

# NEAR POINT-OF-CARE TESTS FOR TUBERCULOSIS: WHAT YOU NEED TO KNOW

## WHO-recommended rapid diagnostics for tuberculosis detection

The World Health Organization (WHO) recommends the use of rapid diagnostics for initial diagnosis of tuberculosis (TB) and for the detection of drug resistance to minimise delays in starting treatment.<sup>1</sup> These initial TB diagnostic tools are broadly classified as WHO-recommended rapid diagnostics (WRDs), defined as diagnostic tests that directly target mycobacterial DNA (molecular assays) or its cell components (biomarker-based assays).

The WRDs—whether or not they include drug-resistance detection—are organised into several classes based on their complexity and operational requirements: high complexity nucleic acid amplification tests (HC-NAAT), moderate complexity automated NAAT (MC-aNAAT), low complexity automated NAAT (LC-aNAAT), low complexity manual NAAT (LC-mNAAT), near point-of-care (nPOC) and true POC (tPOC) (see Annex 1 for the full WHO classification of WRDs for TB).

Informed by Médecins Sans Frontières (MSF)'s extensive operational experience in TB diagnosis and care, this factsheet provides an overview of key technical and operational considerations for the implementation of emerging near point-of-care nucleic acid amplification tests (nPOC-NAATs) for TB. It also includes a focused description of the MiniDock Ultra technology of Guangzhou Pluslife Biotech Co. (China), the first TB nPOC-NAAT test available for procurement through the Global Fund and the Global Drug Facility (GDF). The conclusion outlines recommendations for national TB programmes and other actors to support the effective and sustainable roll-out of this new class of TB diagnostics.



The tuberculosis (TB) ward at the MSF hospital in the Bentiu camp for internally displaced persons (IDP), Unity State, South Sudan.

<sup>1</sup> World Health Organization (WHO). Operational Handbook module 3: diagnosis. TB tests with WHO recommendations. Geneva: WHO; available from: <https://tbksp.who.int/en/node/3097>

## Swab-based near point-of-care tests for tuberculosis

Near point-of-care nucleic acid amplification tests (nPOC-NAAT) are a recently defined WHO class of molecular diagnostics for TB. These tests are designed to be used at the peripheral levels of the health system and differ from other WHO-recommended molecular diagnostics due to their lower operational complexity, minimal training requirements, and their ability to be used without laboratory infrastructure. nPOC-NAATs are engineered to tolerate high temperature and humidity conditions, enabling reliable use in resource-limited settings (see Annex 1).

Easy-to-collect, non-sputum samples—such as tongue swabs—aim to overcome the limitations of sputum collection. This development is especially important for people who have difficulty producing sputum, such as young children and people living with HIV. In August 2024, the WHO updated its target product profile (TPP) for TB diagnosis and drug-resistance detection to include non-sputum sample types.<sup>2</sup>

In November 2025, the WHO convened a Guideline Development Group (GDG) meeting to review evidence on (1) the use of nPOC-NAAT tests for the diagnosis of TB, (2) new non-sputum sample types, including tongue swabs, and (3) a novel testing strategy based on pooling of respiratory samples for LC-aNAAT.

The WHO is expected to issue guidance on these new testing options in early 2026.

International donors are increasingly and rapidly supporting countries to implement nPOC-NAAT tests. For instance, Unitaids has launched a call for improving access to diagnostics through the adoption of tools and approaches, including emerging technologies that are entirely new to the market.<sup>3</sup> The Children's Investment Fund Foundation (CIFF) has committed US\$50 million to the Global Fund to accelerate the introduction and roll-out of innovative diagnostics for TB.<sup>4</sup>

## The MiniDock Ultra from Pluslife

The MiniDock Ultra device and its MTB Nucleic Acid Test Card, manufactured by Pluslife (China), are the first nPOC-NAAT platform eligible for procurement through the Global Fund. In July 2025, the test received an Expert Review Panel for Diagnostics (ERPD) listing, a WHO-hosted independent panel of technical experts that assesses the risks and benefits of diagnostics that are not yet WHO-prequalified or authorised by a stringent regulatory authority (SRA).<sup>5,6</sup> The test is also available for procurement through the Global Drug Facility (GDF), the world's largest supplier of quality-assured TB medicines, diagnostics, and related support, operating under the Stop TB Partnership.<sup>7</sup>

The portable MiniDock Ultra device detects *Mycobacterium tuberculosis* (MTB) DNA from either sputum swabs or tongue swabs, delivering results within 25 minutes. Although the device does not contain a built-in battery, it can be operated using an external Universal Serial Bus (USB) power bank.

### MiniDock Ultra (Pluslife)



#### What it can do

- Detect TB in both sputum swabs and tongue swabs
- Operate as a portable device, suitable for decentralised use
- Provide results within 25 minutes
- Designed for challenging environments (up to 40°C temperature and 80% humidity) \*



#### What it cannot do

- Tongue swabs cannot replace sputum-based testing as reference standard
- Detect resistance to rifampicin or other TB medicines
- Limited throughput (one sample per run)
- Current shelf life of the test cards is 13 months †

\* Yet to be assessed in real-world conditions

† Stability studies to extend the shelf life are ongoing

<sup>2</sup> World Health Organization. Target product profile for tuberculosis diagnosis and detection of drug resistance. Geneva; 2024. [cited 2026 Jan 20]. Available from: <https://iris.who.int/handle/10665/378358>

<sup>3</sup> Unitaids. Improving access to diagnostics through the adoption of tools and approaches that drive integration [Internet]. 2025 Oct 23 [cited 2026 Jan 23]. Available from: <https://unitaid.org/call-for-proposal/improving-access-to-diagnostics-through-the-adoption-of-tools-and-approaches-that-drive-integration/>

<sup>4</sup> Global Fund. CIFF commits additional US\$50 million to the Global Fund to scale up TB diagnosis. 23 September 2025 [cited 2026 Jan 20]. Available from: <https://www.theglobalfund.org/en/news/2025/2025-09-23-ciff-commits-additional-us-50-million-global-fund-scale-up-tb-diagnosis/>

<sup>5</sup> Pluslife. Pluslife MiniDock MTB Test Receives ERPD Listing. 2025 Jul 14 [cited 2026 Jan 20]. Available from: <https://www.pluslife.com/newsinfo/1066491.html>

<sup>6</sup> Global Fund. List of TB diagnostic test kits and equipment classified according to the Global Fund Quality Assurance Policy. Version 24. 30 September 2025 [cited 2026 Jan 20]. Available from: [https://www.theglobalfund.org/media/0dyh31gs/psm\\_productsdiagnosticstb\\_list\\_en.pdf](https://www.theglobalfund.org/media/0dyh31gs/psm_productsdiagnosticstb_list_en.pdf)

<sup>7</sup> Stop TB Partnership, Global Drug Facility (GDF). Diagnostics, Medical Devices & Other Health Products Catalog. Geneva: Stop TB Partnership; 2021 Nov 1 [cited 2026 Jan 20]. Available from: [https://www.stoptb.org/sites/default/files/documents/GDF\\_Diagnostics\\_and\\_MD\\_Catalog.pdf](https://www.stoptb.org/sites/default/files/documents/GDF_Diagnostics_and_MD_Catalog.pdf)

The currently available MTB Nucleic Acid Test Card detects TB only, while a test card capable of detecting rifampicin resistance is under development. Although compatible with sputum swabs, it also supports tongue-swab sampling, enabling testing people who are unable to produce sputum. Recent data from the Rapid Research in Diagnostics Development for TB Network (R2D2) indicate that the Pluslife MTB test on sputum swabs has similar accuracy to current sputum-based molecular tests.<sup>8</sup> Although sensitivity is lower on tongue swabs, its performance meets WHO TPP minimum accuracy thresholds\* for a non-sputum nPOC-NAAT in two studies<sup>8,9</sup> and close to minimum in one study.<sup>10</sup>

The MiniDock Ultra system is a multi-disease platform, with test cards available not only for TB but also for respiratory diseases (RSV, SARS-CoV-2, SARS-CoV-2/FluA/FluB, SARS-CoV-2/FluA/FluB/RSV), sexually transmitted infections (CT/NG/UU, TV/MG, GBS, HPV16/18/45), monkeypox virus (MPXV), and Group A Streptococcus (Strep A).

\* The WHO Target Product Profile (TPP) sets minimum required sensitivity of 80% for LC-aNAAT using non-sputum specimens and 75% for nPOC-NAAT, with a minimum specificity requirement of above 98% compared with liquid culture.<sup>11</sup>

### Pluslife MiniDock Ultra: price information

Item	Price †
MiniDock Ultra (PM001 Ultra)	\$ 155
Pluslife Thermolyse (WD002) ‡	\$ 180
MTB Nucleic Acid Test Card	\$ 3.60
MiniDock Ultra 5-Ports HUB §	\$ 90
MiniDock Ultra installation and training	\$ 400
MiniDock Ultra Warranty Extension - 1 year	\$ 40
MiniDock Ultra Warranty Extension - 2 years	\$ 60
Pluslife Thermolyse Warranty Extension - 1 year	\$ 40
Pluslife Thermolyse Warranty Extension - 2 years	\$ 60
600W Pluslife Portable UPS portable power station ¶	\$ 500
1200W Pluslife Portable UPS portable power station ¶	\$ 1000

† Listed prices are based on the Global Drug Facility catalogue, last accessed January 2026.<sup>12</sup>

‡ The Thermolyse instrument can process up to 3 samples simultaneously, with total run time of 5 min.

§ The MiniDock Ultra 5-Ports HUB allows simultaneous charging and connection of up to five devices.

|| Pluslife offers a two-year free warranty service.

¶ The MiniDock Ultra can also be connected to Uninterruptible Power Supply (UPS) from other suppliers.

### Pluslife MiniDock Ultra: performance data on sputum swabs and tongue swabs for TB detection

Year	Countries	Cohort	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Reference ‡‡
2025	India, Uganda, Vietnam	1050 participants ≥12 years with presumptive TB	Culture-based microbiological reference standard	Sputum swabs: 89.9% (80.2- 95.8%) Tongue swabs: 85.7% (75.3- 92.9%)	Sputum swabs: 98.2% (95.5- 99.5%) Tongue swabs: 100% (98.4-100%)	Steadman <i>et al.</i> <sup>8</sup>
2025	Cameroon	1,097 participants ≥15 years with presumptive TB	TB culture	Sputum swabs: 86% (79-91%) Tongue swabs: 76% (68-82%)	Sputum swabs: 98% (96-99%) Tongue swabs: 99% (98-99%)	Mbuli <i>et al.</i> <sup>9</sup>
2025	China	594 participants >18 years with presumptive TB	Composite microbiological reference standard	Sputum swabs: 94.2% (90.9-96.6%) Tongue swabs: 74.5% (69.1-79.4%)	Sputum swabs: 93.7% (90.3-96.1%) Tongue swabs: 96.0% (93.1-97.9%)	Wu <i>et al.</i> <sup>10</sup>

‡‡ Last searched January 2026, only publicly available data included

<sup>8</sup> Steadman A, Kumar KM, Asege L, Kato-Maeda M, Mukwatamundu J, Shah K, et al. Diagnostic accuracy of swab-based molecular tests for tuberculosis using near-point-of-care platforms: a multi-country evaluation. *EBioMedicine*. 2025 Nov;121:105991. [cited 2026 Jan 20]. doi:10.1016/j.ebiom.2025.105991.

<sup>9</sup> Mbuli C, Jean Bosco TF, Nsamenang R, Nestor B, Nguimfack G, Mbuli NN, et al. Diagnostic performance of the Pluslife MiniDock MTB and Molbio MTB Ultima assays to detect tuberculosis from tongue and sputum swabs among outpatients and in active case finding in Cameroon. *Clinical Infectious Diseases*. 2025 Dec 23; ciaf709. [cited 2026 Jan 21] doi:10.1093/cid/ciaf709.

<sup>10</sup> Wu Z, Yan L, Lai X, Yang J, Liang J, Ma X, et al. Diagnostic accuracy of a novel point-of-care tongue swab assay for pulmonary tuberculosis: a multicentre prospective study. *Clinical Microbiology Infection*. 2025 Nov 15; S1198-743X(25)00561-0. [cited 2026 Jan 20]. doi:10.1016/j.cmi.2025.11.010.

<sup>11</sup> World Health Organization. Target product profiles for tuberculosis diagnosis and detection of drug resistance. Geneva: World Health Organization; 2024 [cited 2026 Jan 20]. License: CC BY-NC-SA 3.0 IGO. Available from: <https://iris.who.int/server/api/core/bitstreams/0f3962a0-d382-4a17-b86f-6eb6208c9f87/content>

<sup>12</sup> Stop TB Partnership, Global Drug Facility (GDF). GDF Product Catalog. Geneva: Stop TB Partnership; [cited 2026 Jan 20]. Available from: <https://www.stoptb.org/what-we-do/facilitate-access-tb-drugs-diagnostics/global-drug-facility-gdf/products-catalog>



## What you need to know about swab-based nPOC-NAAT for TB

**Test sputum swabs when possible.** Publicly available data show that the sensitivity of nPOC-NAAT is higher with sputum swabs than with tongue swabs. Use sputum when available; if a good-quality sputum sample\* cannot be obtained, use tongue swabs.<sup>8,9,10</sup>

**Consider diagnostic yield, not only sensitivity.** Although the sensitivity of nPOC-NAAT can be lower than the standard of care (e.g. GeneXpert or other LC-aNAATs on sputum), the capability to perform testing closer to the communities, within primary health care settings, with a shorter turnaround time, lower costs, and simplified procedures along with the option to use tongue swabs when good-quality sputum samples are not available, may increase the overall number of people accessing TB testing. This improved reach could ultimately compensate for lower sensitivity.

**Remember other diagnostic pathways for TB.** Tongue-swab testing is more likely to miss TB in people with a low bacillary load (e.g., “very low” or “trace” in Xpert Ultra), which is common in children and people living with HIV. A negative swab nPOC-NAAT test result cannot exclude TB and people with high suspicion of TB should be offered empirical treatment based on clinical diagnosis or undergo further testing with complementary TB diagnostics or X-ray when available.

**Recognise current evidence gaps.** Most publicly available performance data come from adults with presumptive TB who were able to produce sputum, so their bacterial loads in sputum swabs and tongue swabs may be higher than in the general population. Insufficient data on the performance of nPOC-NAAT tests in the general population, for instance asymptomatic people with X-ray suggestive of TB, and in key populations, such as children, malnourished people and people living with HIV, remains a gap that must be recognised.

**No drug-resistance tests yet.** Current nPOC-NAAT tests do not yet detect rifampicin resistance or resistance to other first- or second-line TB medicines. This means that samples testing positive in nPOC-NAAT should be followed by WHO-recommended diagnostics for drug-resistance testing, if available.

\* A good quality sputum sample should contain mucoid or purulent material from deep within the lungs, not saliva (watery fluid) or specimens containing food particles, and should have minimum volume of 2 mL.<sup>13</sup>

<sup>8</sup> Steadman A, Kumar KM, Asege L, Kato-Maeda M, Mukwatamundu J, Shah K, et al. Diagnostic accuracy of swab-based molecular tests for tuberculosis using near-point-of-care platforms: a multi-country evaluation. *EBioMedicine*. 2025 Nov;121:105991. [cited 2026 Jan 20]. doi:10.1016/j.ebiom.2025.105991.

<sup>9</sup> Mbuli C, Jean Bosco TF, Nsamenang R, Nestor B, Nguimfack G, Mbuh NN, et al. Diagnostic performance of the Pluslife MiniDock MTB and Molbio MTB Ultima assays to detect tuberculosis from tongue and sputum swabs among outpatients and in active case finding in Cameroon. *Clinical Infectious Diseases*. 2025 Dec 23; ciaf709. [cited 2026 Jan 21] doi:10.1093/cid/ciaf709.

<sup>10</sup> Wu Z, Yan L, Lai X, Yang J, Liang J, Ma X, et al. Diagnostic accuracy of a novel point-of-care tongue swab assay for pulmonary tuberculosis: a multicentre prospective study. *Clinical Microbiology Infection*. 2025 Nov 15; S1198-743X(25)00561-0. [cited 2026 Jan 20]. doi:10.1016/j.cmi.2025.11.010.

<sup>13</sup> Médecins Sans Frontières (MSF). Appendix 3: Collection, storage, and shipment of respiratory specimens [Internet]. Updated September 2023 [cited 2026 Jan 20]. Available from: <https://medicalguidelines.msf.org/en/viewport/TUB/english/appendix-3-sputum-specimen-collection-storage-and-shipment-20323709.html>

While not approved yet by a stringent regulatory authority, several other nPOC-NAAT and LC-aNAAT tests for tongue-swab-based TB diagnosis are available on the market or under development.

## Molecular tuberculosis tests designed for tongue-swab testing: market and pipeline \*

WHO class	Test	Manufacturer (country)	Development stage	Accuracy	Approved by a stringent regulatory authority (SRA)
LC-aNAAT	Truenat MTB Ultima	Molbio (India)	In market	Meets minimum WHO accuracy targets for non-sputum (tongue swab) testing in studies 8,9 †	No
nPOC-NAAT	MiniDock Ultra	Pluslife (China)	In market	Meets minimum WHO accuracy targets for non-sputum (tongue swab) testing in studies 8,9 †	ERPD approved by the Global Fund ‡
nPOC-NAAT	PortNAT	Ustar (China)	Advanced R&D	No data of final prototype published	No
nPOC-NAAT	LumiraDx TB Tongue Swab Assay	LumiraDx/Roche (UK/Switzerland)	Early-stage R&D	No data of final prototype published	No
nPOC-NAAT	CRISPR-based TB tongue swab tests	IntelliGenome, Sherlock Biosciences, VedaBio (amongst others)	Early-stage R&D	No data of final prototype published	No

\* Non-exhaustive list given the rapidly evolving R&D landscape.

† The WHO Target Product Profile (TPP) sets minimum required sensitivity of 80% for LC-aNAAT using non-sputum specimens and 75% for nPOC-NAAT, with a minimum specificity requirement of above 98% compared with liquid culture.<sup>11</sup>

‡ Approved for sputum swabs, pending Expert Review Panel for Diagnosis (ERPD) process to classify tongue swabs.

<sup>8</sup> Steadman A, Kumar KM, Asege L, Kato-Maeda M, Mukwatamundu J, Shah K, et al. Diagnostic accuracy of swab-based molecular tests for tuberculosis using near-point-of-care platforms: a multi-country evaluation. EBioMedicine. 2025 Nov;121:105991. [cited 2026 Jan 20]. doi:10.1016/j.ebiom.2025.105991.

<sup>9</sup> Mbuli C, Jean Bosco TF, Nsamenang R, Nestor B, Nguimfack G, Mbuh NN, et al. Diagnostic performance of the Pluslife MiniDock MTB and Molbio MTB Ultima assays to detect tuberculosis from tongue and sputum swabs among outpatients and in active case finding in Cameroon. Clinical Infectious Diseases. 2025 Dec 23; ciaf709. [cited 2026 Jan 21] doi:10.1093/cid/ciaf709.

<sup>11</sup> World Health Organization. Target product profiles for tuberculosis diagnosis and detection of drug resistance. Geneva: World Health Organization; 2024 [cited 2026 Jan 20]. License: CC BY-NC-SA 3.0 IGO. Available from: <https://iris.who.int/server/api/core/bitstreams/0f3962a0-d382-4a17-b86f-6eb6208c9f87/content>

## Recommendations

### Researchers and R&D funders

- Invest in operational research to generate performance, feasibility and usability data of nPOC-NAAT using sputum swabs and tongue swabs in vulnerable populations and contexts where evidence remains insufficient, such as children, people living with HIV and malnourished people.
- Develop and evaluate pragmatic diagnostic algorithms, incorporating swab-based nPOC-NAAT testing in real-life settings, including settings without access to GeneXpert or other WHO-recommended test for drug resistance.
- Work with Ministries of Health to fast-track implementation and ensure sustainability, for instance by generating local data and developing context-appropriate protocols.

### World Health Organization (WHO)

- Issue policy guidance on when nPOC-NAAT should be used and how it should be integrated into current diagnostic algorithms for diagnosing TB across populations and settings.
- Provide pragmatic operational guidance to support countries in implementing currently available swab-based nPOC-NAAT tests in routine care, including linkage to care across specific contexts.
- Fast-track the assessment of innovative TB tests, such as nPOC NAAT, through the WHO prequalification process to ensure quality, safety, and efficacy standards are met.

### International donors and global actors

- Support countries in sustainable implementation of nPOC-NAAT, including context-specific operational support and training on when and how the test should be used, especially in humanitarian settings.
- Integrate nPOC-NAAT across multiple diseases where feasible, recognising that these devices can support broader test menus beyond TB, such as other respiratory diseases and STIs, and may deliver greater value when planned as multi-disease assets.

### Companies

- Fast track R&D on nPOC-NAAT for drug-resistant TB, prioritising tests that can detect resistance to rifampicin, isoniazid, and fluoroquinolones.
- Ensure harmonised prices and supply terms across disease tests.
- Ensure compliance to the WHO Technical Specifications Series (TSS) and apply for WHO prequalification for nPOC-NAAT tests in the market.<sup>13,14</sup>

### Implementers

- Adapt and apply pragmatic and context-specific diagnostic algorithms for swab-based nPOC-NAAT and consider complementary diagnostic tools for TB diagnosis such as X-ray, computer-aided diagnosis (CAD), TB-LAM test, and WHO-recommended tests for drug-resistance testing.
- Recognise limitations of tongue-swab testing. Tongue-swab-based testing is likely to miss TB in people with a low bacillary load, which is frequent in children and people living with HIV. Implementers should allocate adequate resources to alternative diagnostic strategies for these vulnerable populations, such as WHO-recommended treatment decision algorithms for children under 10 years, including clinical symptoms scoring (with or without X-rays).<sup>15</sup>
- Ensure rapid access to treatment. People diagnosed with TB should receive TB treatment promptly, without unnecessary delay

<sup>13</sup> World Health Organization. In vitro diagnostic (IVD) medical devices used for the qualitative detection of Mycobacterium tuberculosis complex DNA and mutations associated with drug-resistant tuberculosis. Geneva: World Health Organization; 2022. (Technical Specifications Series for submission to WHO Prequalification – Diagnostic Assessment, TSS-17). [cited 2026 Jan 20]. Available from: <https://iris.who.int/server/api/core/bitstreams/b2252f60-b2b4-4093-a403-b8bc8587b9f6/content>

<sup>14</sup> World Health Organization. In vitro diagnostics: Manufacturers [Internet]. Geneva: WHO Prequalification Team; [cited 2026 Jan 22]. Available from: <https://extranet.who.int/prequal/vitro-diagnostics/manufacturers>

<sup>15</sup> World Health Organization. Operational handbook. Module 5: Management of tuberculosis in children and adolescents. Annex 5. Treatment decision algorithms.. Geneva: [cited 2026 Jan 30]. Available from: <https://tbksp.who.int/en/node/2032>

## Annex 1. WHO classification of rapid diagnostics for tuberculosis

WHO class	Specifications	WHO-recommended test (company)	Drug-resistance detection
HC-NAAT	<ul style="list-style-type: none"> <li>High level of operator skill</li> <li>Advanced instrumentation and controlled laboratory environment</li> <li>Complex workflows (e.g. multiple handling and preparation steps)</li> <li>Not intended for peripheral or near-patient use</li> </ul>	<ul style="list-style-type: none"> <li>GenoType MTBDRplus v2 (Bruker-Hain)</li> <li>GenoType MTBDRsl (Bruker-Hain)</li> <li>Genoscholar NTM+MDRTB II (Nipro)</li> <li>Geoscholar PZA-TB II (Nipro)</li> <li>Deeplex Myc-TB (GenoScreen/Illumina)</li> <li>AmPORE-TB (Oxford Nanopore Technologies)</li> <li>TBseq (Shengting Medical Technology Co)</li> </ul>	<ul style="list-style-type: none"> <li>Rifampicin</li> <li>Isoniazid</li> <li>Fluoroquinolones</li> <li>Aminoglycosides</li> <li>Capreomycin</li> <li>Ethambutol</li> <li>Pyrazinamide</li> <li>Streptomycin</li> <li>Linezolid</li> <li>Ethionamide</li> <li>Protonamide</li> <li>Clofazimine</li> <li>Cycloserine</li> <li>Bedaquiline</li> <li>Delamanid</li> </ul>
MC-aNAAT	<ul style="list-style-type: none"> <li>Automated amplification and result interpretation</li> <li>Requires some laboratory infrastructure and trained staff</li> <li>Suitable for intermediate-level laboratory settings where rapid multi-marker detection is needed</li> </ul>	<ul style="list-style-type: none"> <li>RealTime MTB and Realtime MTB RIF/INH (Abbott)</li> <li>BD MAX MDR-TB (Becton Dickinson)</li> <li>Cobas MTB and cobas MTB-RIF/INH (Roche)</li> <li>Fluorotype MTB and Fluorotype MTBDR (Bruker-Hain)</li> </ul>	<ul style="list-style-type: none"> <li>Rifampicin</li> <li>Isoniazid</li> </ul>
LC-aNAAT	<ul style="list-style-type: none"> <li>Fully automated platforms (e.g. cartridge-based systems) that require minimal operator intervention</li> <li>Detect pathogen and primary drug-resistance (e.g. rifampicin in TB) at decentralised labs</li> <li>Designed to reduce technical complexity and operator variability</li> </ul>	<ul style="list-style-type: none"> <li>Xpert MTB/RIF Ultra (Cepheid)</li> <li>Xpert MTB/XDR (Cepheid)</li> <li>Truenat MTB Plus and Truenat MTB-RIF Dx (Molbio)</li> </ul>	<ul style="list-style-type: none"> <li>Rifampicin</li> <li>Isoniazid</li> <li>Fluoroquinolones</li> <li>Ethionamide</li> <li>Amikacin</li> <li>Kanamycin</li> <li>Capreomycin</li> </ul>
LC-mNAAT	<ul style="list-style-type: none"> <li>Manual isothermal NAATs (e.g. LAMP) require fewer equipment resources than automated tests but demand more human resources</li> <li>LAMP tests generally require only basic equipment (no thermocycler) and visual readout.</li> <li>Suitable for basic laboratories with minimal infrastructure</li> </ul>	<ul style="list-style-type: none"> <li>Loopamp MTBC Detection Kit (TB-LAMP) (Eiken Chemical)</li> </ul>	No drug resistance detected
nPOC-NAAT	<ul style="list-style-type: none"> <li>All reagents in closed, disposable containers, does not require special storage, No or single pipetting step</li> <li>Requires only basic technical skills (minimal training)</li> <li>Can operate in peripheral settings without laboratory infrastructure and tolerate high temperature/humidity environments</li> <li>Automated or manually result readout</li> </ul>	NEW – no products recommended by WHO yet *	No drug resistance detected <sup>†</sup>
tPOC	<ul style="list-style-type: none"> <li>Performed at the patient's side during the same clinical encounter</li> <li>No separate laboratory space required</li> <li>Minimal technical skill needed</li> <li>No or single pipetting step</li> <li>Battery or low-resource operation</li> <li>Rapid turnaround (often &lt;1 hour)</li> </ul>	<ul style="list-style-type: none"> <li>Determine TB LAM Ag (Alere/Abbott)<sup>‡</sup></li> </ul>	No drug resistance detected

\* WHO guidance on the use of nPOC-NAAT on respiratory and tongue-swab samples is expected in early 2026

<sup>†</sup> Drug-resistance tests for nPOC-NAAT are in the R&D pipeline

<sup>‡</sup> For adults and adolescents with HIV who have signs or symptoms of TB, screen positive for TB, are seriously ill or have advanced HIV disease (defined as a CD4 cell count of <200 cells/mm<sup>3</sup> or the presence of a WHO stage 3 or 4 AIDS-defining illness), concurrent testing using low-complexity automated NAATs (LC-aNAATs) on respiratory samples and lateral flow LAM (LF-LAM) on urine should be used as the initial diagnostic strategy for diagnosing TB rather than LC-aNAATs on respiratory samples alone. For children living with HIV who have signs or symptoms of TB or screen positive for pulmonary TB, concurrent testing using LC-aNAATs on respiratory and stool samples together with LF-LAM on urine may be used as the initial diagnostic strategy for diagnosing TB rather than low-complexity automated NAATs on respiratory or stool samples alone.<sup>16</sup>

<sup>16</sup> World Health Organization. WHO guidelines on the management of advanced HIV disease. Geneva: World Health Organization; 2025. ISBN: 978-92-4-011816-4 (electronic), 978-92-4-011817-1 (print). [cited 2026 Jan 22]. Available from: <https://www.who.int/publications/i/item/9789240118164>

## Glossary

95% CI	95% confidence interval
CAD	Computer-aided detection
CIFF	Children's Investment Fund Foundation
CRISPR	Clustered regularly interspaced short palindromic repeats
CT	<i>Chlamydia trachomatis</i>
ERPD	Expert Review Panel for Diagnostics
FluA	Influenzavirus A
FluB	Influenzavirus B
GBS	Group B Streptococcus
GDF	Global Drug Facility
GDG	Guideline Development Group
HC-NAAT	High complexity nucleic acid amplification tests
HPV	<i>Human papillomavirus</i>
IDP	Internally displaced persons
LF-LAM	Lateral flow lipoarabinomannan
LC-aNAAT	Low-complexity automated NAAT
LC-mNAAT	Low-complexity manual NAAT
MC-aNAAT	Moderate-complexity automated NAAT
MG	<i>Mycoplasma genitalium</i>
MPXV	Monkeypox virus
MTB	<i>Mycobacterium tuberculosis</i>
NG	<i>Neisseria gonorrhoeae</i>
nPOC	Near point-of-care
nPOC-NAAT	Near point-of-care nucleic acid amplification tests
R&D	Research and development
RSV	Respiratory syncytial virus
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SRA	Stringent regulatory authority
STI	Sexually transmitted infection
Strep A	Group A streptococcal infections
TB	Tuberculosis
TB-LAM	Tuberculosis lipoarabinomannan
tPOC	True point-of-care tests
TV	<i>Trichomonas vaginalis</i>
TPP	Target product profile
UPS	Uninterruptible power supply
UU	<i>Ureaplasma urealyticum</i>
USB	Universal serial bus
WHO	World Health Organization
WRD	WHO-recommended rapid diagnostic