

# The Need

- In 2022, an estimated 10.6 million people worldwide developed tuberculosis, with an incidence rate of 133 per 100,000 population<sup>(1)</sup>.
- In 2022, 6.2 million cases of pulmonary tuberculosis were diagnosed globally, of which 37% were not confirmed bacteriologically<sup>(1)</sup>.
- TB caused 1.3 million deaths globally in 2022, nearly double the deaths caused by HIV/AIDS<sup>[1]</sup>.
- Early and accurate detection of TB is essential for improving case management and significantly preventing transmission.

## **Ongoing Challenges**

- In resource-limited settings, the lack of advanced diagnostic technologies delays accurate testing, leading to delayed treatment and misdiagnosis.
- Traditional TB diagnostic methods, like sputum, smears and cultures, take too long, delaying treatment and increasing transmission risk.
- Outdated infrastructure in low- and middle-income countries hampers large-scale TB testing due to old equipment, insufficient training, and supply chain issues.
- Diagnosing TB in children is challenging due to the inability to produce sputum, low bacterial load, and reliance on non-specific clinical signs, which often leads to delayed diagnosis and treatment.
- Molecular POCT offers rapid results, but high costs and operational complexity limit its widespread use in many regions.

#### The Solution

PortNAT TB Assay provides the convenience of on-demand testing with rapid and precise results. Key benefits include:

- High-quality results within approximately 30 minutes
- · Ability to perform testing anytime, anywhere
- · Less than 1 minute of handling time, with no specimen preparation required
- Utilize a power bank for operation in locations without electrical supply
- Supports ambient temperature transportation

PortNAT TB Assay, conducted on Ustar's PortNAT® system, ensures accurate results, simplifies the testing process, and offers the flexibility to deliver results when and where they are needed to meet timely testing demands.

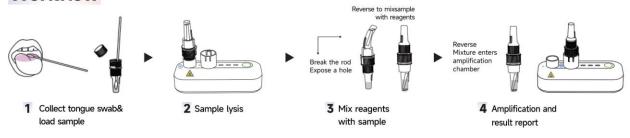


## The Impact

PortNAT TB Assay delivers on-demand testing with point-of-care results within approximately 30 minutes, allowing healthcare providers to offer care and treatment directly at the point of need.

1	Accelerating diagnosis and treatment to improve workflow effectiveness.
2	Rapidly detecting possible cases to minimize the risk of community transmission.
3	Cutting down on staff time and training demands.
Л	Offering timely insights to guide vaccination and prevention efforts

#### Workflow



### **Performance**

Specificity	93.30%	Overall percent agreement	96.80%
Sensitivity	100.00%	LOD for the assay is 400 CFU/mL	
Product	PortNAT TB Assay	Shelf life	12 months
Sample type	Tongue Swab	Storage conditions	2-8°C
Specification	20 Tests/box	Transport conditions	Ambient
Applicable instrument	PortNAT Molecular Analyzer	'	

[1]Global Tuberculosis Report 2023.

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