Pipeline Report » 2025

Tuberculosis Diagnostics

TAG
Treatment Action Group

Tuberculosis Diagnostics Pipeline Report 2025

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Introduction and Background

Tuberculosis (TB) is the leading cause of death from an infectious disease worldwide, claiming an estimated 1.25 million lives in 2023. Of the 10.84 million people estimated to have developed TB that year, only 8.16 million were diagnosed and reported — leaving 2.7 million people missing: undiagnosed, unreported, untreated, and not cured.[1] This persistent diagnostic gap highlights the shortcomings of existing tools and the urgent need for better ones.

Decades of reliance on smear microscopy and culture, inadequate access to World Health Organization (WHO)–recommended rapid diagnostics tests (WRD), and the high price and technical complexity of modern molecular tests have left millions without timely diagnosis.[2] In 2023 alone, currently available rapid diagnostic tests failed to reach 4.3 million people with TB (a figure that does not account for individuals with TB diagnosed or missed in the private sector).[3] Across the diagnostic pathway, from screening to treatment monitoring, losses occur at multiple steps, preventing people from accessing curative treatment when they need it most.

Recent progress in the pipeline offers hope. A new class of near point-of-care (nPOC) TB tests, undergoing WHO review in November 2025, brings a focus on decentralization, faster turnaround times, and the use of nonsputum samples. By enabling testing closer to the point of care, simplifying sample collection by using oral swabs, and delivering rapid results (within 30 minutes), these nPOC tests aim to increase access to testing, reduce losses to follow-up, and accelerate treatment initiation — key steps in closing the TB diagnostic gap.

The 2025 TB diagnostics pipeline is broad and diverse, with multiple tools now in late-stage development approaching policy and regulatory review. Yet innovation alone will not close the diagnostic gap. **To translate scientific progress into lives saved, these new tools must be taken up by governments through the exercise of strong political will, well-designed programs, sustained funding, and deliberate strategies for equitable access**. Several things must happen at once: replacement of outdated technologies accompanied by rapid scale-up of proven tests enabled by commitments to affordability and integration into health systems. This year's *TB Diagnostics Pipeline Report* adopts a stance of cautious optimism about the potential of the innovations emerging in the pipeline, particularly tools in the nPOC class, while emphasizing the urgent need for decisive investment, accelerated uptake, and dedicated efforts to guarantee access. Without these, millions of people currently missed by TB diagnosis will remain beyond even the reach of new tools.

Highlight Box 1: Tools Featured in This Report

This report highlights "late-stage" technologies, defined here as those undergoing large-scale clinical validation or early commercialization and for which active policy planning is underway with ongoing regulatory and policy engagement. It features four tables at the end of the report detailing tools in late-stage development for TB screening, diagnosis, drug-susceptibility testing, and treatment monitoring. This report does not cover tests for TB infection, computer-aided detection (CAD), or ultra-portable chest X-rays — areas that remain active and important within the pipeline but are not the focus of this year's review. TAG plans to reintroduce these areas in future annual reports.

Organized by the technology type, the tables provide data on intended level of care, development stage, validated sample type, accuracy, time to result, and anticipated price. While most tools are in late stages of development, some are categorized as "commercially available," which means the tool is currently in the process of commercialization and awaiting WHO review for policy recommendations. The tables are not exhaustive; only tools with publicly available information or for which product sponsors have submitted data to TAG are included. Cells marked "NA" indicate that data is not available, either because TAG did not receive it from developers or because it isn't available in the public domain. As tests progress in their development and data becomes ready for dissemination, they will be incorporated into subsequent annual pipeline reports.

TB Screening

Screening is typically the first step in identifying people who are at elevated risk of TB and referring them for timely diagnostic evaluation, yet the tools currently available remain insufficient to meet this need at scale. In August 2025, WHO released a new target product profile (TPP) for TB screening, emphasizing the urgent need for fast, affordable tools that can be deployed widely and adapted to diverse settings.[4] This guidance outlines three potential approaches: (1) high-sensitivity, high-specificity tests for single-step screening; (2) highly sensitive tests for two-step screening strategies; and (3) moderate-sensitivity, high-specificity tools for use in low-access settings (or areas that are not currently well served by healthcare systems). Innovative screening tools currently in the pipeline (see table 1) have the potential to satisfy the criteria for these approaches, depending on their accuracy and operational characteristics.

The use of machine-learning tools, sometimes called artificial intelligence (AI), has accelerated the development of scalable screening solutions. Recently updated (June 2025) WHO guidelines now include recommendations for three additional CAD software products for chest X-ray interpretation, bringing the total number of WHO-approved CAD tools to six.[5] The Stop TB Partnership maintains a CAD database and resource center (ai4health.org) with more information on available CAD products.

Emerging innovations have the potential to expand the reach of screening to underserved and hard-to-reach populations.

- **Point-of-care ultrasound (POCUS)** offers a portable, low-cost option for detecting both pulmonary and extrapulmonary manifestations of TB, particularly where access to radiology is limited.
- **AI-based cough apps** analyze recorded cough sounds using machine learning, enabling rapid triage with just a smartphone and helping to prioritize people for confirmatory testing.

- **Digital stethoscopes**, powered by AI, are emerging as another possible screening device. These highly portable devices analyze lung sounds to rapidly detect pulmonary TB, offering a solution that can be deployed in community settings and primary care, even by nonspecialist health workers.
- **Biomarker-based tests**, detecting TB bacterial components (such as DNA or lipoarabinomannan [LAM] or host-response signatures [proteins, mRNA, immune markers]) are advancing as rapid, nonsputum screening options that can identify individuals with TB earlier, including among populations with paucibacillary disease (characterized by low bacterial loads).

Together, these innovations represent a growing and diversified toolkit that holds promise to decentralize TB screening, making it more accessible and adaptable to different epidemiological and health system contexts. However, it is not only the test characteristics but how and where these tools are implemented that will determine their real impact. By equipping programs to proactively reach individuals in their communities, rather than relying on individuals to present themselves at health facilities, these tools enable a much-needed transition from passive to active case finding. This shift is essential for finding people with TB earlier, reducing transmission, and truly closing the persistent diagnostic gap.

Diagnosis

Molecular TB diagnostics are currently expensive and require substantial infrastructure, making them difficult to deploy close to where many people with TB seek care. Sputum-based tests further limit access for children, people living with HIV (PLWHIV), and others who struggle to produce sputum or have extrapulmonary TB. To reach the 4.3 million individuals currently missed by WRDs, diagnostics must become more accessible — both through greater decentralization and through use of nonsputum sample types.

Recognizing these barriers, WHO's TPP (updated in 2024) for tests for TB diagnosis and detection of drug resistance prioritizes development of nPOC tests: portable, battery-powered molecular platforms that need little infrastructure and minimal training, enabling use in primary clinics or remote settings.[6] By moving testing closer to where people present for care, nPOC tools can reach underserved populations and reduce diagnostic delays.

The TPP acknowledges expected trade-offs with test accuracy; that is, as molecular diagnostic tools adopt easier-to-collect sample types and become less complex to enable use closer to the point of care, this often comes at the cost of sensitivity. Modeling suggests that nPOC tests with minimum sensitivities of 75 percent (nonsputum) and 85 percent (sputum) could match or exceed current case detection rates at the population level by broadening access. This is particularly true with more accessible sample types like tongue swabs. Affordability of tests and sample collection devices will be critical for scale. The TPP sets a target price of ≤US$6 (optimal ≤US$4) for nPOC tests, compared to ~$7.90 for the WRDs most widely used currently (Xpert MTB/RIF Ultra, Truenat MTB/RIF Dx). In the event that nPOC tests can offer lower per-test costs, decentralized placement, and accessible sample types, they could increase diagnostic yield even if individual test accuracy is lower. This could potentially enable mass testing within limited budgets and the expansion of TB screening test access to high-risk but currently missed populations.

Supporting this, data from one modeling study projects that screening with a moderate-sensitivity nPOC test could reduce TB mortality by 24% – 42% at a per capita cost of $3.49 – $3.63, achieving similar

impact to higher-sensitivity tests with a higher cost ($5.04 – $5.83 per capita).[7] These findings suggest that nPOC tests, when implemented at scale in community settings, could enable substantial reductions in TB mortality and save lives.

Multiple products in the pipeline (see table 2) will likely meet WHO's TPP criteria for nPOC tests and are advancing toward formal review and potential policy recommendation. For details on the upcoming WHO evaluation and review process, see Highlight Box 2.

Highlight Box 2: Near Point-of-Care Tests: Progress, Policy, and Programmatic Use

Multiple suppliers have pipeline products meeting WHO's TPP for nPOC tests. In November 2025, WHO will convene a Guideline Development Group (GDG) to review this new class of tests and evaluate evidence for novel sample types — including tongue swabs — on nPOC platforms and existing molecular systems.[8] Initial WHO guidance will reflect evidence available in 2025, expanding as additional products undergo review.

In July 2025, PlusLife's MiniDock MTB assay was approved by the Global Fund Expert Review Panel for Diagnostics (ERPD), making the test eligible for procurement under Global Fund-supported programs.[9] While the MiniDock MTB assay is considered a first-in-class nPOC test, multiple "fast followers" are expected, which would create a choice of tests within this class. While these products are classified similarly, minor differences in their product characteristics will allow programs to select options best suited to their context. However, experience with Xpert MTB/RIF tempers optimism: anticipated fast followers to Xpert MTB/RIF were "late comers" that took longer than expected to reach the market.[10] This highlights the importance of ensuring PlusLife's MiniDock MTB assay does not remain the sole nPOC option for long. Healthy competition among suppliers will be key to driving prices down and expanding equitable access globally.

As countries prepare for the introduction of nPOC TB tests, it is important to define clear use cases for these tests and choose the right technology for each situation while also considering cost impact. The nPOC tests can work alongside existing low-complexity molecular tests (such as Xpert Ultra and Truenat MTB/RIF) by acting as the first test to confirm TB, allowing the other tests to focus more on checking for drug resistance. This approach could potentially generate cost savings without a significant impact on case notifications. The new tests might replace sputum microscopy as the initial test, helping more people get access to higher quality TB testing. Ultimately, using these tests widely outside of labs could help programs find more people with TB, but it may cost more to set up, so transitioning to this use-case would need careful planning.

Further decentralization can be achieved with true point-of-care (POC) tests. As per the WHO TPP, true POC tests require no specific instruments or infrastructure and can be used in settings without laboratories or specialized staff.[11] An example of true POC tests in the pipeline are urine-based lipoarabinomannan (LAM) tests. These are instrument-free tools that offer rapid diagnosis and can be performed as a self-test or by health workers with minimal training. While currently available LAM tests have primarily served PLWHIV in the context of advanced HIV disease management, several urine-LAM assays in late-stage development now show improved accuracy for all PLWHIV, regardless of disease stage (see table 2). Importantly, these new LAM tests show early potential to be used beyond the population of those living with HIV, expanding access to most or all individuals at risk of TB at the true point of care.

The 2024 *TB Diagnostics Pipeline Report* asked whether a TB self-test was possible; this year's report suggests that it could be within reach, although timelines depend heavily on the funding environment. Highlight Box 3 discusses the far-reaching impacts of funding cuts on the TB diagnostics pipeline.

Highlight Box 3: A Pipeline at Risk – The Threat of Funding Cuts

The United States Government (USG) has long been the largest global funder of TB diagnostics research and development (R&D).[12] Critical advances in the pipeline — spanning basic science, technology scouting, preclinical work, early- and late-stage clinical development, and translation of evidence into policy — have been made possible through sustained USG investments. However, disruptions to the US research ecosystem — including the dismantling of USAID, threats to the President's Emergency Plan for AIDS Relief (PEPFAR), government shutdowns and associated layoffs, and pervasive uncertainty about National Institute of Health (NIH) funding — are jeopardizing not only scientific progress but also the timely delivery of lifesaving tools to millions of people with TB.

Cuts to USG funding for R&D and for TB programs overall have triggered a cascade of detrimental effects across the TB diagnostic ecosystem. Federally supported clinical research networks, such as the NIH-funded FEND-TB, R2D2, and ENDxTB networks, are key to technology scouting, clinical validation, and helping developers prepare products for market introduction.[13] These networks generate indispensable data that directly inform global policy, acting as essential bridges between innovation and practical deployment, but they are now facing imminent risk with the funding shortfall. Some programs have been refunded with reduced budgets and narrower scopes, prioritizing an "America First" approach to health and innovation, which limits their capacity to address the needs of low- and middle-income countries at the same scale. Universities reliant on federal funding are experiencing disruptions, including delays in crucial modeling studies that assess the cost-effectiveness and trade-offs of new diagnostic tools.[14] Meanwhile, multilateral agencies such as the WHO, the Global Fund to Fight AIDS, TB, and Malaria, and the Stop TB Partnership are unable to fully execute financing and program support in countries most affected by TB.[15,16]

The impact of these funding cuts is already visible in a pipeline of diagnostic tests that has constricted as many developers have paused or scaled back work due to resource constraints. Even products in late-stage development, including those not dependent on USG funding, now confront a steeper climb to reach the market. If funding is not restored, some promising products may not resume development, which would lead to a shrinking pipeline in the future. Close readers may also note the absence of Abbott's LAM test from this year's tables — Abbott has informed TAG that TB product development and commercialization efforts have been paused due to limited resources available and competing priorities. This stands in sharp contrast to the urgent global need for high-sensitivity urine-based TB LAM tests. Compounding the effects of USG turmoil, the Foundation for Innovative New Diagnostics (FIND), a key player in global TB diagnostic development, has suffered sharp donor funding suspensions, widespread layoffs and loss of critical staff and has halted programs amid a reported leadership crisis, further jeopardizing global development efforts.[17]

These funding cuts come at a particularly bad time. The TB diagnostics pipeline is more robust than it has been in decades, with numerous promising technologies rapidly progressing toward regulatory approval and scale-up. Without continued investment, the evidence base necessary for policy decisions risks weakening, slowing the adoption of new tools and undermining global efforts to address the TB diagnostic gap. Sustained funding is critical — not only for ongoing R&D but also for maintaining the clinical research infrastructure and multilateral partnerships essential to integrating innovations within national health programs.

Drug-Susceptibility Testing

The WHO calls for universal drug-susceptibility testing (DST) for every individual tested for TB, emphasizing rapid detection of drug resistance to guide appropriate and effective treatment. As TB diagnostic algorithms evolve to include nPOC tests, it is important to understand that these tests currently detect TB only and do not test for drug resistance. Their use must therefore be paired with reflex testing algorithms, ensuring every individual who tests positive for TB is promptly referred for DST. This underscores the urgent need to decentralize DST capacity and strengthen sample transport systems for timely, efficient referral and treatment initiation.

Promising low-complexity nucleic acid amplification tests (NAATs) for DST are advancing in development (see table 3). These tests require minimal infrastructure and can be placed in peripheral laboratories, expanding drug resistance coverage beyond rifampicin and isoniazid. These tools would also extend DST closer to individuals, reducing delays. Nonetheless, comprehensive genotypic resistance profiling for a wider range of TB drugs still relies on line-probe assays and targeted next-generation sequencing (tNGS), which is placed in central laboratories due to its complex infrastructure requirements. TB culture remains indispensable for phenotypic resistance testing, especially for drugs such as bedaquiline, delamanid, pretomanid, cycloserine, and linezolid, where current tNGS tools have limited accuracy.[18] This dependence on centralized tNGS highlights the continuing need to invest in efficient sample transport and to develop simpler, accurate DST tools for the drugs at the heart of shorter regimens to treat drug-resistant TB.

The landscape of TB drug resistance is evolving and will require revising DST algorithms to better reflect changing local patterns of resistance and newly emergent concerns. Recent cohort studies in India and South Africa reveal clinically significant undetected bedaquiline resistance, including among individuals whose TB organism is still susceptible to fluoroquinolones (FQs).[19,20] Current testing algorithms, which only screen for bedaquiline resistance in individuals with FQ-resistant TB, would miss these individuals. These findings call for surveillance-informed, regionally tailored algorithms incorporating up-front bedaquiline resistance testing in settings with a high prevalence of drug-resistant TB — or for true universal DST for all widely used TB drugs, as the WHO has called for.

Achieving universal DST will demand a multipronged approach: scaling decentralized low-complexity DST, improving access to sequencing, investing in sample transport, and updating algorithms to match resistance trends. Without these efforts, new diagnostic tools will fall short of WHO goals, leaving individuals vulnerable to delayed and ineffective treatment.

Treatment Monitoring

Treatment monitoring remains a crucial yet underdeveloped area in the TB diagnostics pipeline. Tool development needs to be focused on optimizing treatment by identifying individuals at risk of poor treatment outcomes at three critical stages: (1) before or at the start of treatment, based on disease severity or risk factors that may require more intensive regimens; (2) during treatment, by assessing response to the current regimen; and (3) at the end of treatment, confirming durable cure by identifying those at risk of relapse. Other important areas related to TB biomarker development include distinguishing early disease states, such as incipient and asymptomatic TB, predicting progression from infection to active disease, and differentiating resolved from current infection.

The importance of these tools is clear: without understanding if individuals are at risk of a poor treatment outcome, treatment cannot be tailored to their individual needs. There have been some efforts to support TB biomarker development by prioritizing use cases; despite this, treatment monitoring remains underdeveloped and would benefit from increased investment and focused research. Emerging host-response tests and quantitative bacterial load tests (see table 4) show promise but require further validation. Additionally, more work is needed to determine how best to integrate these tools into care to improve management of individuals with TB.

Advocacy Priorities

As advocates push for equitable access to TB diagnostic tools, there are some critical priorities for the global TB community to champion. Advocates must hold countries, donors, policymakers, and diagnostic developers accountable to ensure that vulnerable populations, especially children, are included in R&D. Equally important is broadening access to emerging technologies like CAD, demanding transparency in pricing to foster fair markets, and pushing for more inclusive data in policy guidelines. These priorities are essential to drive innovation while ensuring that lifesaving tools reach all people affected by TB without delay or disparity. Strengthening TB diagnosis also requires obtaining greater visibility into testing and treatment practices in the private sector, alongside advocacy for quality-assured testing and standardized reporting wherever people seek care.

Include Children in Research and Development

A top advocacy priority — underscored in last year's report and vital to reiterate here — is the urgent need to include vulnerable populations, particularly children, in TB diagnostic R&D. Current tools and those in development underserve this population and fail to meet their needs, as most screening and diagnostic tests are only validated for individuals aged 15 and older. Clinicians must often rely on treatment decision algorithms rather than definitive diagnostic tests to manage pediatric TB.[21] Developers should prioritize infants and children as primary target populations, reversing the current adults-first, children-later evaluation approach to ensure diagnostics are safe, accurate, and tailored for children with TB.[22]

Broaden Access to Computer-Aided Detection

Despite rapid technological advances and widescale adoption of CAD for TB screening, access to CAD remains inequitable. CAD is currently recommended for children over the age of 15, with validation in younger children lacking. Training CAD software with a robust repository of pediatric chest X-rays is essential to improve accuracy in this population. Additionally, CAD developers must be transparent about how they collect and use data to train their AI algorithms. This transparency is essential to ensure ethical use, avoid bias, protect patient privacy, and build trust in AI-powered health tools. Pricing transparency, including for warranties and software updates, is needed to make these tools more affordable and accessible.

Demand Transparency in Cost of Goods Sold

Transparency in pricing remains a long-standing challenge in TB diagnostics. Historically subject to the distorted and inefficient dynamics of Cepheid's Xpert monopoly, the field is now seeing growing competition. This presents a ripe opportunity to establish new norms to promote fair pricing and accessibility. One step toward this goal would be consensus on clear, standardized methodologies for calculating cost of goods sold (COGS) to inform fair product pricing. Understanding cost components and incorporating best practices for COGS+ pricing will help ensure sustainable, equitable access to TB diagnostic tools.

Incorporate Broader Data in Upcoming Guidelines

While developers submit data for WHO policy and prequalification (PQ) evaluations, innovations are needed in how these data are assessed. Beyond accuracy, global and national guidelines already reflect metrics such as acceptability, feasibility, diagnostic yield, and patient-important outcomes. These metrics, such as how easy the test is to use, the speed of treatment initiation after diagnosis, and overall treatment success rates, should be more prominently reflected to better capture real-world impact. Meaningful engagement with affected communities is critical. Understanding their preferences, acceptability, and practical feasibility will ultimately drive the successful uptake and impact of these new innovations. Forthcoming guidelines should also provide clear guidance for programs on introducing and scaling-up new tests to maximize their benefit alongside existing instruments with more established footprints. It is also important to ensure timely opening of PQ pathways so that technologies falling under class-based recommendations can undergo quality assessment as soon as recommendations are issued. Accelerating these PQ pathways alongside consideration of expanded data metrics will better support the timely adoption of diverse diagnostic innovations.

Conclusion

The global landscape for TB diagnostics is on the verge of a transformative shift. With a new class of tools soon to be recommended, diagnostic algorithms will evolve significantly. The challenge will be to use these new tools to close the persistent diagnostic gap while managing costs within increasingly constrained TB program budgets. Given the wide range of available tools in late-stage development/coming down the pipeline, TB programs must carefully assess their unique challenges and select tools that best address their specific needs.

As new products progress through development, maintaining a strong focus on equitable access is essential — prioritizing both affordability and inclusion of vulnerable populations. Fostering a transparent and competitive market environment, supported by collaboration among stakeholders, is crucial for sustainable progress. Together, these efforts can move us closer to a future where everyone with TB is diagnosed and treated without delay.

Table 1: Tests for TB Screening

Technology	Tool (Developer)	Intended Level of Care	Stage of Development	Sample	Accuracy	Time to Result	Price (USD)
Point-of-care ultrasound (POCUS)	**Butterfly iQ** (Atrium Health/Butterfly Network, USA)[23]	Primary care center	Late	Imaging	Ultrasound: SE: 91%, SP: 61%, AUC: 86%	<1 minute, 2+ hours scan time per battery charge	$2,699 Global access pricing available
	Vscan Air (GE Healthcare, USA)[24]	Primary care center	Commercially available	Imaging	NA	NA	NA
AI-based cough apps	**AudibleHealth AI** (RAIsonance, USA)[25]	Primary care center	Commercially available	Cough sounds	SE: ≥90%, SP: ≥70%	<1 minute	NA
	Swaasa (Salcit Technologies, India)[26]	Primary care center	Commercially available	Cough sounds	SE: 80%, SP: 65%	<1 minute	<$5
	TimBre (Docturnal, India)[27]	Primary care center	Late	Cough sounds	SE: 85.0%, SP: 92.0%, AUC: 62% – 84%	<20 seconds	$0.50; $1.00 (including consumables)
Digital Stethoscopes	**AID.TB™ + Ostium™** (AI Diagnostics, South Africa)[28]	Primary care center	Commercially available	Lung sounds	SE: 90%, SP: 50%	3 minutes	$0.5 – $1.5 per use; Hardware rental included
	Dx Assist (Audium Health, USA)	Primary care center	NA	Lung sounds	NA	NA	NA
	imPulse Una (Level 42 AI, USA)[29]	Primary care center	Late	Lung sounds	Vibrations and audible sounds: SE: ≥70%, SP: ≥85%	Within minutes	≤$100
	Stethee Pro (M3DICINE, Australia)[30]	Primary care center	NA	Lung sounds	NA	NA	NA

Technology	Tool (Developer)	Intended Level of Care	Stage of Development	Sample	Accuracy	Time to Result	Price (USD)
Biomarker-based tests	**FIND-TB** (SolutionDx, USA)[31]	District laboratory	Late	Blood	SE: 96%, SP: 98%	15 minutes	$6 – $7
	Ichroma CRP (Boditech, South Korea)[32]	Primary care center	Commercially available	Blood	SE: 89%, SP: 72%	Within minutes	NA
	IRISA-TB (Antrum Biotech, South Africa)[33]	District laboratory	Late	Pleural, peri-cardial, CSF	Pleural and peri-cardial – SE: 89%, SP: 95%; cerebrospinal fluid – SE: 76%, SP: 98%	90 minutes	$15
	LumiraDx CRP (Lumira Dx, United Kingdom)[34]	Primary Care Center	Commercially available	Blood	Close correlation with lab-based methods	4 minutes	Test: ~$2, Instrument: $3,300
	MARTI "point-of-care TB diagnostic test" (MARTI TB Diagnostics, South Africa)[35]	Primary care center	Late	Blood	NA	30 minutes	NA

Note: This table does not include computer-aided detection (CAD) software and ultra-portable chest X-ray devices.
Note: NA = Not Available

Table 2: Tests for TB Diagnosis

Technology	Tool (Developer)	Intended Level of Care	Stage of Development	Sample	Accuracy	Time to Result	Price (USD)
nPOC molecular tests	**MiniDock MTB Assay** (Guangzhou Pluslife Biotech Co. Ltd., China)[36]	Primary care center	ERPD approved	Oral swab/ sputum	Sputum – SE: 85.7%, SP: 97.6%; Tongue swab – SE: 79.6%, SP: 99.5%	≤25 minutes	Test: $3.6, MiniDock Ultra (Device): $155, Pluslife Thermolyse: $180
	Truenat MTB Ultima (Molbio, India)[37]	Primary care center	Late	Oral swab/ sputum	SE: 77.5%, SP: 98%	<1 hour	Test: NA, Device: $10,000 – $18,000
	PortNAT TB Assay (Ustar Biotech, China)[38]	Primary care center	Commercially available	Oral swab/ sputum	SE: ≥88.89%, SP: ≥100%	45 minutes	Test: $3.5, Device: $600
	CYCLE tbLab (FRIZ Biochem, Germany)[39]	Primary care center	Late	Tongue swab, sputum dipped swab	NA	30 minutes	$8.19[1]
	FlashDetect LyocartE MTB Assay (Coyote Bioscience, China)[40]	Primary care center	Late	Oral swab/ sputum	SE: 98.95%, SP: 98.69%	<30 minutes	Cartridge: <$4; Instrument: <$1500
	POCT TB Test (Anbio Biotechnology, China/Germany)[41]	Primary care center	Late	Oral swab/ sputum	Tongue swab – SE: 95.79%, SP: 100%; Sputum – SE: 97.88%, SP: 100%	37 minutes	Total Assay COGS: ≤$2.45/test
	DASH MTB Assay (Nuclein, USA)[42]	Primary care center	Early	Oral swab	NA	15 minutes	NA
	LumiraDx TB POC (LumiraDx, United Kingdom)[43]	Primary care center	Early	Oral swab	NA	20 minutes	Test: NA, Instrument: $3,300
	Co-Dx Logix Smart MTB (Co-Diagnostics Inc., USA)	Primary care center	Late	Oral swab/ sputum	NA	45 – 66 minutes	NA

Technology	Tool (Developer)	Intended Level of Care	Stage of Development	Sample	Accuracy	Time to Result	Price (USD)
Decentralized molecular tests	**Breath aerosol PCR** (Avelo, Switzerland)[44, 45]	Primary care center	Late	Breath	SE: 71.0%, SP: 92.3%	NA	NA
	CitaXpress TB (Eradicus, France)	District laboratory	Late	Sputum	NA	NA	NA
	DMN-Tre (OliLux, USA)	District laboratory	Early	Sputum	NA	NA	NA
	TB detect (Genes2Me, India)[46]	Primary care center (district lab with the Rapi-Q platform)	Commercially available	Sputum	SE: 98%, SP: 99%	98 minutes on the OnePCR platform, 60 minutes on the Rapi-Q platform	Test: $12, Instruments – OnePCR: $10,000, Rapi-Q: $17,000
	UniAMP MTB (Huwel Life Sciences, India)	Primary care center	Commercially available	Oral swab/ sputum	NA	7 – 30 minutes	NA
	CRISPR-TB blood test kit (Intelligenome, USA)[47]	Primary care center	Commercially available	Blood	SE: 81%, SP: 94%	2 hours benchtop	$5
	Lab-in-A Tube TB Assay (Intelligenome, USA)[48]	Primary care center	Late	Blood	NA	30 minutes	$5
	TB-EASY (Hugo Biotech, China)[49,50]	District laboratory	Late	Oral swab/ sputum	Tongue swab – SE: 89.6%, SP: 96.2%; Sputum – NA	~3.5 hours	$4 (bulk price)
	MoiM MTB (iGENETECH, South Korea)	District laboratory	Late	Sputum	NA	~2 hours	NA
	NanoDisk-MS (Nanopin, USA)	District laboratory	Late	Blood	NA	NA	NA

Technology	Tool (Developer)	Intended Level of Care	Stage of Development	Sample	Accuracy	Time to Result	Price (USD)
Urine-LAM tests	**Fujifilm SILVAMP TB LAM II** (Fujifilm, Japan)[51]	Primary care center	Commercially available	Urine	PLWHIV – SE: 70.7%, SP: 90.9%; HIV-negative individuals – SE: 53.2%, SP: 98.9%	1 hour	NA
	ichroma LAM Ag (Boditech, South Korea)[52]	Primary care center	Early	Urine	SE: 93%, SP: 78%	<20 minutes	NA
	PF-LAM (Brightest Bio, USA)[53]	Primary care center	Late	Urine	Adults – SE: 54%, SP:100%; Adults with HIV – SE: 71%, SP: 92%	60 minutes	Test: <$4, Instrument: <$250
	Biopromic TB LAM assay (Biopromic AB, Sweden)[54, 55]	Primary care center	Late	Urine	SE: 63%, SP: 93%	NA	NA
	FLOW TB Urine-LAM Assay (Salus Discovery, USA)	Primary care center	Late	Urine	NA	NA	NA

Note: NA = Not Available

1) 7 euros (conversion rate: 1 Euro = 1.1697 USD)

Table 3: Tests for Drug Resistance

Technology	Tool (Developer)	Intended Level of Care	Stage of Development	Sample	Accuracy	Time to Result	Price (USD)	Drugs
Molecular Tests	**IRON qPCR RFIA kit (MDR-TB & preXDR-TB)** (Bioneer Corporation, South Korea)[56]	Primary care center	Late	Sputum	LoD: 80.5 CFU/mL (1.81 Log10 CFU/mL) SE, SP: NA	40 minutes	Test: $15 (Global Access Pricing target)	rifampicin, isoniazid, fluoroquinolones, aminoglycosides
	LiquidArray MTB XDR (Hain Lifescience, Germany)[57]	District laboratory	Commercially available	Sputum	TB - SE: 85.4%, SP: 99.4%; FQ - SE: 94.3%, SP: 99.3%; LZD - SE: NA, SP: 100%; LZD - - SE: 75-87.5%, SP: 100%; EMB - SE: 84.5%, SP: 97.5%	3 – 5.5 hours for up to 96 samples	$14.62[1]	fluoroquinolones, amikacin, linezolid, and/or ethambutol
	mfloDx™ MDR-TB (EMPE Diagnostics, Sweden/India)[58]	District laboratory	Commercially available	Sputum	TB - SE: 97%, SP: 100%; RIF - SE: 93%, SP: 100%;	<3 hours	Test: $28.15[2]	rifampicin, isoniazid
	MultiNAT MTB/RIF Assay (Ustar Biotech, China)[59]	Primary care center	Commercially available	Sputum/BALF/ Paraffin-tissue / Gastric fluid / Cerebrospinal fluid / Puncture fluid	MTB - SE: 99.32%, SP: 99.47%; RIF - SE: 100%, SP: 100%	119 minutes	Test: MTB – $3, MTB/RIF – $6; Device: $14,500 – 2 model/ $24, 500 – 4 model	rifampicin
	POCT Sputum Test TB/ RIF, MTB/NTM (Anbio Biotechnology, China/Germany[60]	Primary care center	Late	Sputum	TB/RIF - SE: 94.02%, SP: 99.09%; MTB/NTM - SE: 96.45%, SP: 99.21%	TB/RIF – 39 – 45 minutes; MTB/NTM – 37 minutes	Total Assay COGS: ≤$2.95	rifampicin
	Phenotech (Resistell, Switzerland)[61]	District laboratory	Late	Sputum	NA	7 – 21 hour	NA	rifampicin, isoniazid, macozinone, BTZ043
	Quanitplus MDR-TB Fast Detection Kit (Huwel Life Sciences, India)	District laboratory	Commercially available	Oral swab / sputum	NA	NA	NA	NA
	Standard M10 MTB-RIF/ INH (SD Biosensor, South Korea)[62]	District laboratory	Late	Sputum	NA	99 minutes	NA	MTB, rifampicin (rpoB), isoniazid (katG, inhA)
	TBfind (Genes2Me, India)[63]	Primary care center (district lab with Rapi-Q platform)	Commercially available	Sputum	OnePCR platform – SE: 97% SP: 98%; Rapi-Q platform – SE: 98%, SP: 100%	OnePCR platform: 112 minutes; Rapi-Q platform: 60 minutes	Test: $12, Instrument – OnePCR: $10,000; Rapi-Q: $17,000	rifampicin, isoniazid

Technology	Tool (Developer)	Intended Level of Care	Stage of Development	Sample	Accuracy	Time to Result	Price (USD)	Drugs
	Truenat MTB-INH (Molbio, India)[64]	Primary care center	Commercially available	Sputum	SE: 100%, SP: 96.15%	<1 hour	Test: $8, Instrument: $10,000 – $18,000	isoniazid
	TB-RIFNET KIT (Amunet S.A. de C.V, Mexico)	District laboratory	Late	Oral / nasal swab	NA	NA	NA	rifampicin
	Genechip MDR kit (CapitalBio Technology, China)	District laboratory	Late	Sputum	NA	NA	NA	rifampicin, isoniazid
	AAICare (Aarogya AI, India)	District laboratory	NA	Digital health	NA	NA	NA	NA
Line-Probe Assay	**Genoscholar FQ+KM-TB II** (Nipro, Japan)[65]	Central laboratory	Late	Sputum	FQ – SE: 93%, SP: 100%; KM – SE: 100%, SP: 95.1%	6 hours	Test: $30, Instrument (MULTIBLOT NS-4800): $15,000	fluoroquinolone, kanamycin
Targeted Next-Generation Sequencing	**Tuberculini** (Clemedi, Switzerland)[66]	Central laboratory	Commercially available	Sputum	RIF – SE: 95.5%, SP: 93.5%; INH – SE: 92.9%, SP: 100%; EMB – SE: 81.8%, SP: 74.4%; PZA – SE: 61.1%, SP: 100%; LFX – SE: 100%, SP: 100%; MFX – SE: 100%; SP: 80.6%	24 – 48 hours	NA	isoniazid, rifampicin, ethambutol, pyrazinamide, levofloxacin, moxifloxacin, linezolid, amikacin, ethionamide/ proteonamide, streptomycin, capreomycin, kanamycin
	TB Pro (Hugo Biotech, China) [67]	Central laboratory	Late	Blood, Sputum, BALF, CSF, Pleural Fluid, Ascitic Fluid, Tissue	SE: 98.1% –100%, SP: 99.7% – 100% (WGS reference standard)	12 – 16 hours	$99 (bulk price)	up to 18 anti-TB drugs (including bedaquiline, linezolid, and delamanid) (as well as 8 anti-NTM drugs) Note: NA = Not Available

Note: NA = Not Available

1) 12.5 EUR, conversion: 1 Euro = 1.1697 USD (GDF catalogue)

2) INR 2500 (conversion rate: 1 INR = 0.011 USD)

Table 4: Tests for Treatment Monitoring

Technology	Tool (Developer)	Intended Level of Care	Stage of Development	Sample	Accuracy	Time to Result	Price (USD)
Host-response tests	**ISIT-TB** (bioMérieux, France)[68]	District laboratory	Late	Blood	NA	2 hours	NA
	Risk6 signature assay (TB HIRA / QuantuMDx, United Kingdom)[69]	District laboratory	Late	Blood	Progression to active TB ≤1 year – SE: 75%, SP: 50.3%	30 minutes	NA
	Xpert MTB Host-Response assay (Cepheid, USA)[70]	District laboratory	Late	Blood	Results correlate with treatment response	45 minutes	NA
Quantitative bacterial load test	**Capilia TB-Neo** (TAUNS, Japan)[71]	District laboratory	Commercially available / WHO endorsed	Sputum	MPB64 detection – SE: 99.4%, SP: 100%	15 minutes	$1[1]
	PATHFAST TB LAM Ag (PHC Corporation, Japan)	Primary care center	Commercially available	Sputum	SE: 88.8%, SP: 100%	47 minutes	$32 – $54
	TB-MBLA (LifeArc/University of St Andrews, United Kingdom)[72]	District laboratory	Late	Sputum	SE: ≥80%, SP: ≥98%	~4 hours	<$15
	TMKmt (Makerere University, Uganda)	NA	NA	Blood, Sputum	Blood: 100% specific to TB among PLWHIV; Sputum: Detectable at low bacillary loads	NA	NA

Note: NA = Not Available

1) $100 for a pack containing 100 units (GDF Catalog, January 2025)

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