lead
to TB incidence and deaths

Latent TB: Not Easy to Notice

After infection, the immune system locks Mtb inside a granuloma, resulting in no symptoms or infectiousness, making it hard to detect without the right test.

If the right test is performed, preventive treatment is possible. This can reduce the risk of developing TB by up to 90% and save a significant amount of money. [2,3]

40X ~ 1,200X

Latent TB

Active TB
(Including MDR/XDR-TB)
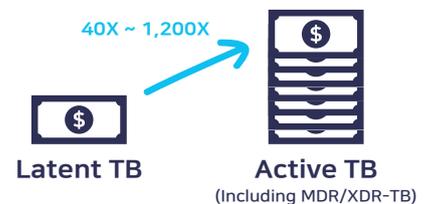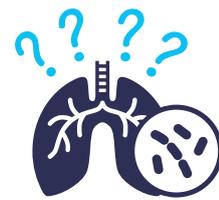
We offer a solution - the right test to gain insight into who is infected through an individual's immune response to Mtb

Experience the fast and reliable insights
with ichroma™ IGRA-TB

Unlocking Simplicity and Reliability in Latent TB Detection

Fast & Efficient
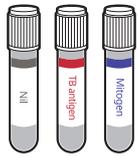
Optimal Results with 3 Tubes:
Achieve the best outcomes without unnecessary complexity.
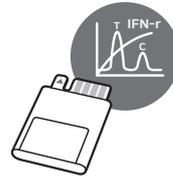
No Calibration Needed:
Streamline the process by eliminating calibration steps.

Test Even a Single Patient:
Start testing immediately,
no matter the patient count.
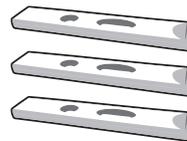
Rapid Results in 15 Minutes:
Get quick answers to
move forward faster.

Simple & Convenient

1 Dispense venous blood into culture tubes

NiL   TB   Mito

💧 Each 1 mL (N ▸ A ▸ M)

2 Incubate for 20±4 hours

37 ℃

3 Centrifuge for 15 minutes

⏳ 15 min
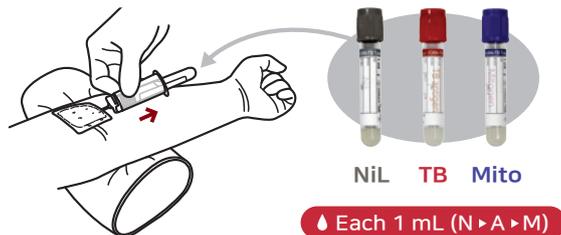
4 Interferon gamma release assay (IGRA)

N A M   N   A   M   N A M   N A M
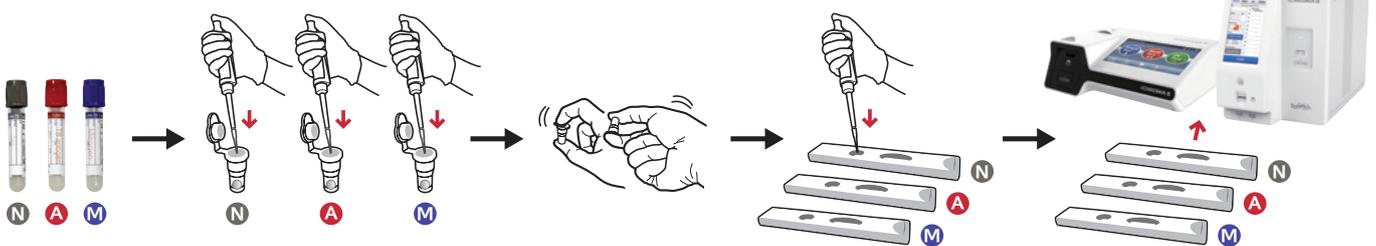
*Please refer to the insert for the ichroma™ M2 / Ichroma™-50 manual.

Clinical performance

		Comparator A		Total
		Positive	Negative	
ichroma™ IGRA-TB	Positive	102	6	108
	Negative	23	232	255
Total		125	238	363

Overall Percentage Agreement:	92.0% (95% C.I. 88.8 ~ 94.4%)
Positive Percentage Agreement:	81.6% (95% C.I. 73.9 ~ 87.4%)
Negative Percentage Agreement:	97.5% (95% C.I. 94.6 ~ 98.8%)
Cohen's kappa (κ):	0.817 (95% C.I. 0.754~0.881); "Very good" agreement

* This data was used to obtain approval for domestic use from South Korea Ministry of Food and Drug Safety (MFDS, Korean FDA).

Specification

Blood collection tubes	ichroma™ IGRA-TB Tube	
Assay type	IGRA	
Sample type	Whole blood	
Storage	2-30℃ (up to 20 months)	
Box content	50 Nil tubes 50 TB antigen tubes 50 Mitogen tubes	100 Nil tubes 100 TB antigen tubes 100 Mitogen tubes

Cartridge	ichroma™ IGRA-TB 25	ichroma™ IGRA-TB
Assay type	TRF-LFA	
Sample type	Plasma (from ichroma™ IGRA-TB Tube)	
Sample volume	50 μL	
Reaction time	15 min	
Storage	2-30℃ (up to 20 months)	
Box content	150 Cartridges 150 Detector tubes 6 Detector diluents **(for testing 50 patients)**	300 Cartridges 300 Detector tubes 12 Detector diluents **(for testing 100 patients)**
Platform	ichroma™ II / III / M2	ichroma™-50

Ordering information

Reagent

ichroma™ IGRA-TB Tube	CFPO-206	150 T/Box 300 T/Box
ichroma™ IGRA-TB 25	CFPC-86-1	150 T/Box
ichroma™ IGRA-TB	CFPC-86	300 T/Box
Boditech IGRA-TB Control	CFPC-294	Set

Analyzer

ichroma™ II	FPRR021	Set
ichroma™ III	FPRR037	Set
ichroma™ M2	FPRR031	Set
ichroma™-50	FPRR022	Set

Boditech IGRA-TB control is traceable to 1st WHO International standard (hunman IFN-γ, #Gg 23-907-530); Not included.

References
1) World Health Organization, Global tuberculosis report 2023
2) National TB Elimination Programme, Guidelines for the programmatic management of Tb preventive therapy in India, 2021
3) Centers for Disease Control and Prevention, CDC Estimates for Latent TB and TB Treatment Cost, 2020

Boditech Med ichroma™ IGRA-TB in Articles
• Hur YG et. al., A Feasibility Study for Diagnosis of Latent Tuberculosis Infection Using an IGRA Point-of-Care Platform in South Korea. Yonsei Med J. 2019. 60:375-380. doi: 10.3349/ymj.2019.60.4.375. PMID: 30900424.
• Hamada Y, et. al., Tests for tuberculosis infection: landscape analysis. Eur Respir J. 19:2100167. 2021. doi: 10.1183/13993003.00167-2021. PMID: 33875495.
• Lee HH et. al., Evaluation of a lateral flow assay-based IFN-γ release assay as a point-of-care test for the diagnosis of latent tuberculosis infection. Clin Rheumatol. 2021. 40:3773-3781. doi: 10.1007/s10067-021-05663-1. PMID: 33666781.
• Kweon OJ et. al., Performance evaluation of newly developed fluorescence immunoassay-based interferon-gamma release assay for the diagnosis of latent tuberculosis infection in healthcare workers. J Microbiol Immunol Infect. 2021. S1684-1182(21)00104-3. doi: 10.1016/j.jmii.2021.05.007. PMID: 34127404.
• Migliori GB et. al., The definition of tuberculosis infection based on the spectrum of tuberculosis disease. Breathe 2021; 17: 210079. DOI: 10.1183/20734735.0079-2021.
• WHO Global Tuberculosis Report (2020), p 179 FIG. 9.2 An overview of progress in the development of TB diagnostics, August 2020. https://apps.who.int/iris/bitstream/handle/10665/336069/9789240013131-eng.pdf