

Specification

Product Name	AFIAS IGRA-TB	
Assay type	TRF-LFA	
Sample type	Plasma (available Lithium Heparin only)	
Sample volume	100 µL	
Reaction time	15 min	
Storage	2-30°C (up to 20 months)	
Platform	AFIAS-10	



IGRA-TB control is traceable to 1st WHO International standard (human IFN- γ , #Gg 23-901-530); Not included.

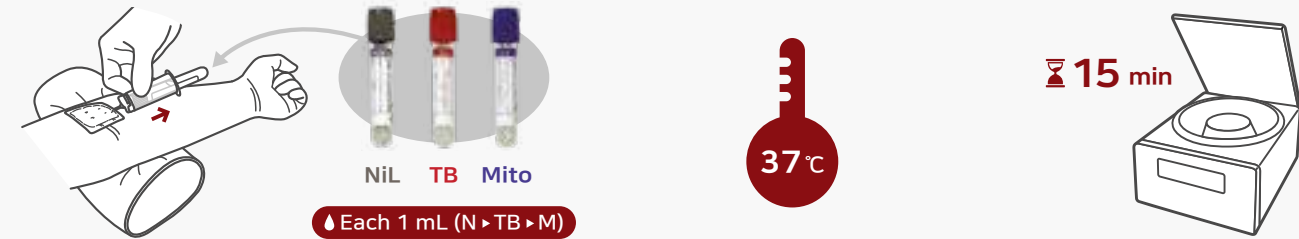
Ordering Information

AFIAS-10 Instrument	56398	Unit
AFIAS IGRA-TB	56618	24 tests/box
AFIAS IGRA-TB TUBE	56915	24 tests/box
IGRA-TB QC	56817	Unit

*Nil, TB-Ag, & Mitogen tubes are 8 each

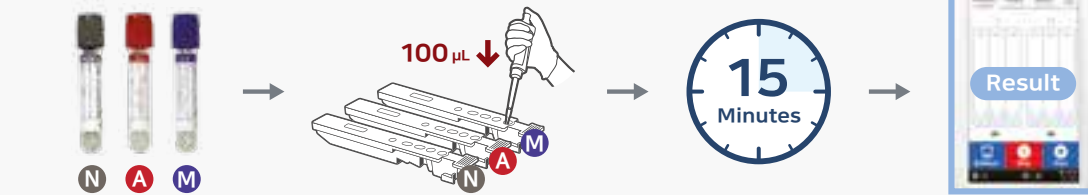
Test procedures

- 1 Dispense venous blood into culture tubes
- 2 Incubate for 20±4 hours
- 3 Centrifuge for 15 minutes



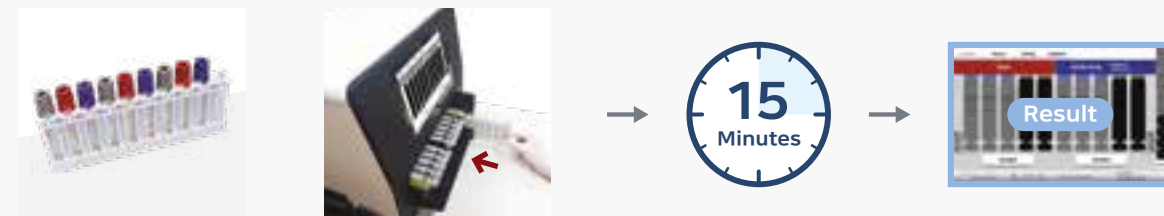
Dispensing each sample into each cartridge (AFIAS-6 / AFIAS -10)

- 4 Dispense each sample into each cartridge



Mounting the tubes to the rack (AFIAS-10)

- 4 Mount the tubes to the rack
- 5 Mount the rack to the device



All-in-One cartridge for AFIAS platform

- All the reagents for assay contained
- Over 50 test parameters
- Ready-to-use cartridge

AFIAS-10 can provide

- Convenient testing procedure to users
- High throughput results with various parameters
- Multi testing performance
- Prompt result derived from medical decision
- Quick transmission of medical information



For Professionals only

Specifications

Model	AFIAS-10
Ordering Information	56398
Dimensions	426 x 443 x 395 mm
Weight	20 kg
Analyzer Input	100~240V AC, 50/60Hz, 2.6-1.0 A
User Interface	10.1" TFT LCD touch screen
Data Output	Internal Printer / RS232 port
Operating Temperature	15-35 °C
Connectivity	<ul style="list-style-type: none"> • RS232C • 3 USB port • 1 mini USB port • LAN port • SD card slot

References

- 1) Tuberculosis; the fact sheet. (Oct. 14, 2020). <https://www.who.int/news-room/fact-sheets/detail/tuberculosis>
- 2) Gopaldaswamy R and Subbian S. Corticosteroids for COVID-19 Therapy: Potential Implications on Tuberculosis (2021). Int J Mol Sci. 22: 3773. doi: 10.3390/ijms22073773. PMID: 33917321
- 3) Boulle A et. al., Risk factors for COVID-19 death in a population cohort study from the Western Cape Province, South Africa (2020). Clin Infect Dis. :ciaa1198. PMID: 32860699; PMCID: PMC7499501.
- 4) The potential impact of the covid-19 response on tuberculosis in high-burden countries: A modeling analysis (WHO World Stop TB report, May 6, 2020) http://www.stoptb.org/assets/documents/news/Modeling%20Report_1%20May%202020_FINAL.pdf
- 5) Aznar ML et. al., Impact of the COVID-19 pandemic on tuberculosis management in Spain (2021). Int J Infect Dis. 108:300. doi: 10.1016/j.ijid.2021.04.075. PMID: 33930543
- 6) Saunders MJ and Evans CA. COVID-19, tuberculosis and poverty: preventing a perfect storm (2020). Eur Respir J. 56:2001348. PMID: 32444399. doi:10.1183/13993003.01348-2020
- 7) Gopaldaswamy R and Subbian S. Corticosteroids for COVID-19 Therapy: Potential Implications on Tuberculosis (2021). Int J Mol Sci. 22: 3773. doi: 10.3390/ijms22073773. PMID: 33917321
- 8) Chan Y et. al., Active or latent tuberculosis increases susceptibility to COVID-19 and disease severity (2020). medRxiv. doi: <https://doi.org/10.1101/2020.03.10.20033795>
- 9) Mack U et. al., LTBI: latent tuberculosis infection or lasting immune responses to M. tuberculosis? A TBNET consensus statement (2009). Eur Respir J. :33: 956-73. doi: 10.1183/09031936.00120908. PMID: 19407047.

AFIAS IGRA-TB Novel Laboratory test for Latent TB Diagnosis

- **Innovative technological advance**
Fluorescent Immunoassay based on lateral flow.
- **Objective**
Unlike TB skin test, AFIAS IGRA-TB is a controlled and objective assay.
- **Single visit test**
AFIAS IGRA-TB requires only one visit for patient.
- **Effective in BCG-vaccinated patients**
Unaffected by BCG vaccination.
- **On-demand testing**
1 patient, 1 test, 1 result
- **Ready-to-use reagents**



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AFIAS IGRA-TB

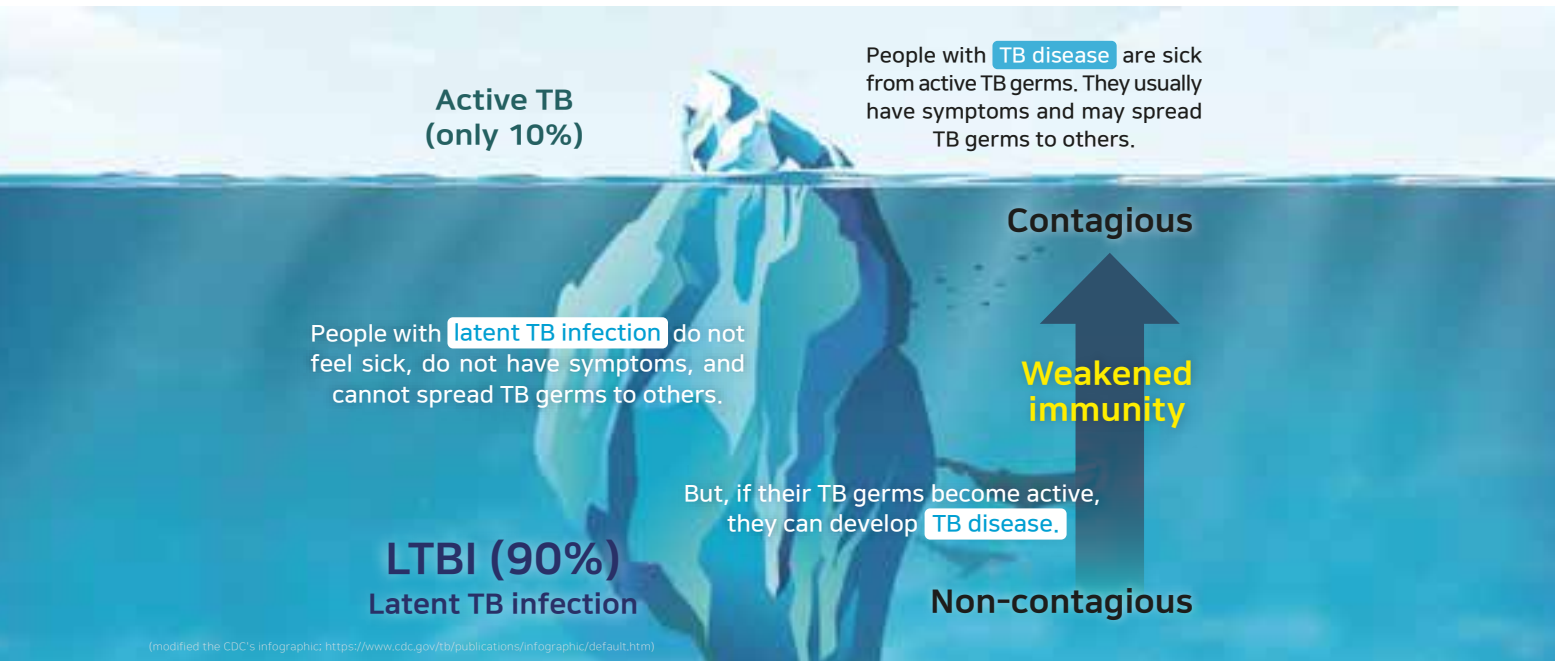
Affordable and Accessible Test for Latent TB diagnosis

AFIAS IGRA-TB

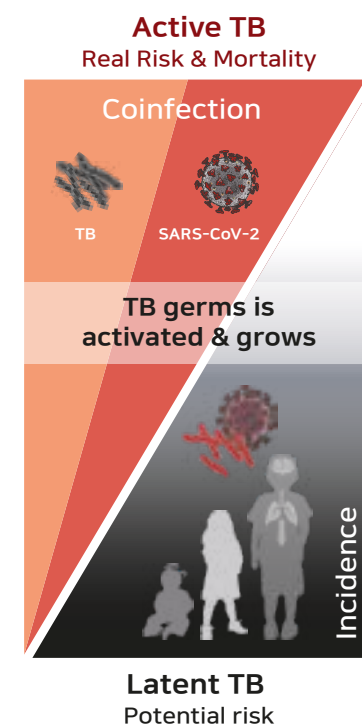
Cost-efficient Lab test for Latent TB Diagnosis

TB Disease: Only the Tip of the Iceberg [1]

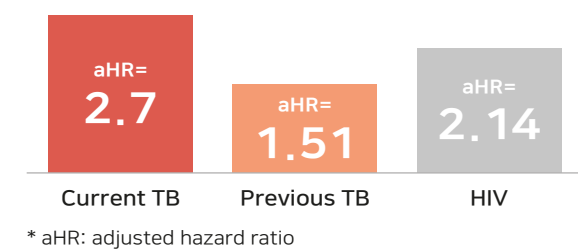
Tuberculosis (TB) is the leading cause of death from a single infectious disease worldwide to the extent that WHO recommends the development of **cost-effective diagnostics to eradicate latent TB** (90%, undiagnosable), which underlies active TB (10%, diagnosable).



Current TB can increase COVID-19 mortality [2]



The **current COVID-19 pandemic** has collapsed near the 80% of global control for tuberculosis (TB), and the fatal risk of TB outbreak and **co-infection** with COVID-19 will act as a global double burden.



TB increased the risk of COVID-19 more than 1.5-fold, even in those who had recovered from TB already compared to 2.7-fold in current TB. [3]

In the COVID-19 pandemic, children will be the biggest victims of respiratory infections and tuberculosis.

How the COVID-19 Pandemic Exacerbates the Tuberculosis Outbreak ; dual burden of TB & COVID-19 [4-8]

- Public health & socioeconomic exhaustion
- Promote reactivation of latent TB to active TB
- The collapse of essential TB treatment & services
- Significant increase in the biological and clinical risk of co-infection
- Misdiagnosis or missing the one of the infections in coinfection cases of COVID-19 and tuberculosis

Comparisons of IGRA tests for diagnosis of Latent TB

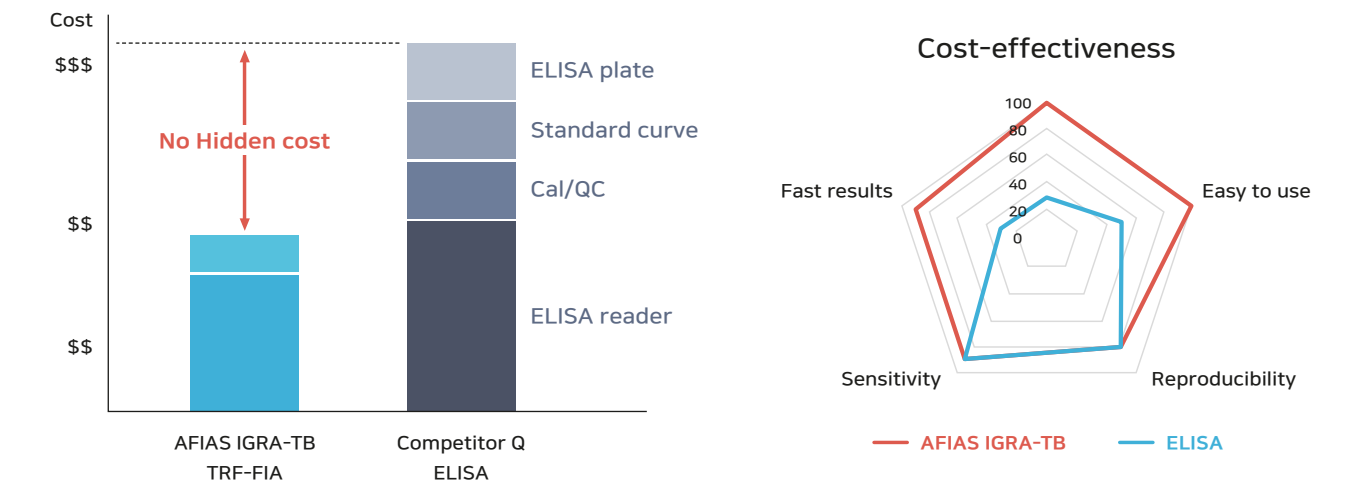
Despite the improved performances compared to the Tuberculin skin test (TST), current IGRA tests are cumbersome, inefficient, and uneconomical. [9]

	TST *	IGRA tests		
		ELISpot	ELISA	RDT (Fluorescent-LFIA)
Commercial products	-	Competitor A	Competitor B	AFIAS IGRA-TB
Standard curve for Calibration	None	Yes	Yes	No needed preserved in ID-chip
Test substrate	Skin	Purified PBMC	Whole blood	Whole blood
Time required Incubation (CMI)	~72 h	~20 h	~24 h	~24 h
Time required for Result (IGRA)		4 h	2~3 h	15 min
Result (units)	mm (millimeters)	IFN-r spot forming cells	IU/mL	IU/mL
Equipment	None	ELISpot reader	ELISA reader	AFIAS platform
Performance	Very low sensitivity and specificity	Sensitivity > ELISA	Specificity > ELISpot	Comparable to ELISA
Requirement of trained Staff (proficiency)	★ Highly trained	★ Highly trained	★★ trained	★★★★★ Anyone
Storage condition	2~8°C (cold chain)	2~8°C (cold chain)	2~8°C (cold chain)	2~30°C (20 Months)
Price/test	★★★★★ Affordable (about 1/10 of ELISA)	★★ Expensive	★ Very expensive	★★★★ Cost-efficient

* Tuberculin skin test (TST)

All-inclusive kit & No hidden cost

The **AFIAS IGRA-TB** with standardized and faster results, offers a solution easy to use for laboratories.



Affordable and Accessible Test for Latent TB diagnosis

