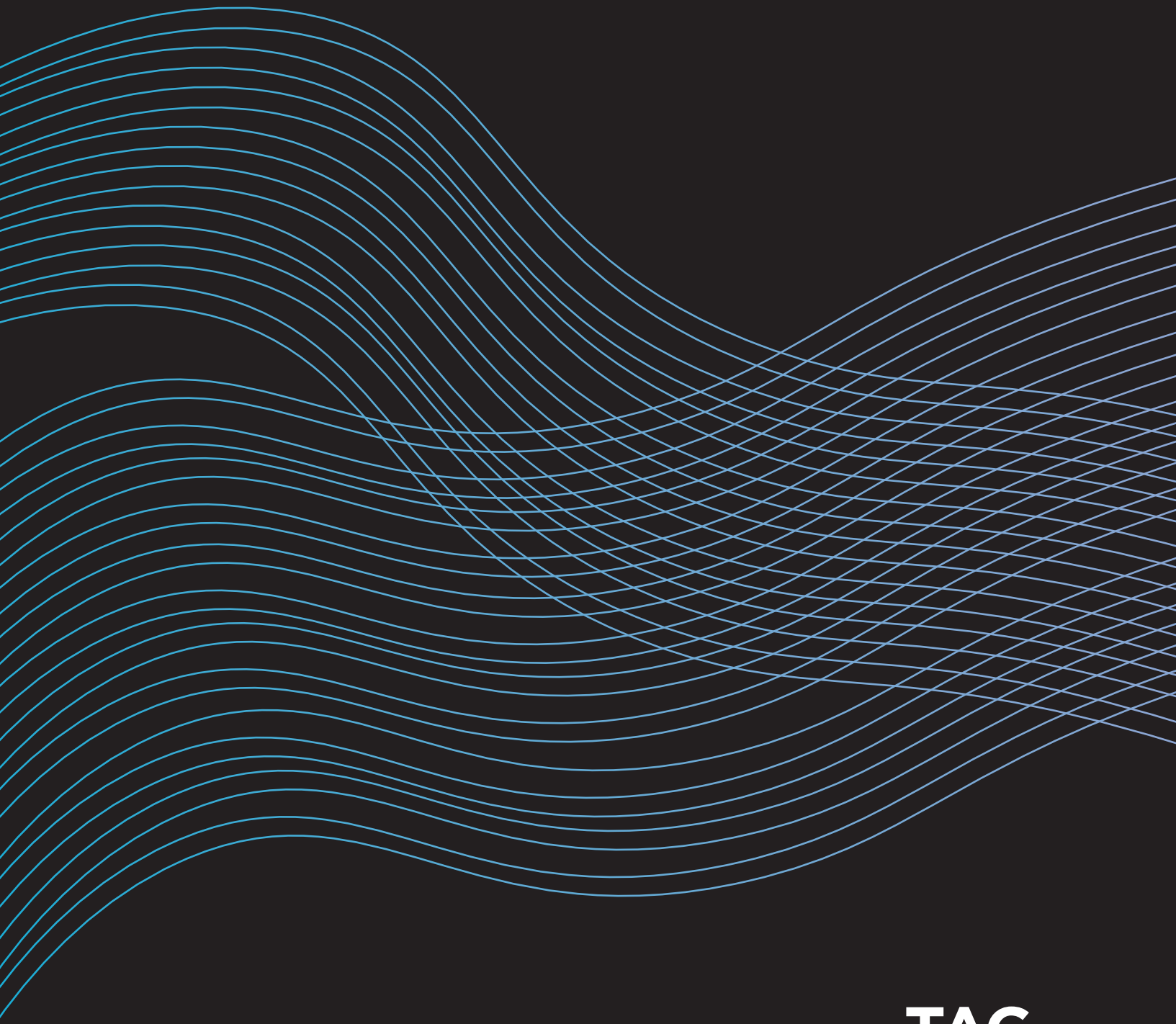
Pipeline Report » 2024

Tuberculosis Diagnostics



TAG
Treatment Action Group

Tuberculosis Diagnostics

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Introduction

Tuberculosis (TB) continues to be a leading cause of mortality from an infectious disease, causing an estimated 1.25 million deaths in 2023.[1] These deaths are avoidable with timely and accurate diagnosis, the weakest link in the TB **cascade of care**. Of the estimated 10.84 million incident TB cases in 2023, only 8.16 million people were reported as diagnosed and started on treatment, revealing a diagnostic gap of 2.7 million "missing" people.[2,3] To close this gap, we need to change the way TB screening and diagnosis are approached, accelerate advancement of next generation TB testing technologies, and ensure access to these innovations for all communities that are affected by TB.

Cascade of care: the entire pathway of TB care, including diagnosis, treatment, and cure

Background

Advancements in molecular testing and artificial intelligence have expanded the types of TB screening and diagnostic tools that are recommended by the World Health Organization (WHO). Yet, sample type, test accuracy, placement, and price remain challenges. Most of the WHO-recommended diagnostic tools still rely on sputum samples and have limited **sensitivity** in children, people living with HIV (PLHIV), and in **asymptomatic** and early stages of disease when TB bacterial loads are low. Chest x-rays are better able to identify people in early stages of TB disease but have low **specificity**, necessitating further confirmatory testing. Urine- and stool-based tests are recommended by the WHO for use in certain populations (urine for severely ill people living with HIV and stool molecular tests for children), but current versions are challenged by limited sensitivity. Additionally, few existing tools can be used to diagnose TB in community settings. Current rapid molecular diagnostic testing platforms are placed at central, district, or subdistrict laboratory levels and not at the point of care, closest to where people live and work and first seek diagnosis. This is because these testing platforms require electricity, temperature control, and dust-free environments that are not available in many community settings in high-TB-burden countries. Obtaining a TB diagnosis then requires samples to be transported from the point of care to the laboratory, lengthening the turnaround time for a result and treatment initiation. Such delays contribute

Sensitivity (SE): the percentage of people with a disease that a test correctly identifies as having the disease

Asymptomatic TB refers to a disease state that lacks typical clinical symptoms but can be detected through radiological or microbiological testing

Specificity (SP): the percentage of people without a disease that a test correctly identifies as not having the disease

to gaps in the cascade of care. Price is also an extremely important consideration as access to molecular tests remains limited due to the high costs of tests, equipment, and service and maintenance.[4]

New diagnostic technologies in the pipeline are designed to address these challenges. Tests in development use alternate, easy-to-attain sample types such as oral swabs and urine and are intended for use at the point of care (see Table 2). New molecular tests also incorporate additional **targets**, enabling detection of more complicated drug-resistance patterns in decentralized settings (see Table 4). There are also promising tools for screening in the pipeline such as **point-of-care ultrasounds** and digital stethoscopes that have accuracy (sensitivity ranging from 70 percent to 91 percent) which is comparable to existing tools (symptom screening, chest x-rays, and **computer-aided detection** [CAD]) but with improved access parameters: better portability, lower costs, and potentially quicker turnaround times (see Table 1).[5,6]

The **TB infection** tests in the pipeline (see Table 3) have enhanced access parameters compared to existing **interferon-gamma release assays (IGRAs)** and **TB-specific skin tests** (e.g., lower costs, decentralized placement, and operational advantages facilitating use in low-resource settings). While none of the currently available tests can distinguish between latent TB infection and active TB disease, there are tests in development for predicting disease progression (see Table 5).[7] Considering efforts to scale up **TB preventative treatment** to a broader population of people at risk of TB, and in anticipation of new TB vaccines entering late-stage development, we need tests that can provide this information.

To maximize the potential of the diagnostic technologies in the pipeline, the systems these new tools will be introduced into need renovations only possible with some reimagination. This year's *Pipeline Report* takes a critical look at TB tests in development and the systems they will be introduced into.

Targets: identifiable genetic markers or molecular indicators that tests use to detect drug resistance

Point-of-care ultrasound (POCUS): portable, radiation-free imaging device that detects tissue damage associated with TB

Computer-aided detection (CAD): artificial intelligence-based software that interprets chest X-rays with high accuracy comparable to skilled human readers

TB infection: Also known as latent TB infection, the TB bacteria is in the body but is inactive and not causing symptoms.

Interferon-gamma release assays (IGRAs): tests that detect interferon-gamma, a biomarker of the body's immune response to TB, in blood samples

TB-specific skin tests (TBST): in-vivo tests for the detection of TB infection that use Mtb-specific antigens

TB Preventative Treatment (TPT): a course of one or more anti-tuberculosis medicines given with the intention of preventing the development of TB disease. TPT is primarily given to people who are infected with TB bacteria or have been exposed to it and are at a higher risk of developing TB disease than the general population.

Highlight Box 1: How to Read the Tables

The report features five tables at the end detailing tools in the pipeline for TB screening, diagnosis, infection testing, drug susceptibility testing, disease progression, and treatment monitoring. Grouped by type of technology, the tables provide information on stage of development, accuracy, time to result, and price, as well as the sample types and the level of the health system each technology is intended for. For stage of development, technologies that are concept locked and undergoing lab evaluations are categorized as "early," technologies that are design locked and undergoing clinical validation studies are categorized as "late," and technologies that are commercially available (even if only in a select few countries) are categorized as "commercialized." These tables are not exhaustive and not every technology included in the tables has accuracy results, time to result information, or known prices. Information that is publicly available or that has been provided by product sponsors has been included.

Systems Change

The pathway to TB diagnosis is currently too long.[8] TB tests are rarely available beyond the subdistrict level, yet people who are unwell often first present to primary healthcare providers with nonspecific symptoms or may be seeking care for comorbidities. To shorten the pathway to diagnosis and address gaps in the cascade of care, tests need to be available at more peripheral levels of the health system, or even at home. This requires a shift in the importance assigned to test accuracy in favor of other characteristics, especially those that improve accessibility or diagnostic integration.

Tests intended for more peripheral levels of the health system require accessible sample types and simple assays, both of which can affect test accuracy. The trade-off between reduced accuracy and increased accessibility can still, at the population level, result in increased rates of TB case detection referred to as **diagnostic yield**,[9] because accessibility enables more frequent and widespread testing. A modeling study by Nooy et al. that simulated diagnostic pathways found that point-of-care TB tests with minimum sensitivities of 70 percent for nonsputum samples and 78 percent for sputum samples could achieve comparable or better case detection rates than current standards of care (i.e., Xpert or smear microscopy in Kenya; four-symptom screening and Xpert confirmatory testing in South Africa; and Xpert or Truenat, smear microscopy, and clinical diagnosis in India).[10] The next generation urine-based **lipoarabinomannan (LAM)** tests in the pipeline (see Table 2) are examples of tools with lower sensitivity (ranging from 53.2 percent to 93 percent) but the potential to confer higher diagnostic yield, as they are meant to be available at the primary care level. Tongue swabs are another example. Tongue swabs are expected to be less sensitive than sputum samples (52 percent to 91 percent vs. ~90 percent), but the accessibility of the sample type is expected to provide higher diagnostic yield.[11,12] To close gaps in diagnosis and get more people into the TB care cascade, research and product sponsors and policymakers need to shift the focus from sensitivity to other elements of target product profiles that affect test accessibility.[13]

Diagnostic Yield: A metric to measure the performance of a test; the proportion of people who are identified with a disease using a diagnostic test out of the total number of people who were eligible to be tested

Lipoarabinomannan (LAM): a component of the outer cell wall of TB bacteria that is discarded in the body and that is detectable in urine

Highlight Box 2: Why We Still Need Sputum

Research and product sponsors are leveraging advances from COVID-19 diagnostics to develop improved point-of-care molecular tests for TB. This includes evaluating tongue swabs on both existing and new molecular tests (e.g., the USAID-funded SMART4TB Project **ADAPT** and ADAPT for Kids trials).[14] However, even after tongue swab-based testing for TB is introduced, sputum will remain a relevant and important sample type because it is still necessary to test for drug resistance and for treatment monitoring. Existing phenotypic and genotypic drug susceptibility tests (DST), including line probe assays and targeted next-generation sequencing (tNGS), run on sputum and a handful of other more invasive sample types, and there are currently no reliable DSTs being evaluated on more accessible sample types such as oral swabs.

ADAPT: Assessing Diagnostics At Point-of-care for Tuberculosis

Drug-susceptibility testing (DST): tests used to determine Mycobacterium tuberculosis' resistance to TB drugs

Sputum samples are also used to monitor the effectiveness of TB treatment over time. By **culturing** sputum at different times during treatment, doctors can assess whether the infection is responding to the prescribed medications. Currently, smear microscopy and mycobacterial cultures are the primary methods for monitoring TB treatment progress. Tools in the pipeline for treatment monitoring are mostly being evaluated on sputum samples, however, there are some promising alternatives being developed for use on blood and stool samples that offer comparable accuracy parameters (see Table 5). This is an area of the pipeline that could benefit from an infusion of resources and attention. Tools that can indicate a positive or negative response to treatment more quickly than culture will become increasingly important as TB drug and regimen developers drive toward shorter and shorter treatment regimens. In 2023, the WHO published a Target Product Profile (TPP) to guide the development of these types of tools.[15]

Culturing: a method of growing bacteria in a liquid or solid medium for up to six weeks to detect the presence of TB bacteria or determine drug resistance

Unsurprisingly, implementing existing TB tests at the point of care can help to address gaps in the cascade of care. Two large-scale clinical trials – **TB-CAPT**[16] and **XPEL-TB**[17] – demonstrated that providing rapid molecular TB testing at the point of care in high-burden countries leads to faster diagnosis, quicker treatment initiation, reduced patient loss to follow-up, and increased overall TB case detection compared to centralized testing. The XPEL-TB study found that the intervention strategy of placing molecular tests at community health centers led to a 56 percent higher rate of treatment for confirmed TB within 14 days compared to routine care. The TB-CAPT study found that implementing the Molbio Truenat test in primary care settings resulted in 82.9 percent of people with TB diagnosed and started on treatment on the same day that they presented to care, and 98 percent started on treatment within seven days of presenting to care.[18] The placement of tests in development that may be even more fit for purpose (see Table 2) can be expected to similarly affect benchmarks further down the cascade of care with less loss to follow up anticipated the closer testing and treatment initiation are to the point of care.

CAPT: Close the gap, increase Access, Provide adequate Therapy

XPEL-TB: Xpert Performance Evaluation for Linkage to Tuberculosis Care

Self-tests have been WHO-recommended for HIV since 2016 and for hepatitis C as of July 2024.[19,20] Innovations in response to the COVID-19 pandemic resulted in, for the first time, the availability of over-the-counter molecular tests.[21] The COVID-19 pandemic also normalized the use of nasal swabs and rapid antigen tests at home. Sample self-collection options are available for sexually transmitted infections such as chlamydia, gonorrhea, and HPV.[22] Now that many populations affected by TB have access to at-home tests for common co-infections, TB advocates are right to ask if we will ever have a self-test for TB. COVID-19 self-testing massively expanded testing coverage during pandemic peaks and would be expected to play a similarly game-changing role in closing the diagnostic gap for TB.

The closest thing to a self-test for TB is the TB Lipoarabinomannan (LAM) test: a rapid point-of-care urine test currently recommended for diagnosing TB in people with advanced HIV. Next generation TB-LAM tests (see Table 2) are expected to be more sensitive than the currently available Determine TB LAM test and indicated for use in a broader population.[23] Another promising tool in the pipeline that could facilitate self-testing for TB is AI-based cough apps (see Table 1) that analyze cough sounds to detect patterns indicative of respiratory conditions, including TB.

Multidisease detection platforms in the pipeline present new opportunities and impetuses for health programs and financing mechanisms to break silos and move towards **integrated models** of testing and care. These platforms allow for the diagnosis of multiple conditions using a single platform, enabling more efficient use of laboratory resources, equipment, and personnel. Rapid molecular testing platforms already in use have this capacity – the GeneXpert, Truenat, and Abbott Realtime are examples of platforms that can run tests for TB and other infections like HIV, HCV, COVID-19, flu, and RSV. New multi-disease detection platforms in the pipeline (see Table 2) offer increased portability for point-of-care testing, faster turnaround times, expanded inclusion of diseases tested, and improved accuracy parameters. Some of the promising multi-disease detection platforms in the pipeline designed for point of care are Afinion (Abbott Point of Care), ichroma II/III/M2/M3 (Boditech), Co-Dx PCR Pro (Co-Dx), FlashDetect Nano /Flash10 (Coyote Bioscience), UniAMP (Huwel Life Sciences), umPulse Una (Level 42 AI), LumiraDx (LumiraDx), Truenat (Molbio), DASH (Nuclein), Q-POC (QuantuMDx), STANDARD M10/F (SD Biosensor), and PortNAT (Ustar Biotechnologies). These tests have the capability to detect a wide range of both infectious and non-communicable diseases.

Integrated models: coordinated approaches that combine TB services with other health services to provide comprehensive, patient-centered care that improves diagnosis, treatment, and outcomes for people with TB and related comorbidities

Highlight Box 3: The Need for Better Diagnostics for Pediatric TB

TB in children is a critical yet often overlooked health issue that requires urgent attention and prioritization. According to WHO estimates, 1.3 million children (below 10 years) and young adolescents (10–14 years) developed TB in 2023, but only half were reported to public health programs.[24] Diagnosing TB in children can be difficult due to the nonspecific symptoms, challenges in obtaining good quality specimens, and **paucibacillary disease**.[25,26] TB in younger children also often presents as a general febrile illness and is therefore often mistaken for other diseases. This makes diagnosis in settings without molecular tools even harder. In addition, children are usually taken to integrated health or pediatric specific clinics, where healthcare workers may have less TB experience. Under the current scenario for TB diagnostics research and development, most tests are developed first for adults and only subsequently evaluated in children. A TB diagnostics pipeline oriented toward adult diagnosis will inevitably lead to delays in extending the benefits of improved testing to children and necessitate the continued use of **treatment**

Paucibacillary disease: the presence of small amounts of the TB bacteria in the body and thereby the samples, which can be difficult to detect using the current molecular tests

decision algorithms and other approaches to clinically diagnosing TB in children.[27] The pipeline is rife with opportunities to rebalance efforts with greater attention to the diagnostic needs of young people. For example, with new computer-aided detection (CAD) tools in the pipeline for reading chest x-rays (CXR) there is a need for developing an algorithm to train new (and existing) CAD tools for pediatric TB. The **CAPTURE** consortium by Stellenbosch University, UCSF, and FIND seeks to develop a CAD algorithm that can analyze chest x-rays for pediatric pulmonary TB. They aim to validate current algorithms that note an indication for children and support pediatric-specific algorithm development by developing a cloud-based repository of chest x-ray images from children with presumptive TB and creating an associated clinical dataset.

Developing tools that work specifically in children requires including them in the R&D process, not as an afterthought but instead as a priority. A consensus statement developed by Bijker et al. (2024) for the Child TB Diagnostics Consensus Group recommends including children and adolescents in all phases of TB diagnostic development – from early research to postmarket surveillance.[28] Their recommendations include stratifying results by age group to capture the nuanced differences between the years of childhood and adolescence, testing alternate sample types such as stool and urine samples, validating new specimen collection methods that are less invasive for pediatric use, and ensuring sample sizes are adequate for drawing meaningful conclusions for pediatric subgroups.

Treatment decision algorithms: tools to help clinicians to make a decision to start TB treatment in a child, based on microbiological, clinical and radiological evidence.

CAPTURE: Catalyzing Artificial intelligence for Paediatric Tuberculosis Research

Access Conditions

The high cost of TB tests, particularly for advanced molecular tests, poses a significant barrier to widespread implementation in high burden settings, limiting access to timely and accurate diagnosis. Currently, many countries struggle to afford the number of tests required for their existing instruments. For example, Nigeria has a significant number of GeneXpert machines, but struggles to procure enough cartridges to run these machines at full capacity. Nigeria has only been able to utilize 30 percent of its GeneXpert machines' testing capacity due to the high cost and limited availability of cartridges.[29] Lower prices would expand testing capacity.

However, the relationship between price and demand is complex in the current market. While suppliers face some pressure to lower prices, the lack of robust competition and limited alternatives mean they retain significant power to set TB test prices. This market dynamic disadvantages TB-affected communities, particularly in resource-limited settings, and underscores the importance of fostering a more competitive TB diagnostics market. **To improve access to lifesaving TB diagnostics, enhanced governance, mediation between stakeholders, and efforts to foster market competition are crucial for progress.** Global health actors should work collaboratively with new manufacturers and facilitate cooperation among funders, high-burden country governments,

and civil society. Governments and policymakers must ensure the benefits of research and scientific progress are accessible and transformative, in line with Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), and support initiatives that improve the affordability and availability of TB diagnostics.[30]

Additionally, public and philanthropic investments subsidizing the development, evaluation, and introduction of new TB diagnostic tools need to come with more strings attached. A study by Gotham et al. estimated that the development of GeneXpert was subsidized by $250 million in public sector funds.[31] These funds were invested without asking the product sponsor, Cepheid, to make commitments necessary to ensure access.[32] Cepheid then held a decade-long monopoly on molecular testing for TB, only very recently agreeing to lower the price of the Xpert TB test from $9.98 to $7.97 after coming under intense public pressure.[33] The hard-won lessons of the Cepheid experience make clear that donors need to negotiate access conditions at much earlier stages of development if new tests are going to implemented at the scale required to end TB by 2030.

Conclusion

The TB diagnostics landscape is at a critical juncture, demanding a paradigm shift in our approach to innovation, implementation, and access. Systems need to be redesigned to place tests closer to people, even if this means favoring accessibility over diagnostic accuracy. A competitive market is a healthy market, and donors can promote the health of the TB diagnostics market by investing to foster competition and insisting on access conditions at earlier stages of test development. We need to find innovative approaches to allow efficient use of existing testing capacity, for example, through integrated models of testing and care, while also making sure that TB tests are available at the point of care. There is a need for a systems change, and while not quick or easy, it is fundamental that this is worked on, in parallel with the pipeline.

A fundamental question that should inform our research and development priorities moving forward is the nature of the “missing” people with TB. Are these primarily people with asymptomatic TB, or are they individuals with symptoms who lack access to testing? The answer to this question is likely a combination of both, highlighting the need for a two-pronged approach: (1) improving TB testing accessibility using easier-to-collect sample types and simpler technologies, and (2) developing tests and screening strategies capable of detecting TB before people develop classic TB symptoms. This understanding should guide not only our R&D efforts but also how we reimagine the systems new diagnostics will be introduced into.

Table 1: TB Screening Tools (for people at risk of TB)

Technology	Tool Developer	Level	Stage of Development	Sample	Accuracy	Time to Result	Price
Point of care ultrasound (POCUS)	**Butterfly iQ** [34] (Atrium Health (Butterfly Network, USA)	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
Digital stethoscopes	**Stethee Pro** [35] (M3DICINE, Australia)	Primary care center	Early	Lung sound	NA	<1 minute	$499 Includes limited-time subscription
	DxAssist [36] (Audium Health, USA)	Primary care center	Early	Lung sound	NA	NA	NA
	imPulse Una [37] (Level 42 AI, USA)	Primary care center	Early	Lung sound	Vibrations and audible sounds: SE: ≥ 70%, SP: ≥ 85%	Within minutes	≤ $100
	StethoMe [38] (StethoMe, Poland)	Primary care center	Early	Lung sound	NA	<1 minute	$230 per annual subscription Includes warranty
AI-based cough apps	**TimBre** [39] (Docturnal, India)	Primary care center	Late	Cough sounds	Cough sounds: SE: 85.0%, SP: 92.0% for pulmonary TB	<1 minute	Instrument Cost: $100, cost per screening: $1.50 (including consumables), $0.75 for monitoring
	ResApp [40] (ResApp Health, Australia)	Primary care center	Early	Cough sounds	NA	Within minutes	NA
	Swaasa [41] (Salcit Technologies, India)	Primary care center	Late	Cough sounds	Cough sounds: SE: 90.36%, SP: 84.67% [42]	<1 minute	≤ $1 per test for high-volume testing, $5 per test for low-volume testing

Technology	Tool Developer	Level	Stage of Development	Sample	Accuracy	Time to Result	Price
Biomarker-based tests	**ichroma CRP** [43] (Boditech, South Korea)	Primary Care Center	commercialized	Blood	SE: 89%, SP: 72%	Within minutes	NA
	Afinion CRP [44] (Abbott Point of Care, Norway)	Primary Care Center	Commercialized	Blood	SE: 50%, SP: 72.3%	Within minutes	NA
	LumiraDx CRP [45] (LumiraDx, United Kingdom)	District laboratory	Commercialized	Blood	Close correlation with lab-based methods	Within minutes	Test: $2, Instrument: $3,300 with 2-year warranty
	SeroSelect TB [46] (SeroSelectTB Consortium, Norway)	District laboratory	Late	Blood	NA	<1 minute	NA
	cfRNA-TB [47] (Cornell University, USA)	Central laboratory	Early	Blood	Plasma: SE: 97%, SP: 98%	1–2 days	NA

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

Table 2: TB Diagnostic Tools (for people with TB symptoms or a positive screening test)

Technology	Tool Developer	Level	Stage of Development	Sample	Accuracy	Time to Result	Price
Molecular tests	**Lab-in-A Tube TB Assay**[48] (Intelligenome, USA)	Primary care center	Late	Blood, saliva, and Sputum	NA	30 mins	NA
	FlashDetect [49] **LyocartE MTB Assay** (Coyote Bioscience, China)	Primary care center	Late	Tongue swab/ Sputum	NA	<30 minutes	NA
	MiniDock MTB Test[50] (Pluslife Guangzhou Biotech, China)	Primary care center	Late	Tongue/ Sputum swab	Sputum: SE: >95%, SP: >98% Tongue swab: SE: >83%, SP: >95%	10–15 mins	Test: <$4, Instrument: <$150
	TB Assay [51] (FRIZ Biochem, Germany)	Primary care center	Late	Tongue swab	NA	30 minutes	Test: $30
	mfloDx MDR-TB [52] (EMPE Diagnostics, India)	Primary care center	Late	Sputum	NA	<2 hours	NA
	LumiraDx TB POC [53] (LumiraDx, United Kingdom)	Primary care center	Early	Tongue swab	NA	20 minutes	Test: NA, Instrument: US$3,300 with 2-year warranty

Technology	Tool Developer	Level	Stage of Development	Sample	Accuracy	Time to Result	Price
Molecular tests	**Logix Smart MTB** [54] (Co-Dx, USA)	Primary care center	Early	Tongue swab	NA	<30 minutes	NA
	DASH MTB Assay [55] (Nuclein, USA)	Primary care center	Early	Tongue swab	NA	15 minutes	NA
	MTB Ultima [56] (Molbio, India)	Primary care center	Early	Tongue swab	NA	<40 mins	Device: $10,000–18,000
	3STEP [57] (Salus Discovery, USA)	Primary care center	Early	Tongue swab	NA	<30 minutes	Test: ~$3, Instrument: <$1000
	TB Tongue Swab [58] Testing (GH Labs, USA)	Primary care center	Early	Tongue swab	NA	NA	NA
	TB Assay [59] (Biomeme, USA)	Primary care center	Early	Tongue swab	NA	<1 hour	NA
	TB Assay [60] (Sherlock Biosciences, USA)	Primary care center	Early	Tongue swab	NA	NA	NA
	NABIT [61] (Conservation X Labs, USA)	Primary care center	Early	Tongue swab	NA	NA	NA
	NuRapid [62] (Jiangsu MicroDiag, China)	Primary care center	Early	Tongue swab	NA	40 minutes	NA
	AveloCollect [63] (Avelo, Switzerland)	Primary care center	Early	Breath	NA	NA	NA
	PathCrisp TB Assay [64] (CrisprBits, India)	Primary care center	Early	Tongue/ nasal swab	NA	1 hour (post-nucleic acid extraction)	NA
	OnePCR [65] (Genes2Me, India)	Primary care center	Commercialized	Sputum	NA	60–70 minutes	Test: $12, Instrument: $10,000
	CRISPR-TB Blood test kit [66] (Intelligenome, USA)	Primary care center	Commercialized	Blood, saliva, and Sputum	Adults: SE: 93.3%, SP: 93.4% Children with HIV: SE: 83.3%, SP: 95%	2 hours	$5
	STANDARD M10 MDR-TB TB-RIF/ INH [67] (SD Biosensor, South Korea)	District laboratory	Late	Sputum	NA	80 minutes	Test: $8, Instrument: $10,000–18,000

Technology	Tool Developer	Level	Stage of Development	Sample	Accuracy	Time to Result	Price
Molecular tests	**Truenat MTB-Covid19** [68] (Molbio, India)	District laboratory	Late	Sputum/ nasal swab	NA	1 hour	Test: US$16, Instrument: $10,000–18,000
	ExAmplar MTB kit [69] (Boditech, South Korea)	District laboratory	Early	Sputum	NA	30–55 minutes	NA
	PortNAT MTB [70] (USTAR, China)	District laboratory	Early	Tongue swab	NA	40 minutes	NA
	IsoAmplar MTB Kit [71] (Boditech, South Korea)	District laboratory	Early	Tongue swab	NA	40 minutes	NA
	DMN-Tre [72] (OliLux, USA)	District laboratory	Early	Sputum swab	NA	<30 minutes	NA
	Xpert MTB/RIF Ultra [73] (Cepheid / UW, USA)	District laboratory	Commercialized	Tongue swab	SE: 72.4%, SP: 100%	<90 minutes	Test: $7.97, Instrument: $9,420–19,500
	MultiNAT MTC/ MDR [74] (Ustar biotech, China)	District laboratory	Commercialized	Respiratory specimens	NA	45–65 minutes	NA
	EasyNAT/ MultiNAT TB assay [75] (Ustar biotech, China)	District laboratory	Commercialized	Tongue swab	NA	25 minutes	NA
	TBfind [76] (Genes2Me, India)	District laboratory	Commercialized	Pulmonary specimens	NA	1 hour	Test: $12, Instrument: $17,000
	Rapi-Q / Tbdtect [77] (Genes2Me, India)	District laboratory	Commercialized	Pulmonary specimens	NA	1 hour	Test: $12, Instrument: $17,000
	Smart Sure MTB Screening Kit [78] (Genetix, India)	District laboratory and Primary health care facility	NA	Pulmonary and EPTB specimens	NA	<60 minutes	Test: MDR $9.65, MTB $4.50, Instrument: $8,000–17,000
	IRON q-PCR RFIA Kit [79] (Bioneer, South Korea)	District laboratory	NA	Sputum	MTB: SE: 100%, SP: 100% RR-TB: SE: 100%, SP: 80%	80 minutes	NA

Technology	Tool Developer	Level	Stage of Development	Sample	Accuracy	Time to Result	Price
Molecular tests	**Pathodetect-MTB and Rifampicin and Isoniazid Detection Kit** [80] (MyLAB, India)	District laboratory	NA	Sputum swab	NA	<2 hours	NA
	MTB/MDR Kit [81] (Prodiag, Netherlands)	District laboratory	NA	Sputum swab	Sputum: MTB SE, SP: >94.5% RIF SE: 95.8%, SP: 96.4% INH SE: 88%, SP: 97.2%	3 hours	Test: $9, Instrument: $14,000
	TB & RIF Resistance Kit [82] (Sansure, China)	District laboratory	NA	Tongue swab/ Sputum	NA	1 hour	NA
	RAPID TB [83] (Nanjing Difei Med, China)	District laboratory	Early	Tongue swab/ Sputum	NA	30 minutes	NA
Urine-LAM tests	**High-sensitivity TB LAM** [84] (Abbott, USA)	Primary care center	Early	Urine	NA	<45 minutes	NA
	ichroma LAM Ag [85] (Boditech, South Korea)	Primary care center	Early	Urine	SE: 93%, SP: 78%	<20 minutes	NA
	STANDARD F TB LAM Ag FIA [86] (SD Biosensor, South Korea)	Primary care center	Early	Urine	SE: 68.3%, SP: 98%	30 minutes	NA
	Flow-TB [87] (Salus Discovery, USA)	Primary care center	Early	Urine	Limit of detection <10 pg/mL60 40-200X increase in detectable LAM due to urine concentration	NA	$1–2
	TB LAM urine LFA [88] (Biopromic, Sweden)	Primary care center	Early	Urine	People living with HIV SE: 78%, SP: 89% HIV-negative people SE: 65%, SP: 93%	50 minutes	$4
	SILVAMP TB LAM [89] (Fujifilm, Japan)	Primary care center	Commercialized	Urine	People living with HIV SE: 70.7%, SP: 90.9% HIV-negative people SE: 53.2%, SP: 98.9%	1 hour	US$6.60

Table 3: Tests for TB Infection

Technology	Tool Developer	Level	Stage of Development	Sample	Accuracy	Time to Result	Price
Point-of-care IGRAs	**ichroma IGRA-TB** [90] (Boditech, South Korea)	Primary care center	Commercialized	Blood	Blood: 95.2% concordance with QFT-Plus	Incubation: 16–24 hours Test: <15 minutes	NA
	AFIAS IGRA-TB [91] (Boditech, South Korea)	Primary care center	Commercialized	Blood	Blood: 95.3% concordance with QFT-PLUS	Incubation: 16–24 hours, Test: 15 minutes	NA
	STANDARD F TB Ag FIA[92] (SD Biosensor, South Korea)	Primary care center	Global Fund ERPD approved	Blood	Blood: SE: 100%, SP: 91.5%	Incubation: 16–24 hours Test: <15 minutes	Test: $4
	VIDAS TB-IGRA [93] (bioMérieux, France)	Primary care center	Commercialized	Blood	SE: 97.5%, SP: 97.6%	16 hours	NA
TB skin test	**Cy-TB** [94] (Serum Institute of India, India)	Primary care center	Commercialized	Skin	SE: 76.0%, SP: 98.0% (pooled accuracy for TBST class)	48–72 hours	NA
	Diaskintest [95] (Generium, Russia)	Primary care center	Commercialized	Skin	SE: 76.0%, SP: 98.0% (pooled accuracy for TBST class)	72 hours	NA
	C-TST [96] (Anhui Zhifei Longcom Biopharma-ceutical, China)	Primary care center	Commercialized	Skin	SE: 90.64%, SP (in BCG-vaccinated individuals not infected with Mtb): 92.0%	48–72 hours	NA

Table 4: Tests for Drug-Resistance

Technology	Tool Developer	Level	Stage of Development	Sample	Accuracy	Time to Result	Price	Drugs
Molecular tests	**IRON-qPCR RFIA Kit** [97] (Bioneer, South Korea)	District laboratory	Late	Sputum	NA	40 minutes	Instrument: $20,869	MTB, RIF, INH, FQ, AMK
	Truenat MTB-BDQ [98] (Molbio. India)	District laboratory	Late	MTB positive specimens	NA	1 hour	Test: TBD, Instrument: $10,000–18,000	INH, FQ, BDQ
	Truenat MTB-RIF [99] (Molbio, India)	Primary care center	Commercialized	Tongue swab	SE: 100%, SP: 96%	1 hour	Test: $8, instrument: $10,000–18,000	NA
	Truenat MTB-INH [100] (Molbio, India)	District laboratory	Late	MTB-positive pulmonary and extrapulmonary specimens	SE: 100%, SP: 96.15%	1 hour	Test: $7.90, Instrument: $10,000–$18,000	NA
	Truenat MTB-FQ [101] (Molbio, India)	District laboratory	Late	MTB positive specimens	NA	1 hour	Test: US$12, Instrument: $10,000–18,000	NA
	Truenat MDR-TB Plus [102] (Molbio, India)	District laboratory	Early	MTB positive specimens and EPTB samples	NA	<1 hour	Test: TBD, Instruments: $10,000–18,000	RIF, INH, FQ
	LiquidArray MTB-XDR [103] (Hain Lifescience GmbH, Germany)	Central laboratory	Late	Sputum	SE: 85.4%, SP: 99.4% FQ: SE: 94.3%, SP: 99.3% LZD: SE: NA, SP: 100%	2.5–5 hours	NA	FQ, LZD, AMK, EMB
	Genoscholar FQ+KM-TB II [104] (Nipro, Japan)	Central laboratory	Late	Sputum	FQ: SE: 93%, SP: 100%. KM: SE: 100%, SP: 95.1%	6 hours	Test: $30, Instrument: $15,000 per unit	FQ, KM
	Standard M10 MDR-TB [105] (SD Biosensor, South Korea)	District laboratory	Late	Sputum	NA	80 minutes	NA	MTB, RIF, INH
	ExAmplex MTB Kit [106] (Boditech, South Korea)	District laboratory	Commercialized	Sputum	NA	90 minutes	NA	NA

Technology	Tool Developer	Level	Stage of Development	Sample	Accuracy	Time to Result	Price	Drugs
tNGS	**Deeplex Myc-TB** [107] (Genoscreen, France)	Central laboratory	Commercialized	Sputum	Sputum: SE: 93.1–98.5%, SP: 95.3–98.5% (WGS reference standard)	1–2 days	Test: $50	up to 15 drugs (BDQ, LZD)
	Deeplex TB XL[108] (Genoscreen, France)	Central laboratory	Early	Sputum	NA	1–2 days	NA	up to 17 drugs (BDQ, LZD, PTD, DLM)
	DeepChek Assay 13-Plex KB DST [109] (ABL Diagnostics, France)	Central laboratory	Early	Sputum	NA	29 hours	NA	up to 13 drugs (BDQ)
	NanoTB [110] (Oxford Nanopore Technologies, United Kingdom)	Central laboratory	Commercialized	Sputum	RIF, INH, FQ: SE: >94%, SP: >99%1	<24 hours	NA	RIF, INH, FQ, AMK, LZD, STM
	TBSeq [111] (ShenTing Biotech, China)	Central laboratory	Commercialized	Sputum	Sputum: SE: 94.8%, SP: 97.9%	1–2 days	NA	up to 16 drugs
	CleanPlex [112] (Paragon Genomics, USA)	Central laboratory	Late	Sputum	NA	1–2 days	NA	NA
	Tuberculini [113] (Clemedi, Switzerland)	Central laboratory	Late	Sputum	SE: 84%, SP: 95%	<24 hours	NA	up to 12 drugs
Culture	**Sensititre** [114] (Thermo Fisher Mesabiotech, USA)	Central laboratory	Early	Sputum	NA	10–21 days	NA	up to 12 drugs
	Phenotech [115] (Resistell, Switzerland)	Central laboratory	Early	Sputum	≥100 bacteria in specimen: SE: 97.4%, SP: 100%	21 hours	Test: $4.50, Sensor: $67, Instrument: $83,438	RIF, INH

AMK = amikacin, BDQ = bedaquiline, DLM = delamanid, EMB = ethambutol, FQ = fluoroquinolones, INH = isoniazid, KM = kanamycin, LZD = linezolid, MTB = mycobacterium tuberculosis, PTD = pretomanid, RIF = rifampicin, STM = streptomycin.

Table 5: Tests for TB Disease Progression or Treatment Monitoring

Technology	Tool Developer	Level	Stage of Development	Sample	Accuracy	Time to Result	Price	Type
Host-response tests	**Xpert MTB-HR** [116] (Cepheid, USA)	District laboratory	Early	Blood	Results correlate with treatment response	45 minutes	NA	Sweeny 3 RNA signature
	RISK6 signature assay [117] (TB HIRA) (QuantuMDx, United Kingdom)	District laboratory	Early	Blood	Progression to active TB ≤1 year SE: 75%, SP: 50.3%	30 minutes	NA	RISK6 RNA signature
	ISIT-TB [118] (bioMérieux, France)	District laboratory	Early	Blood	NA	120 minutes	NA	30-Marker mRNA signature
Quantitative bacterial load tests	**TB-MBLA** [119] (University of St. Andrews/ LifeArc, United Kingdom)	District laboratory	Early	Sputum/ Stool	Sputum: SE: 99%, SP: 91%,Stool: SE: 77%, SP: 87%	4 hours	<$15	Detects 16S rRNA
	Capilia TB-Neo [120] (TAUNS, Japan)	District laboratory	Commercialized	Sputum	Cultured isolate: Treatment monitoring Day 14: SE: 54.8%, SP: 89.5% Day 28: SE: 81%, SP: 72.4%	1–3 weeks for liquid culture, 15 minutes to results	NA	Detects MPT64
	PATHFAST TB LAM Ag [121] (PHC Corporation, Japan)	Primary health care	Commercialized	Sputum	SE:88.8%, SP: 100%	47 minutes	$32-54	Immunoassay
	TMKmt [122] (Makerere University, Uganda)	NA	Early	Blood/ Sputum	Blood: 100% specific to TB among people living with HIV Sputum: Detectable at low bacillary loads	NA	NA	Detects TMKmt

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