

◆◆ The Third-party Evaluation Cases ◆◆

Precision: CV < 5%

Between Day Precision ➡ Analyte: TB-IGRA

Machine/ Model: Autobio A1000

	CONTROLS	Level 1	Level 2
	Mean	0.525	3.097
	Reference Range	0.393-0.657	2.323-3.871
	1	0.529	2.792
	2	0.508	2.760
DAY 1	3	0.492	2.816
	4	0.494	2.910
	5	0.474	2.650
	6	0.458	2.701
DAY 2	7	0.494	2.487
	8	0.489	2.823
	9	0.501	2.831
DAY 3	10	0.502	2.754
	11	0.491	2.939
	12	0.525	2.845

	CONTROLS	Level 1	Level 2
	Mean	0.525	3.097
	Reference Range	0.393-0.657	2.323-3.871
	13	0.535	2.865
	14	0.527	2.850
DAY 4	15	0.485	2.860
	16	0.499	2.983
	17	0.479	2.879
DAY 5	18	0.543	2.902
	19	0.544	2.943
	20	0.546	2.817
	n	20	20
	Mean	0.506	2.820
	SD	0.025	0.113
	CV (%)	5.00%	4.00%

High coincidence rate between two CLIA method

Figure 1. Raw data in the clinical evaluation

NO.	Sex	Age	Department	Clinical Diagnosis	Autobio	Dia*
1	F	53	Centro Hospitalar Leiria/Microbiologia		+	+
2	F	27	Centro Hospitalar Leiria/Microbiologia		-	-
3	F	34	Centro Hospitalar Leiria/Microbiologia		-	-
4	M	80	Centro Hospitalar Leiria/Microbiologia		-	-
5	F	55	Centro Hospitalar Leiria/Microbiologia		-	-
6	F	75	Centro Hospitalar Leiria/Microbiologia		-	-
7	F	55	Centro Hospitalar Leiria/Microbiologia		+	+
8	F	36	Centro Hospitalar Leiria/Microbiologia		+	+
9	F	55	Centro Hospitalar Leiria/Microbiologia		+	+
10	F	64	Centro Hospitalar Leiria/Microbiologia		-	-
11	F	49	Centro Hospitalar Leiria/Microbiologia		-	-
12	F	55	Centro Hospitalar Leiria/Microbiologia		-	-
13	F	30	Centro Hospitalar Leiria/Microbiologia		-	-
14	M	76	Centro Hospitalar Leiria/Microbiologia		Inconclusivo	+

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Autobio TB-IGRA (CLIA)

Bring Revolution In Tuberculosis Detection

Autobio Diagnostics Co., Ltd.

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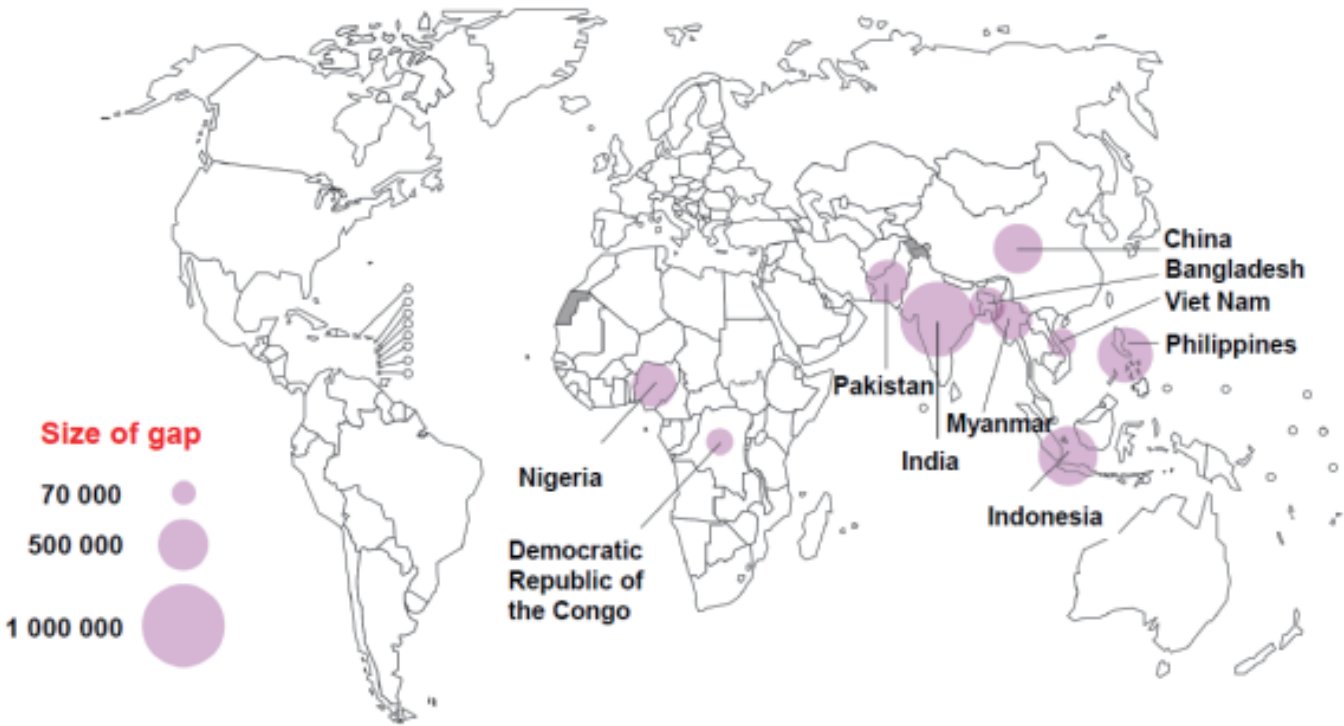
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Key Facts You Should Know About Tuberculosis

- A total of 1.3 million people died from TB in 2022 (including 167 000 people with HIV).  
Worldwide, TB is the second leading infectious killer after COVID-19 (above HIV and AIDS).
- In 2022, the largest number of new TB cases occurred in WHO ' s South-East Asian Region (46%), followed by the African Region (23%) and the Western Pacific (18%). Around 87% of new TB cases occurred in the 30 high TB burden countries, with more than two-thirds of the global total in Bangla-  
desh, China, Democratic Republic of the Congo, India, Indonesia, Nigeria, Pakistan and the Philippines.

10 countries account for 71% global gap between TB incidence and reported cases



Reference: WHO Global Tuberculosis Report 2023

According to WHO, from global perspective, increased coverage of diagnosis and treatment of particular importance in these countries.

Benefits of Autobio TB-IGRA

More sensitive in clinical use

- ◆ Significantly improve the detection capacity of TB infection, especially for the auxiliary diagnosis of tuberculosis.
- ◆ Testing with **whole blood** to effectively detect tuberculosis outside the lungs and latent TB infections.
- ◆ **Eliminating interference from BCG** and non-tuberculosis which can reduce false positive rates.
- ◆ Detectable in active TB disease and latent infection.

Automatic and labor-free

- ◆ Direct onboard detection after incubation stimulation without manual operation.
- ◆ Detection time is around 34 minutes, up to 40 patients/hour (A 2000 Plus).
- ◆ Fully automatic interpreting results and upload directly to LIS.
- ◆ Onboard calibration is valid for 28 days.

Cost effective

- ◆ No extra cost for consumption of special tubes.

Traditional Method of TB Test

	Bacteriological diagnosis		Molecular detection	immunologic diagnosis	
	Phlegm smear microscopic exam	Bacterial culture	PCR	Antibody detection	Tuberculin skin test
Advantages	Low cost	Qualitative and semi-quantitative analysis	High sensitivity	Convenient sampling and simple operation	The latent infection of tuberculosis can be diagnosed
Disadvantages	<ul style="list-style-type: none"><li>◆ Low sensitivity</li><li>◆ Hybrid bacterium contaminants</li><li>◆ Sampling difficulty</li></ul>	<ul style="list-style-type: none"><li>◆ Low detection rate</li><li>◆ Time-consuming: It took a long time (2-6 weeks). Sampling of patients with extrapulmonary tuberculosis is difficult</li></ul>	<ul style="list-style-type: none"><li>◆ High cost and complex operation</li><li>◆ High requirements for experimental conditions and technical personnel</li><li>Sampling of patients with extrapulmonary tuberculosis is difficult</li></ul>	<ul style="list-style-type: none"><li>◆ Patients have different antibody responses suggesting that they have active TB even when they do not. Antibodies may also develop against other organisms, which again could wrongly indicate they have active TB, making test results unreliable.</li></ul>	<ul style="list-style-type: none"><li>◆ Unable to distinguish non-tuberculous mycobacterium infection due to interference of BCG vaccine</li><li>Follow-up is required after 48-72 hours to determine the results.</li><li>False-positive tuberculin tests occur in persons who have been infected with nontuberculous mycobacteria and in persons who have received BCG vaccine.</li><li>HIV-infected persons may have a compromised ability to react to tuberculin skin tests because of cutaneous anergy associated with progressive HIV immunosuppression</li></ul>

Difficulties and Demands in Detection of TB in Labs

- All solved by TB IGRA
- 01

The diagnosis of unknown cause fever, hyp immunity, and immunosuppression patients.
- 02

Differential diagnosis of extrapulmonary tuberculosis
- 03

The diagnosis of HIV infection in early stage, renal dialysis, and organ transparent patients.
- 04

Assist diagnosis of children's tuberculosis.
- 05

Screening for high risk of tuberculosis infection population.

Specification

	Autobio	T s*	QF*	Li*	Vi*
Method principle	CLIA	T-spot ELISA	ELISA	CLIA	ELFA
Test time	34 min	2-3 hour	3 hour	/	43 min
Calibrator	6 * 2	/	4 * 2	2 * 3	1 * 2
Calibration interval	28 day	/	96 well plate	28 day	56 day
	Or new lot			Or new lot	Or new lot
Detection method	3T	4T	4T	4T	3T
Biomaterial	T : EAST-6, CFP-10	Panel A : EAST-6	TB1 : EAST-6 , CFP-10	TB1 : EAST-6 , CFP-10	T : EAST-6, CFP-10
		Panel B : CFP-10	TB2 :EAST-6, CFP-10, TB7.7, TB37.6	TB2 :EAST-6, CFP-10, TB7.7, TB37.6	
Stimulating cell type	T cell	T cell	CD4* , CD8*	CD4* , CD8*	T cell
Sample storage time before incubation	24 hours at room temperature	8 hours at room temperature	16 hours at room temperature	16 hours at room temperature	8 hours at room temperature
		Can be extended up to 54 hours by reagent	Up to 53 hours	Up to 53 hours	31 hours at 2-8℃
Result interpretation	Automatic interpretation	Manual interpretation	Automatic ( By independent software )	Automatic ( By independent software )	Automatic interpretation
Sampling	Normal tubes	Normal tubes	Special tubes	Special tubes	Normal tubes
Centrifugation	×	√	√	×	×