



A Comprehensive Systematic Review of The Effectiveness of Rapid Diagnostic Tests for Tuberculosis in Resource Limited Settings

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ABSTRACT

Introduction: Tuberculosis (TB) remains a leading cause of mortality in resource-limited settings, where conventional diagnostic methods such as smear microscopy have suboptimal sensitivity and cannot detect drug resistance. Rapid diagnostic tests (RDTs) offering results within hours may address these limitations, but their effectiveness across diverse settings requires comprehensive evaluation.

Methods: This review synthesized evidence from 126 studies conducted in low- and middle-income countries across Africa, Asia, and South America. Studies evaluating RDTs for active TB diagnosis against reference standards (culture, molecular tests, or clinical diagnosis) were included. Data extraction covered diagnostic accuracy, drug resistance detection, speed, implementation feasibility, cost factors, and clinical impact.

Results: Xpert MTB/RIF demonstrated pooled sensitivity of 88-89% and specificity exceeding 98%, with substantial variation by

smear status (98% in smear-positive vs 55-77% in smear-negative). Truenat assays showed comparable performance (90.6% sensitivity, 95.7% specificity), while TB-LAMP demonstrated 80% sensitivity and 98% specificity. Urine LAM testing achieved 66.7% sensitivity in severely immunocompromised HIV patients (CD4<50). For rifampicin resistance detection, Xpert MTB/RIF showed 94-95% sensitivity and 98% specificity. Time to results reduced from weeks to hours, with Xpert delivering results in <2 hours versus 16-30 days for culture. Implementation increased bacteriologically confirmed cases by 23-39% and reduced time to MDR-TB treatment from months to 22 days.

Discussion: RDTs substantially improve TB detection over microscopy, particularly for smear-negative and drug-resistant cases. However, mortality benefits remain inconsistent, reflecting effective empirical treatment in control arms and persistent challenges in linkage to care. Cost and infrastructure requirements pose implementation barriers.

Conclusion: RDTs are effective for TB diagnosis in resource-limited settings, but optimal impact requires integration into strengthened health systems with reliable treatment linkage.

Keywords: Tuberculosis, rapid diagnostic tests, Xpert MTB/RIF, resource-limited settings, diagnostic accuracy, drug resistance

INTRODUCTION

Tuberculosis (TB) remains a global public health emergency, with an estimated 10 million new cases and 1.5 million deaths annually, disproportionately affecting low- and middle-income countries (LMICs) (Steingart et al., 2014). Resource-limited settings face the dual burden of high TB incidence and constrained diagnostic infrastructure, where conventional sputum smear microscopy—the mainstay of diagnosis for over a century—detects only 50-60% of culture-confirmed cases and cannot identify drug resistance (Boehme et al., 2011; Steingart et al., 2013). The HIV co-epidemic further compounds this challenge, as HIV-associated TB is frequently paucibacillary and smear-negative, leading to missed diagnoses and delayed treatment initiation (Lawn et al., 2012; Theron et al., 2011).

The development of rapid diagnostic tests (RDTs) based on nucleic acid amplification technology has transformed the TB diagnostic landscape. These assays, including Xpert MTB/RIF, Truenat, and loop-mediated isothermal amplification (LAMP), can detect *Mycobacterium tuberculosis* complex and drug resistance mutations within hours rather than weeks, offering the potential for same-day diagnosis and treatment initiation (Boehme et al., 2010; Penn-Nicholson et al., 2021). The World Health Organization has endorsed several such technologies, yet questions persist regarding their real-world effectiveness, cost-effectiveness, and clinical impact in the diverse contexts of resource-limited health systems (McNerney and Zumla, 2015).

Despite the proliferation of diagnostic accuracy studies, significant research gaps remain. First, the translation of improved diagnostic accuracy into reduced mortality and morbidity has not been consistently demonstrated, with several randomized trials showing no mortality benefit despite increased case detection (Churchyard et al., 2015; Theron et al., 2014). Second, comparative effectiveness across different RDT platforms in head-to-head evaluations remains limited (Ngangue et al., 2022). Third, implementation factors affecting real-world performance—including infrastructure requirements, supply chain reliability, and healthcare worker training—are

understudied relative to accuracy metrics (Ardizzoni et al., 2015). Fourth, the cost-effectiveness of these technologies in different epidemiological and health system contexts requires further elucidation (Pooran et al., 2019).

The novelty of this review lies in its comprehensive synthesis of evidence across multiple RDT platforms, populations, and outcomes, moving beyond diagnostic accuracy to examine implementation feasibility, clinical impact, and health system considerations. By including studies from diverse geographic regions and healthcare levels, this review aims to provide actionable insights for policymakers and program managers in resource-limited settings.

The primary objective of this review is to evaluate the effectiveness of rapid diagnostic tests for tuberculosis detection in resource-limited settings. Specific objectives include: (1) assessing diagnostic accuracy for TB detection and drug resistance identification; (2) examining performance in key subpopulations including people living with HIV (PLHIV) and children; (3) evaluating speed, workflow, and operational characteristics; (4) analyzing implementation feasibility and cost factors; and (5) synthesizing evidence on clinical and public health impact. We hypothesize that while RDTs consistently demonstrate superior sensitivity compared to smear microscopy, their effectiveness is modulated by contextual factors including HIV prevalence, health system strength, and the availability of effective treatment linkage.

The findings of this review are expected to benefit multiple stakeholders: national TB programs seeking evidence-based diagnostic algorithms; healthcare workers implementing RDTs in peripheral settings; policymakers allocating limited resources; and researchers identifying priority areas for further investigation.

METHODS

Protocol

The study strictly adhered to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) 2020 guidelines to ensure methodological rigor and accuracy. This

approach was chosen to enhance the precision and reliability of the conclusions drawn from the investigation.

Criteria for Eligibility

This systematic review aims to evaluate the effectiveness of rapid diagnostic tests for tuberculosis in resource limited settings.

Screening

We screened in sources based on their abstracts that met these criteria:

- **Target Population:** Does the study include patients suspected of having tuberculosis or at high risk for TB in resource-limited settings?
- **Rapid Diagnostic Test:** Does the study evaluate rapid diagnostic tests for tuberculosis detection that provide results within hours rather than days?
- **Resource-Limited Setting:** Was the study conducted in low- and middle-income countries or resource-constrained healthcare settings (not exclusively in high-resource settings with unlimited laboratory infrastructure)?
- **Diagnostic Outcomes:** Does the study report diagnostic accuracy outcomes (sensitivity, specificity, positive/negative predictive values) or clinical outcomes?
- **Reference Standard:** Does the study compare rapid tests to established reference standards (culture, molecular tests) or clinical diagnosis?
- **Study Design:** Is the study a primary research study (cross-sectional, cohort, case-control, or randomized controlled trial) or a systematic review/meta-analysis?
- **Active TB Focus:** Does the study focus on active tuberculosis diagnosis (not exclusively on latent tuberculosis infection screening)?
- **Clinical Context:** Does the study include clinical context with patient populations (not laboratory-only studies without clinical context)?

- **Study Type:** Is the study a robust research design (not a case report, case series, editorial, or opinion piece)?

We considered all screening questions together and made a holistic judgement about whether to screen in each paper.

Search Strategy

The keywords used for this research based PICO :

Element	P (Population)	I (Intervention/Exposure)	C (Comparison/Context)	O (Outcome)
Keyword 1	Resource-Limited Settings	Rapid Diagnostic Tests	Conventional Methods	Effectiveness
Keyword 2	Low and middle-income countries	Rapid Molecular Tests	Sputum Smear Microscopy	Diagnostic Accuracy
Keyword 3	Developing countries	Nucleic Acid Amplification Tests (NAATs)	Ziehl-Neelsen (ZN) Microscopy	Sensitivity
Keyword 4	Primary Care Clinics	Xpert MTB/RIF	Fluorescence Microscopy	Specificity

The Boolean MeSH keywords inputted on databases for this research are: (*"Resource-Limited Settings"* OR *"Low and middle-income countries"* OR *"Developing countries"* OR *"Primary Care Clinics"*) AND (*"Rapid Diagnostic Tests"* OR *"Rapid Molecular Tests"* OR *"Nucleic Acid Amplification Tests (NAATs)"* OR *"Xpert MTB/RIF"*) AND (*"Conventional Methods"* OR *"Sputum Smear Microscopy"* OR *"Ziehl-Neelsen (ZN) Microscopy"* OR *"Fluorescence Microscopy"*) AND (*"Effectiveness"* OR *"Diagnostic Accuracy"* OR *"Sensitivity"* OR *"Specificity"*)

Data extraction

- **Diagnostic Test:**

Extract details about the rapid diagnostic test being evaluated for tuberculosis, including:

- Name and manufacturer of the test
- What the test detects (TB, rifampicin resistance, other drug resistance)
- Technology type (PCR, line-probe assay, LAMP, etc.)
- Sample type required (sputum, processed sputum, etc.)
- Level of automation (fully automated, semi-automated, manual)

- **Setting Context:**

Extract information about the resource-limited setting where the test was evaluated, including:

- Geographic location and country income level
- Healthcare facility type (primary care clinic, district hospital, reference laboratory)
- Population characteristics (HIV prevalence, TB burden, drug resistance rates)
- Existing diagnostic infrastructure and capacity
- Specific resource limitations mentioned (staff, equipment, electricity, etc.)

- **TB Detection Performance:**

Extract performance metrics for tuberculosis detection specifically, including:

- Sensitivity and specificity with 95% confidence intervals
- Positive and negative predictive values
- Overall accuracy
- Performance stratified by smear status (smear-positive vs smear-negative TB)
- Performance in HIV-positive vs HIV-negative patients

- Reference standard used for comparison

- **Drug Resistance Detection:**

Extract performance metrics for drug resistance detection in resource-limited settings, including:

- Sensitivity and specificity for rifampicin resistance detection
- Sensitivity and specificity for other drug resistance (isoniazid, MDR)
- Positive and negative predictive values for drug resistance
- Reference standard used
- Clinical significance of drug resistance detection capability

- **Speed and Workflow:**

Extract information about diagnostic speed and workflow requirements, including:

- Time to results (hours/days)
- Comparison of turnaround time vs conventional methods
- Sample processing requirements and complexity
- Hands-on time required
- Throughput capacity (samples per day)
- Impact on diagnostic delay reduction

- **Implementation Feasibility:**

Extract factors affecting implementation feasibility in resource-limited settings, including:

- Infrastructure requirements (electricity, temperature control, maintenance)
- Training and technical expertise needed
- Equipment reliability and maintenance issues
- Supply chain considerations (cartridges, reagents)

- Workflow integration challenges
- Staff acceptance and usability

- **Cost Factors:**

Extract cost-related information relevant to resource-limited settings, including:

- Test cost per sample or unit cost
- Equipment/instrument costs
- Cost comparisons with existing methods
- Cost-effectiveness analysis results
- Economic impact or cost savings mentioned
- Affordability considerations for the setting

- **Clinical Impact:**

Extract information about clinical and public health impact in resource-limited settings, including:

- Effect on case detection rates and TB case notification
- Impact on time to treatment initiation
- Patient outcomes (morbidity, mortality, treatment success)
- Impact on TB transmission and control
- Effect on loss to follow-up
- Changes in clinical decision-making or patient management

- **Comparative Performance:**

Extract how the rapid test compared to existing methods in resource-limited settings, including:

- Performance vs sputum smear microscopy

- Performance vs conventional culture methods
- Incremental case detection compared to existing methods
- Relative advantages and limitations
- Which method served as the primary comparator
- Head-to-head comparison results

Table 1. Article Search Strategy

Database	Keywords	Hits
Pubmed	<i>("Resource-Limited Settings" OR "Low and middle-income countries" OR "Developing countries" OR "Primary Care Clinics") AND ("Rapid Diagnostic Tests" OR "Rapid Molecular Tests" OR "Nucleic Acid Amplification Tests (NAATs)" OR "Xpert MTB/RIF") AND ("Conventional Methods" OR "Sputum Smear Microscopy" OR "Ziehl-Neelsen (ZN) Microscopy" OR "Fluorescence Microscopy") AND ("Effectiveness" OR "Diagnostic Accuracy" OR "Sensitivity" OR "Specificity")</i>	2
Semantic Scholar	<i>("Resource-Limited Settings" OR "Low and middle-income countries" OR "Developing countries" OR "Primary Care Clinics") AND ("Rapid Diagnostic Tests" OR "Rapid Molecular Tests" OR "Nucleic Acid Amplification Tests (NAATs)" OR "Xpert MTB/RIF") AND ("Conventional Methods" OR "Sputum Smear Microscopy" OR "Ziehl-Neelsen (ZN) Microscopy" OR "Fluorescence Microscopy") AND ("Effectiveness" OR "Diagnostic Accuracy" OR "Sensitivity" OR "Specificity")</i>	4
Springer	<i>("Resource-Limited Settings" OR "Low and middle-income countries" OR "Developing countries" OR "Primary Care Clinics") AND ("Rapid Diagnostic Tests" OR "Rapid Molecular Tests" OR "Nucleic Acid Amplification Tests (NAATs)" OR "Xpert MTB/RIF") AND ("Conventional Methods" OR "Sputum Smear Microscopy" OR "Ziehl-Neelsen (ZN) Microscopy" OR "Fluorescence Microscopy") AND ("Effectiveness" OR "Diagnostic Accuracy" OR "Sensitivity" OR "Specificity")</i>	343
Google Scholar	<i>("Resource-Limited Settings" OR "Low and middle-income countries" OR "Developing countries" OR "Primary Care Clinics") AND ("Rapid Diagnostic Tests" OR "Rapid Molecular Tests" OR "Nucleic Acid Amplification Tests (NAATs)" OR "Xpert MTB/RIF") AND ("Conventional Methods" OR "Sputum Smear Microscopy" OR "Ziehl-Neelsen (ZN) Microscopy" OR "Fluorescence Microscopy") AND ("Effectiveness" OR "Diagnostic Accuracy" OR "Sensitivity" OR "Specificity")</i>	4,710
Wiley Online Library	<i>("Resource-Limited Settings" OR "Low and middle-income countries" OR "Developing countries" OR "Primary Care Clinics") AND ("Rapid Diagnostic Tests" OR "Rapid Molecular Tests" OR "Nucleic Acid Amplification Tests (NAATs)" OR "Xpert MTB/RIF") AND ("Conventional Methods" OR "Sputum Smear Microscopy" OR "Ziehl-Neelsen (ZN) Microscopy" OR "Fluorescence Microscopy") AND ("Effectiveness" OR "Diagnostic Accuracy" OR "Sensitivity" OR "Specificity")</i>	185

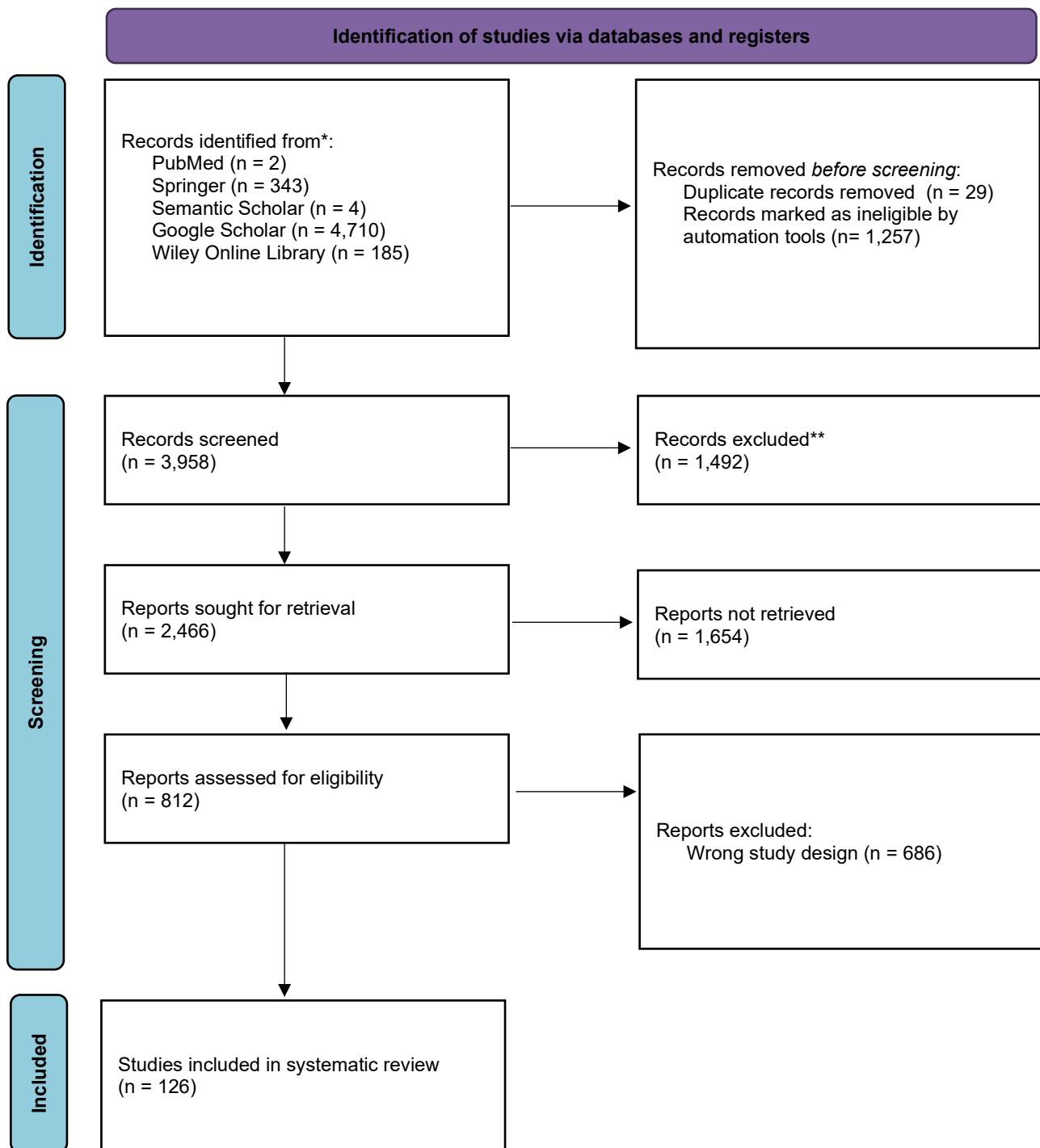


Figure 1. Article search flowchart

RESULTS

Study Characteristics

The included studies represent a broad range of investigations into rapid diagnostic tests (RDTs) for tuberculosis (TB), predominantly conducted in resource-limited settings across Africa, Asia, and South America. Geographic locations spanned countries with high TB and HIV burdens, including South Africa, India, Peru, Uganda, Tanzania, Zambia, Zimbabwe, Cameroon, Ethiopia, Myanmar, Nepal, and others. Healthcare facilities ranged from peripheral primary care clinics and community health centers to district and tertiary referral hospitals and national reference laboratories.

Study designs were predominantly cross-sectional or prospective cohort studies evaluating diagnostic accuracy, with some randomized controlled trials assessing clinical impact. Populations were characterized by high HIV prevalence in many settings, ranging up to 73%. Sample sizes varied widely. The main RDTs evaluated were nucleic acid amplification tests (NAATs), primarily the Xpert MTB/RIF and Xpert Ultra assays, but also loop-mediated isothermal amplification (LAMP) tests like TB-LAMP, and molecular assays like Truenat. Line probe assays (LPAs) for drug resistance, such as GenoType MTBDRplus, were also assessed. Non-molecular RDTs included antigen-detection tests like the lateral flow urine lipoarabinomannan (LAM) assay and phage-based tests.

Reference standards were consistently mycobacterial culture, using either solid (Löwenstein-Jensen) or liquid media (e.g., MGIT), often in combination. For drug resistance, the reference standard was phenotypic drug susceptibility testing (DST). Resource limitations frequently mentioned included the high cost of molecular tests, need for stable electricity, and limited laboratory infrastructure or technical expertise, particularly in peripheral settings.

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
C. Boehme et al., 2011	Peru, South Africa, India, Azerbaijan, Philippines, Uganda	Urban health centers, drug-resistance screening facilities, emergency room	6648	Adults with suspected TB or MDR-TB	Xpert MTB/RIF	PCR	Sputum	Sputum culture
C. Boehme et al., 2010	Peru, Azerbaijan, South Africa, India	Not specified	1730	Patients with suspected drug-sensitive or MDR-TB	Xpert MTB/RIF	Real-time PCR	Untreated sputum	Sputum culture
G. Theron et al., 2014	South Africa, Zimbabwe, Zambia, Tanzania	Primary-care health-care facilities	1502	Adults with symptoms suggestive of active TB	Xpert MTB/RIF	PCR	Sputum	Sputum culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
K. Steingart et al., 2013	Multiple low- and middle-income countries	Reference laboratories	7517	Adults with suspected pulmonary TB or MDR-TB, with or without HIV	Xpert MTB/RIF	PCR	Respiratory specimens (processed sputum or tissue)	Culture
M. Barnard et al., 2008	Cape Town, South Africa	Routine diagnostic laboratory	536	Patients at increased risk of MDR-TB, high HIV prevalence setting	Line-probe assay	Molecular line-probe assay	Smear - positive sputum	Liquid culture and drug susceptibility testing
H. Albert et al., 2002	Cape Town, South Africa	Primary health care clinics	853	Individuals with no previous history of TB treatment	FASTPlaqueTB	Phage-based	Sputum	Löwenstein-Jensen culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
K. Steingart et al., 2014	Multiple low- or middle-income countries	Intermediate- and peripheral-level laboratories	9557	Adults with suspected pulmonary TB, rifampicin-resistant or MDR-TB, with or without HIV	Xpert MTB/RIF	PCR	Respiratory specimens	Culture
S. Lawn et al., 2012	Gugulethu, South Africa	Community-based ART clinic	602	HIV-infected adults screened for TB before ART	Determine TB-LAM Ag	Lateral flow assay	Urine	Sputum culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
H. Zar et al., 2013	Cape Town, South Africa	Primary care clinic	384	Children (<15 years) with suspected pulmonary TB	Xpert MTB/RIF	PCR	Induced sputum, nasopharyngeal aspirate	Culture and smear microscopy on induced sputum
G. Calligaro et al., 2017	Cape Town, South Africa; Harare, Zimbabwe	Mobile van, local clinic	875	Community-based intensified case finding in high TB and HIV prevalence settings	Xpert-MTB/RIF and Determine TB LAM	PCR and lateral flow assay	Sputum and urine	Culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
A. Rachow et al., 2011	Mbeya, Tanzania	Referral hospital	292	Adults with suspected TB; 58.9% HIV-positive	Cepheid Xpert MTB/RIF Assay	Real-time PCR	Sputum	Culture
L. Scott et al., 2011	Johannesburg, South Africa	Primary health care clinic	311	Adults with suspected TB; 70% HIV-positive	Xpert MTB/RIF, MTBDRplus, LightCycler Mycobacterium Detection	Hemi-nested real-time PCR, Line probe assay, PCR	Processed sputum	Liquid culture
A. Bojang et al., 2016	The Gambia	Peripheral health clinics	441	Patients with symptoms of TB and confirmed TB patients on treatment	TB-LAMP and GeneXpert MTB/RIF	LAMP and NAAT	Sputum	MGIT culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
G. Carriquiry et al., 2012	Lima, Peru	Tertiary hospitals	131	HIV-positive patients with high clinical suspicion of TB	Xpert MTB/RIF	Real-time PCR	Untreated sputum	Löwenstein-Jensen (LJ) and liquid culture (MGIT)
K. Sachdeva et al., 2015	India	Sub-district level TB programme units	81231	Presumptive TB patients in diverse settings	Xpert MTB/RIF	PCR	Sputum	Conventional Drug Susceptibility Testing (DST)

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
A. Penn-Nicholson et al., 2021	Peru, India, Ethiopia, Papua New Guinea	Primary healthcare centres and reference laboratories	1807	Participants with TB signs/symptoms; 15% RIF-resistant among culture-positive	Truenat MTB, MTB Plus, and MTB-RIF Dx	Molecular assays	Not specified (likely sputum)	Culture and phenotypic drug susceptibility testing
N. Shah et al., 2011	Rural South Africa	District hospital	534	Adult TB suspects; 73% HIV-positive	Microscopic Observation Drug-Susceptibility (MODS) assay	Microscopic observation	Sputum	Culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
M. Shah et al., 2014	Uganda	Not mentioned	208	HIV-infected individuals with signs/symptoms of TB	Xpert MTB/RIF and urinary lipoarabinomannan (LAM) assays	PCR, lateral flow test, ELISA	Sputum and urine	Culture
Y. R. Ngangue et al., 2022	Cameroon	Hospital outpatient departments	945	Adult outpatients with presumptive TB; high HIV/TB burden setting	Truenat MTB Plus assay	Molecular test	Sputum	TB culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
A. Esmail et al., 2023	Cape Town, South Africa	Community-based mobile clinic	584	Individuals with HIV infection or symptoms of TB in periurban informal settlements	GeneXpert	DNA-based molecular diagnosis	Sputum	Culture
M. Kasaro et al., 2017	Zambia	Peri-urban clinics	1353	HIV-infected adult patients	Xpert MTB/RIF (GXP) and LAM	PCR and antigen detection	Sputum and urine	Culture
B. Saavedra et al., 2021	Southern Mozambique	Healthcare services and community settings	1671	Symptomatic adults and close contacts in a high TB/HIV burden area	Xpert MTB/RIF Ultra	PCR	Respiratory specimens	Liquid and solid culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
P. Shete et al., 2019	Multiple high TB burden countries	Reference labs and peripheral microscopy centers	4760	Presumptive pulmonary TB patients	TB-LAMP	LAMP	Sputum	Mycobacterial culture
R. McNerney et al., 2015	TB endemic countries	Primary healthcare clinics	Not specified	Not specified	Xpert MTB/RIF	Automated PCR-based test	Sputum	Not mentioned
J. L. Davis et al., 2013	Low-income countries	Not mentioned	7771	Patients with suspected tuberculosis	Same-day microscopy vs. standard microscopy	Light microscopy, fluorescence microscopy	Sputum	Culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
G. Theron et al., 2011	South Africa	Not mentioned	496	Patients with suspected TB in a high HIV prevalence setting	Xpert MTB/RIF	Molecular diagnostic	Spot-sputum samples	M. tuberculosis culture
G. Theron et al., 2011a	South Africa	Primary care clinic	480	Patients with suspected TB in a resource-poor setting	Xpert MTB/RIF	PCR	Sputum	Liquid culture
K. Steingart et al., 2013a	Low and middle-income countries	Peripheral laboratories and health clinics	18 studies (nearly 8000 participants)	Adults suspected of having TB, with or without HIV	Xpert MTB/RIF	Automated PCR	Sputum (implied)	Not mentioned
A. Rachow et al., 2012	Mbeya, Tanzania	Referral hospital	164	Children with suspected TB in a high TB/HIV-burden setting	Xpert MTB/RIF assay	NAAT	Sputum	M. tuberculosis culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
L. Kivihya-Ndugga et al., 2003	Nairobi, Kenya	Specialised chest clinic	1398	TB suspects	Ziehl-Neelsen (ZN) and fluorescence microscopy (FM)	Microscopy	Sputum	Löwenstein-Jensen culture
T. V. D. Handel et al., 2015	Central Karoo, South Africa	Facility level or centralised laboratory	1449	Individuals with poor access to TB diagnostics	Xpert MTB/RIF	PCR	Sputum	Not mentioned
F. Haraka et al., 2021	Not specified	Not specified	12 studies (9932 participants in RCTs)	People being investigated for tuberculosis	Xpert MTB/RIF	PCR	Sputum	Not mentioned

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
T. Balcha et al., 2014	Ethiopia	Public health centers	812	HIV-positive adults eligible for ART	Xpert MTB/RIF	Real-time PCR	Sputum, lymph node aspirates	Liquid culture
Jae Hyoung Lee et al., 2022	Multiple, mainly LMICs	Primary care facilities or laboratories	45 studies	Patients with drug-sensitive or drug-resistant TB	Xpert and LPA	PCR and line probe assay	Sputum	Smear microscopy and culture DST

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
C. Nikam et al., 2013	India	Tertiary care hospital	226	Patients with suspected pulmonary TB	Truenat MTB	Real-time PCR	Clinical sputum specimens	Composite reference standard (smear, culture, clinical follow-up)
G. Churchyard et al., 2015	South Africa	Primary care clinics	4656	Adults giving sputum for TB investigation; 62% HIV-positive	Xpert MTB/RIF	PCR (implied)	Sputum	Not mentioned

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
C. Modongo et al., 2011	Resource-limited countries	Not specified	Not specified	Patients suspected of TB or MDR-TB, including HIV co-infected	MTB/RIF test	Nucleic-acid amplification assay	Sputum, other clinical samples	Culture
C. Habeenzu et al., 2017	Zambia	University Teaching Hospital	200	New tuberculosis (TB) suspects	In-house LAMP and Xpert MTB/RIF	LAMP and real-time PCR	Sputum	Culture
J. Malacarne et al., 2019	Brazil	Indigenous health care service	4048	Indigenous people with respiratory symptoms	GeneXpert (Rapid Molecular Testing)	Nucleic acid amplification test	Sputum	Sputum culture
A. V. Rie et al., 2013	South Africa	Primary care clinic	199	Smear-negative TB suspects, 72% HIV-positive	Xpert MTB/RIF	PCR	Sputum	Liquid culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
E. Ardizzoni et al., 2015	18 countries (varied settings)	District and sub-district laboratories	52863 samples	Presumptive TB cases, including high-risk groups (MDR-TB, HIV, pediatric)	Xpert MTB/RIF	PCR	Sputum and extrapulmonary samples	Smear microscopy and culture
P. Shete et al., 2017	Rural Uganda	Primary care health centers	1212	Adults with presumed TB, 53% HIV-positive	Xpert MTB/RIF	Molecular assay	Sputum	Not mentioned (focus on feasibility)
S. V. van Kampen et al., 2015	Indonesia	Provincial public hospitals	2397	Individuals at risk of drug-resistant TB	Xpert MTB/RIF	Automated molecular test	Sputum	Conventional culture and DST

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
G. Alvarez-Uria et al., 2012	India	District hospital	Not specified	HIV-infected patients with suspected pulmonary and extrapulmonary TB	GeneXpert MTB/RIF	PCR	Sputum, CSF, pleural fluid, etc.	Culture
A. Pooran et al., 2019	South Africa, Zambia, Zimbabwe, Tanzania	Primary health-care facilities	1502	Patients presenting to primary health-care facilities	Xpert MTB/RIF	Nucleic acid amplification	Sputum	Not mentioned (focus on economic outcomes)

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
D. Nair et al., 2016	Tamil Nadu, India	Not specified	524	MDR-TB patients	Rapid molecular tests	Molecular (implied)	Sputum	Culture and drug sensitivity testing (CDS T)
R. Philipsen et al., 2015	Cape Town, South Africa	Urban clinic	388	Suspected TB subjects, 33% HIV-positive	Automated digital chest radiography (as triage for Xpert)	Digital imaging	Not applicable	Culture
D. Wilson et al., 2023	South Africa	Patient care settings (inpatient)	10202	HIV-positive adults being evaluated for TB	Alere Determine TB LAM (AlereLAM)	Laternal flow assay	Urine	Xpert or culture from any site

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
S. Walmsley et al., 2015	Not specified	Not specified	18 studies (n=4461)	Adults or children with suspected extrapulmonary TB	Xpert MTB/RIF	PCR	Lymph node aspirate/tissue, CSF	Mycobacterial culture or composite reference standard
L. Inbaraj et al., 2025	Low- and middle-income countries	Not specified	10 studies	Adults and adolescents with presumptive pulmonary TB	Truenat assays (MTB, MTB Plus, MTB-RIF Dx)	Molecular diagnostic test	Sputum	Culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
R. Yadav et al., 2017	North India	Tertiary care hospital	530	Patients with PTB symptoms	TB-LAMP assay	LAMP	Raw sputum	Mycobacterial culture
J. Cavanaugh et al., 2016	Western Kenya	HIV treatment centers	778	People living with HIV	GeneXpert MTB/RIF (Xpert)	Automated PCR	Sputum	Liquid culture or Xpert
C. Hanrahan et al., 2013	Johannesburg, South Africa	Primary care clinic	641	TB suspects, 69% HIV-infected	Xpert MTB/RIF	PCR	Sputum	Sputum smear microscopy and liquid culture
Jacob Creswell et al., 2015	Eastern Nepal	Routine case finding sites	9723 tests	Presumptive TB patients	Xpert MTB/RIF	PCR	Sputum	Liquid culture (implied)

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
N. Raizada et al., 2018	Four major cities in India	Public and private health care facilities; high-throughput labs	42238	Pediatric (0-14 years) presumptive TB cases	Xpert MTB/RIF	PCR	Various (pulmonary and extra-pulmonary)	Sputum smear microscopy (for comparison)
S. Hermans et al., 2017	Cape Town, South Africa	Not specified	102007	Adults treated for pulmonary TB, high HIV prevalence	Xpert MTB/RIF	PCR	Sputum	Not mentioned (focus on empirical treatment)

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
Nirajan Bhusal et al., 2018	Nepal	University hospital	500	Patients suspected to have TB	Nanoparticle-based Colorimetric Biosensing Assay (NCBA)	Nanotechnology-based colorimetric assay	Sputum	Xpert MTB/RIF
K. Dheda et al., 2009	South Africa	Not specified	91	Consecutively recruited patients suspected of having TB; 29% HIV+	T-SPOT.TB and QuantiFERON-TB-Gold-In-Tube	ELISPOT/IGRA	Alveolar lavage cells	Clinical diagnosis (definite/probable TB)

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
M. Muyoyeta et al., 2015	Lusaka, Zambia	Primary health care facilities	13926	Presumptive TB patients in high TB and HIV burden setting	Xpert MTB/RIF	PCR	Sputum	Xpert MTB/RIF (used as primary method)
Surabhi Lavania et al., 2018	Not mentioned	Not mentioned	314	Smear-positive & smear-negative TB patients, and healthy volunteers	Aptamer ALISA and Electrochemical Sensor (ECS)	DNA aptamer-based	Sputum	Culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
T. Reza et al., 2020	Uganda	Community health centers	Not specified	Patients evaluated for TB in high-burden settings	GeneXpert Edge	NAAT	Sputum	Not applicable (protocol paper)
A. Penn-Nicholson et al., 2021a	India, Moldova, South Africa	Not specified	710	Individuals with pulmonary TB symptoms and at least one risk factor for drug resistance	Xpert MTB/XDR	Automated molecular assay	Sputum (implied)	Composite of phenotypic DST and whole-genome sequencing

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
R. Nathavitharana et al., 2019	Sub-Saharan Africa	Hospital settings	Not specified	People living with HIV (PLHIV)	Urine lipoarabinomannan (LAM)	Biomarker-based assay	Urine	Not mentioned
N. Javanshir et al., 2010	Kenya	Rural hospitals	498	Patients in chest and HIV clinics	TB-ST Rapid Test	Lateral flow immuno-chromatography	Likely blood sample	Sputum smears
S. LaCourse et al., 2016	Western Kenya	Antenatal care setting	306	HIV-infected pregnant women	GeneXpert MTB/RIF (Xpert) and Urine LAM	PCR and antigen detection	Sputum and urine	Sputum culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
R. Rakotoarivelo et al., 2018	Madagascar	Tertiary care hospital	363	Patients with suspected smear-negative or extrapulmonary TB; HIV prevalence 12.1%	Xpert MTB/RIF	Molecular diagnostic test	Not specified	Clinical classification (proven, probable, possible TB)
N. Tukvadze et al., 2012	Georgia	National TB Reference Laboratory	500	AFB smear-positive TB suspects in a high MDR-TB prevalence area	Genotype MTBDRplus	Line-probe assay	Sputum	Conventional culture and DST

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
E. Walters et al., 2017	Cape Town, South Africa	Hospital setting	379	Children (<13 years) with suspected pulmonary TB; 13.7% HIV infected	Xpert MTB/RIF	PCR	Stool	Bacteriologic confirmation (Xpert and culture of respiratory samples)
S. Auld et al., 2016	Cambodia	Public health sites	1315	PLHIV with TB symptoms and patients with possible MDR-TB	Xpert MTB/RIF	PCR	Sputum	Smear microscopy and culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
A. Muwonge et al., 2014	Uganda	Regional referral hospital	344	Patients with persistent cough or lymphadenitis	Direct Ziehl-Neelsen (DZM) microscopy	Traditional microscopy	Sputum	Direct fluorescent microscopy (DFM)
N. Raizada et al., 2015	India	Sub-district level TB units	2787	HIV-infected presumptive pulmonary TB cases	Xpert MTB/RIF	PCR	Sputum	Culture DST and line probe assay (LPA)
S. Jha et al., 2016	South Africa	National TB Reference Laboratory	Not specified	Not specified	TBDx automated digital microscopy system	Automated digital microscopy	Concentrated sputum	Xpert MTB/RIF

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
A. Hamid Salim et al., 2006	Bangladesh	TB control project	Not specified	Smear-positive sputum from patients with possible treatment failure	Fluorescein diacetate (FDA) vital staining and slide DST	Vital staining and DST	Smear - positive sputum	Culture and Löwenstein-Jensen proportion method
M. Cleeff et al., 2005	Nairobi, Kenya	Chest clinic	Not specified	TB suspects	AMPLICOR MTB PCR	PCR	Sputum	Löwenstein-Jensen culture
N. Raizada et al., 2014	India	Sub-district level TB units	4600	Pediatric presumptive PTB cases	Xpert MTB/RIF	PCR	Sputum	Culture DST/LPA

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
Ehsan Aryan et al., 2013	Not specified	Not specified	101	Sputum from 93 highly suspected TB patients	IS6110-based loop-mediated isothermal amplification (LAMP)	LAMP	Sputum	Culture results or clinical recovery
J. Zarocostas et al., 2010	Peru, Azerbaijan, South Africa, India	Not specified	1462	People with symptoms suggestive of TB	Unnamed automated molecular test	Molecular (implied)	Sputum	Sputum smear test and culture
S. V. van Kampen et al., 2015a	Kazakhstan	National and provincial laboratories	5611 tests	Individuals at risk of MDR-TB	Xpert MTB/RIF	PCR	Sputum	Phenotypic DST

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
P. Ghosh et al., 2025	Bangladesh and Uganda	Tertiary healthcare facilities	200 (planned)	Suspected EPTB patients with cervical lymphadenitis	Recombinase-aided amplification assay (RAA) in Minoo device	RAA	Fine-needle aspirate	Composite reference standard (microscopy, PCR, cytology, culture, Xpert Ultra)
Sekai Chenai Mathabire Rucker et al., 2019	DR Congo, Malawi, Mozambique	Various health centers and hospitals	1555	Adult HIV-positive patients eligible for LAM testing	Determine TB-LAM	Laternal flow assay	Urine	Not mentioned (feasibility study)

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
I. Mutingwen de et al., 2015	Not mentioned	Low infrastructure microscopy centers	306	Patients with suspected pulmonary TB	NWU-TB test	Multiplex-PCR	Sputum	MGIT culture
K. Reither et al., 2015	Tanzania and Uganda	Not specified	451	Children with suspected pulmonary TB	Xpert MTB/RIF assay	PCR	Not specified	Culture
A. Raj et al., 2020	South India	Urban area	831	Suspected pulmonary and extrapulmonary TB cases	CB-NAAT assay	NAAT (PCR)	Not specified	MGIT culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
Jing Peng et al., 2021	China	Tertiary referral hospital	28171	Adult inpatients suspected of having PTB	Xpert MTB/RIF	PCR-based	Sputum, bronchoalveolar lavage fluid (BALF)	Mycobacterial culture
I. Ullah et al., 2017	Pakistan	Not specified	266	Sputum smear-negative pulmonary and extrapulmonary TB suspects	Xpert MTB/RIF	PCR	BALF, extrapulmonary specimens	Culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
A. Gupta-Wright et al., 2020	Zambia	Peri-urban outpatient clinics	Not specified	People living with HIV with presumed TB	Xpert MTB/RIF and urine LAM	PCR and antigen detection	Sputum and urine	TB culture
G. M. Kassa et al., 2021	Amhara region, Ethiopia	Specialized and referral hospitals	574	Drug-Resistant TB patients	Xpert MTB/RIF, Line Probe Assay (LPA)	PCR-based, LPA	Sputum	Solid culture-based DST
C. Vuchas et al., 2023	Cameroon	Reference and peripheral laboratories	10117	Presumptive TB patients	Xpert MTB/RIF and Xpert MTB/RIF Ultra	PCR-based	Sputum	Individual Xpert testing (for in silico analysis)

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
M. Kasaro et al., 2020	Zambia	Peri-urban health facilities	1350	People living with HIV with presumed TB	Xpert MTB/RIF and Determine TB-LAM Ag	PCR-based and lateral flow assay	Sputum and urine	Mycobacterial culture
M. Muyoyeta et al., 2015a	Zambia	Primary health care facilities	13926	Presumptive TB patients	Xpert MTB RIF	PCR	Sputum	Not mentioned
L. Inbaraj et al., 2025a	Low- and middle-income countries	Tertiary hospitals	4 studies (303 participants)	Children (< 10 years) with presumptive pulmonary TB	TB-LAMP	LAMP	Sputum, BAL, gastric aspirate, stool, etc.	Microbiological reference standard (culture)

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
Dana Hassneiah et al., 2025	Sub-Saharan Africa	Inpatient settings	3 RCTs (4602 participants)	Adult inpatients with HIV	LC-aNAAT (Xpert) and urine LF-LAM	PCR and lateral flow assay	Respiratory samples and urine	Not applicable (comparison of interventions)
F. Bwanga et al., 2011	Uganda	National Referral Hospital	245	Re-treatment TB patients	Nitrate Reductase Assay (NRA) and MODS	Visual color change and microscopic observation	Smear - positive sputum	LJ proportion method
K. Kawkitinrong et al., 2017	Thailand	3 large tertiary care hospitals	494	Patients with suspected PTB; high HIV prevalence	Xpert MTB/RIF assay	PCR (implied)	Sputum	Myco bacterial culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
L. Nakiyingi et al., 2018	Kiboga District, Uganda	District hospital and health centers	233	Outpatient presumptive TB adults; 48.5% HIV-infected	Eiken TB-LAMP test	LAMP	Sputum	MTB culture
A. Page et al., 2015	Cambodia, Georgia, Kenya, Swaziland	Not specified	6086	Presumed TB patients	Xpert MTB/RIF	PCR	Sputum	Microscopy
D. Osório et al., 2020	Mozambique	Rural health center	45	Pediatric inpatients with severe acute malnutrition	Urine lipoarabinomannan antigen assay (TB-LAM)	Antigen detection assay	Urine	Clinical diagnosis (primary), culture and Xpert (secondary)

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
K. Sharma et al., 2018	Not mentioned	Not mentioned	225	Patients with suspected TBM, confirmed TBM, and non-TBM controls	Xpert MTB/RIF (GXpert) and Multiplex PCR (MPCR)	PCR-based	Cerebrospinal fluid	Culture (for confirmed cases), rpoB gene sequencing
S. Swaminathan et al., 2012	South Africa	Not specified	Not specified	HIV-associated TB patients before ART	Determine TB-LAM	Lateral-flow urine strip test	Urine	Culture-based diagnosis

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
K. Myo et al., 2018	Mandalay, Myanmar	Tertiary-level children's hospital	231	Children with suspected PTB	Xpert MTB/RIF	PCR (implied)	Gastric lavage aspirate	Revised NIH classification for intrathoracic TB in children
Fatima Zahra et al., 2018	Rawalpindi, Pakistan	Tertiary care hospital	352	Patients aged 18-70 with suspected TB	Gene Xpert MTB/RIF	PCR	Respiratory clinical specimens	MGIT culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
N. Lorent et al., 2015	Cambodia	Referral hospital	299	Presumptive MDR-TB cases	Xpert MTB/RIF	PCR	Sputum	Solid culture /conventional DST and LPA
A. Tihamiyu et al., 2020	Nigeria	Not specified	150	Patients with smear-negative pulmonary TB (SNPTB) in high HIV burden region	Xpert MTB/RIF	PCR (implied)	Sputum	Sputum culture (Löwenstein-Jensen)
B. Phetsuksiri et al., 2020	Thailand	Not mentioned	204	Not specified	In-house loop-mediated isothermal amplification (LAMP)	LAMP	Sputum	Culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
B. Schmidt et al., 2017	South Africa	Community	26370	Adult patients with suspected pulmonary TB	Xpert MTB/RIF	PCR	Sputum	Not mentioned
V. Mittal et al., 2024	Developing countries	Peripheral health centers	239	Suspected cases of tubercular meningitis	TB LAMP assay	LAMP	Cerebrospinal fluid	MGIT TB culture
Sharon Kasa Tom et al., 2018	Papua New Guinea	General hospital	93	Children with suspected PTB	Gene Xpert MTB/RIF	PCR	Sputum or gastric aspirates	Standard clinical criteria
Youngwhan Kim et al., 2015	Not specified	Not specified	321	Patients with phenotypic DST results or diagnosed with RMP-resistant TB by Xpert	Xpert MTB/RIF	PCR	Sputum	Phenotypic DST

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
R. J. Bowerman et al., 2020	Western Alaska, USA	Regional hospital and clinics	223	Patients acutely evaluated for pulmonary TB	Xpert MTB/RIF	PCR	Sputum	Culture
K. Leung et al., 2018	Not specified	Not specified	503	Not specified	In-house duplex nested IS6110 real-time PCR assay	Real-time PCR	Sputum	Bacteriological and clinical information
Hsiang-Wei Lu et al., 2020	High TB burden countries	Primary care settings	45	Clinical TB cases and controls	Prototype integrated nucleic acid testing device	LAMP	Sputum	Manual qPCR-based comparator method

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
S. V. van Kampen et al., 2015b	Kazakhstan	National and provincial laboratories	Not specified	Individuals at risk of MDR-TB	Xpert MTB/RIF	Real-time PCR	Sputum	Phenotypic DST
Sonam Dolker et al., 2012	India	Not specified	261	TB suspected patients	Loop Mediated Isothermal Amplification (LAMP) assay	LAMP	Sputum	Culture
S. Walusimbi et al., 2013	Uganda	Tertiary care facility	430	Smear-negative patients with presumptive TB, HIV-infected	Xpert MTB/Rif, MODS, NRA	Molecular, Culture-based	Sputum	MGIT culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
Ligamena N. Kakoma et al., 2016	Namibia	Reference laboratory	400	Patients with known HIV status suspected of having TB	GeneXpert	PCR	Sputum	Direct microscopy (DM)
Evrevin Marine et al., 2020	France	Prison hospital	76	Inmates with TB symptoms	Xpert MTB/RIF Ultra	PCR	Raw sputum	Culture and DST
Alain Farra et al., 2023	Central African Republic	National Reference Laboratory for TB	101	Rifampicin resistance cases	Xpert MTB/RIF and Line Probe Assay (LPA)	PCR and LPA	Not specified	DST on solid medium

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
Prakash Shrestha et al., 2018	Eastern Nepal	National Anti-Tuberculosis Center and Primary Healthcare Center	1549	Pulmonary TB suspected patients	GeneXpert MTB/RIF assay (Xpert)	Real-time PCR	Sputum	Conventional AFB staining (smear microscopy)
S. Kaswabuli et al., 2022	Uganda	National Referral Hospital	86	Presumptive TB patients	GenoQuick MTB test	PCR-lateral flow test	Sputum	Löwenstein-Jensen culture
M. Singh et al., 2016	New Delhi, India	Tertiary care teaching hospital	50	Children aged 0-14 years with suspected PTB	Xpert MTB/RIF	PCR	Sputum/induced sputum and gastric lavage	MGIT culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
Z. Burger et al., 2022	Myanmar	National level	339358	Patients tested for TB, including PLHIV	Xpert MTB/RIF	PCR	Sputum	Smear microscopy (for comparison)
L. Martinez et al., 2019	Sub-Saharan Africa	Not specified	Not specified	People living with advanced HIV	Point-of-care C-reactive protein (CRP) testing	Biochemical assay	Not specified	WHO-recommended symptom screen

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
Nathakorn Pongpeeradech et al., 2022	Northeastern Thailand	General hospitals	2030	Patients with negative smear results or high risk of MDR-TB	GeneXpert MTB/RIF	NAAT	Sputum	Phenotypic conventional methods (TB culture, DST, LPA)
M. Alao et al., 2021	Southwestern Nigeria	Tertiary health facility	Not specified	Suspected cases of TB	GeneXpert MTB/RIF	Real-time PCR	Sputum and extrapulmonary specimens	AFB-smear

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
Swati B Gajbhiye et al., 2019	Central India	Tertiary care hospital	1589	Suspected TB patients from tribal population	Cartridge-Based Nucleic Acid Amplification Test (CBNAAT)	Molecular (NAA T)	Pulmonary and EPTB specimens	AFB smear and phenotypic culture-based DST
V. Nikolayevsky et al., 2019	Odessa Oblast, Ukraine	Not specified	1888	Patients with suspected TB	Xpert MTB/RIF	PCR	Sputum	Not mentioned
K. Choun et al., 2019	Cambodia	Mobile radiography units	41141	Adults in underserved high-prevalence settings	Xpert MTB/RIF	PCR	Sputum	Clinical diagnosis and bacteriological confirmation

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
Juan Carlos Garberi et al., 2025	Oruro, Bolivia	Not specified	71	Patients with presumptive TB	Orange G3 TBC platform	PCR	Sputum and CSF	Gene Xpert Ultra
A. Penn-Nicholson et al., 2021b	India, Moldova, South Africa	Outpatient clinics and inpatient hospitals	710	Adults with TB symptoms and risk factors for drug resistance	Xpert MTB/XDR	PCR	Sputum	Composite of phenotypic DST and whole genome sequencing
Sri Kartika Sari et al., 2016	Indonesia	Hospitals	81	Suspected and non-tuberculosis patients	TB antigen rapid test device (TB Ag)	Laternal flow immunoassay	Sputum	Lowenstein Jensen media culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
Mansuri M.Z et al., 2025	India	Rural tertiary care teaching center	200	150 PTB and 50 EPTB cases	GeneXpert MTB/RIF (CBNAAT)	PCR-based	Sputum (implied)	Smear microscopy and conventional culture
Gangarathna Krishna et al., 2019	India	Tertiary care teaching hospital	110	Suspected cases of pulmonary TB	Loop-Mediated Isothermal Amplification (LAMP) method	LAMP	Sputum	Lowenstein-Jensen (LJ) medium culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
D. V. van Hoving et al., 2020	Cape Town, South Africa	District hospital emergency centre	414	HIV-positive adults with TB symptoms	Urine lateral flow lipoarabinomannan (LF-LAM) assay and Point-of-care ultrasound (PoCUS)	LF-LAM and ultrasound imaging	Urine, other	Xpert MTB/RIF or culture
F. Saluzzo et al., 2024	Pakistan	Not specified	Not specified	People newly and previously diagnosed with TB	Xpert MTB/XDR	PCR	Sputum (implied)	Phenotypic DST (pDST) and NGS

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
A. Ojo et al., 2021	Not specified	Not specified	100	Symptomatically diagnosed PTB patients	Gene xpert (GX) and Lipoarabinomannan (LAM) assay	Not specified	Sputum and urine	Culture
B. Reeve et al., 2023	South Africa	Primary care clinic	897	PLHIV initiating ART	Xpert MTB/RIF Ultra and Determine LF-LAM	PCR and lateral flow assay	Sputum and urine	Liquid culture
Eunita D. A. Ochola et al., 2024	Nairobi, Kenya	Community Health Center	190	PLWHIV aged ≥ 18 years with presumptive TB	Xpert Ultra, LAM, and Sputum Smear Microscopy (SSM)	PCR, antigen detection, microscopy	Sputum and urine	Bayesian latent class models

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
Isabel Cuella-Martin et al., 2025	Rwanda	Not specified	129	Patients diagnosed with RR-TB by Ultra	Xpert MTB/RIF Ultra	PCR	Sputum (implied)	Repeat Ultra, rpoB sequencing, and pDST
Faridath Massou et al., 2023	Sub-Saharan Africa	Peripheral laboratories	1711	Presumptive and confirmed MDR-TB patients	GeneXpert MTB/XDR and TrueNat XDR	Molecular tests	Sputum (implied)	Composite of pDST and WGS
J. Thoullass et al., 2011	Uganda	District hospital	Not specified	New HIV patients screened for PTB	Not applicable (evaluating algorithms)	Not applicable	Sputum	Myco bacterial culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
T. Malaquias et al., 2020	Rio de Janeiro, Brazil	Reference laboratory	207	TB subjects	Xpert MTB/RIF and Line Probe Assays (LPA)	PCR and LPA	Pulmonary specimens	MGIT 960 culture and DST
A. David et al., 2025	South Africa	Community Health Centre	354	Symptomatic adults, 56% HIV prevalence	Cobas MTB and Cobas MTB/RIF-INH assays	Real-time PCR	Sputum and tongue swabs	Liquid culture

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
Ankur Kumar et al., 2025	Gorakhpur, India	Tertiary care hospitals	2839	Clinically suspected EPTB specimens	Xpert MTB/RIF	NAAT	Lymph node aspirates, pleural fluid, CSF, tissue biopsies	Microscopy and MTB-DR plus line probe assay
K. Suryana et al., 2020	Not specified	Primary Health Care with limited settings	117	Suspected TB cases	Conventional TB diagnostic procedure (screening , CXR, ZN staining)	Microscopy, imaging, clinical screening	Sputum	Gene X-pert MTB/ RIF

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
Dwi Robbiardy Eksa et al., 2025	Indonesia	Hospital	52	Suspected pulmonary TB patients with HIV-negative status and underweight BMI	LF-LAM TB Antigen	Laternal flow assay	Urine	Xpert MTB/RIF assay
Noormohammad Mansoori et al., 2021	Iran	Tuberculosis Reference laboratory	102	Presumptive TB cases	Xpert MTB/RIF assay	PCR	Sputum	Löwenstein-Jensen (LJ) culture
C. H. Ding et al., 2020	Klang, Malaysia	Urban district health facility	103	Smear-positive PTB patients	Xpert MTB/RIF	PCR	Sputum	Mycobacterial culture and DST

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
Sabina Mugusi et al., 2025	Tanzania	Tuberculosis clinics and Central TB Reference Laboratory	200	Adults with symptoms of TB and a positive Xpert result	Sputum smear microscopy (Ziehl-Neelsen)	Microscopy	Sputum	Löwenstein-Jensen culture
Madhumathi Jayaprakasam et al., 2025	India	Three sites	657	Adults (>18 yr) with presumptive TB	Quantiplus MTB FAST	Open real-time PCR (RT-PCR)	Sputum	MGIT liquid culture
Shimba Henerico et al., 2021	Mwanza, Tanzania	Tertiary hospital	250	Presumptive TB patients	Xpert MTB/RIF on pooled sputum	Real-time PCR	Pooled sputum	Individual Xpert MTB/RIF testing

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
T. Perumal et al., 2023	South Africa, Zambia, Zimbabwe, Mozambique	Mobile clinic	1977	Individuals at risk for TB in informal settlements	Point-of-care Xpert	PCR	Sputum	Sputum culture
A. V. Khatawkar et al., 2019	North Karnataka, India	Not specified	Not specified	HIV seropositive subjects with suspected PTB	CBNAAT	Nucleic acid amplification	Sputum	Sputum microscopy
Gayathri Ramasubban et al., 2025	India	Tertiary care center	731	Sputum samples from presumptive TB patients	mfloDx pre-XDR-TB test	Padlock probe-dependent rolling circle amplification (RCA)	Sputum	MGIT culture and DST

Study	Country/Region	Facility Type	Sample Size	Population Characteristics	Rapid Diagnostic Test Evaluated	Technology Type	Sample Type(s)	Reference Standard
R. Lessells et al., 2015	KwaZulu-Natal, South Africa	Clinic level	1297	HIV infected adults and/or at high risk of drug-resistant TB	Xpert MTB/RIF	Real-time PCR	Sputum	Not mentioned
P. Orikiriza et al., 2019	Mbarara, Uganda	Not specified	392 (study 1), 234 (study 2)	Children with presumptive or severe TB	Xpert MTB/RIF and urine LAM	PCR and antigen detection	Sputum, stool, urine	Microbiological reference standard
N. Lorent et al., 2013	Phnom Penh, Cambodia	Referral TB clinic	343	Patients at increased risk of MDR TB	Xpert MTB/RIF	PCR	Sputum	Conventional culture /DST and LPA

Diagnostic Accuracy for Tuberculosis Detection

Rapid diagnostic tests, particularly the Xpert MTB/RIF assay, demonstrated high specificity, generally exceeding 95% across multiple studies. Sensitivity for TB detection showed considerable variation, influenced by the test platform, patient population, and smear status.

Pooled analyses of Xpert MTB/RIF reported sensitivities of 88-89% when used as an initial test. However, sensitivity was substantially lower in smear-negative, culture-positive patients, with estimates ranging from 55% to 76.9%. For example, a multicenter study found Xpert sensitivity was 76.9% in smear-negative, culture-positive patients, while a systematic review reported a pooled sensitivity of 68% in this subgroup. Conversely, in smear-positive patients, the sensitivity was consistently high, often at or above 98%.

Other NAATs showed varied performance. The Truenat MTB Plus assay demonstrated a sensitivity of 90.6% and specificity of 95.7%, which was comparable to Xpert in a head-to-head comparison in Cameroon (91% vs 90% sensitivity, respectively). LAMP-based assays showed a wide range of sensitivities; one study in The Gambia reported a sensitivity of 99%, while others in India and Uganda reported sensitivities of 100% and 55.4%, respectively. A systematic review of TB-LAMP found a pooled sensitivity of approximately 80% and specificity of 98%, similar to Xpert but higher than smear microscopy.

Non-sputum-based tests showed promise in specific populations. The urine LAM test (Determine TB-LAM) had low overall sensitivity but performed better in severely immunocompromised HIV-positive individuals, with sensitivity reaching 66.7% in patients with CD4 counts <50 cells/ μ L. A study on Xpert MTB/RIF using stool samples from children reported a sensitivity of 31.9% but a specificity of 99.7%.

Heterogeneity in performance was evident across studies. This was often attributed to differences in the prevalence of TB and HIV, the proportion of smear-negative patients, and the reference standard used. The reference standard was almost universally culture, although some studies used a composite reference standard that included clinical and radiological findings.

Study	Diagnostic Test	Sensitivity (95% CI)	Specificity (95% CI)	Positive Predictive Value	Negative Predictive Value	Reference Standard
C. Boehme et al., 2011	Xpert MTB/RIF	90.3%	99.0%	Not mentioned	Not mentioned	Culture
C. Boehme et al., 2010	Xpert MTB/RIF	98.2% (smear-positive), 72.5% (smear-negative)	99.2%	Not mentioned	Not mentioned	Culture
G. Theron et al., 2014	Xpert MTB/RIF	83%	95%	Not mentioned	Not mentioned	Culture
K. Steingart et al., 2013	Xpert MTB/RIF	88% (83-92)	98% (97-99)	Not mentioned	Not mentioned	Culture
H. Albert et al., 2002	FASTPlaqueTB	75.2%	98.7%	Not mentioned	Not mentioned	Löwenstein-Jensen culture
K. Steingart et al., 2014	Xpert MTB/RIF	89% (85-92)	99% (98-99)	Not mentioned	Not mentioned	Culture
S. Lawn et al., 2012	Determine TB-LAM	39.0% (26.5-52.6) at CD4 <200	>98%	Not mentioned	Not mentioned	Culture

Study	Diagnostic Test	Sensitivity (95% CI)	Specificity (95% CI)	Positive Predictive Value	Negative Predictive Value	Reference Standard
H. Zar et al., 2013	Xpert MTB/RIF	57.1% (39.1-73.5)	98.9% (96.9-99.6)	Not mentioned	Not mentioned	Culture and smear microscopy
A. Rachow et al., 2011	Xpert MTB/RIF	88.4% (78.4-94.9)	99% (94.7-100.0)	Not mentioned	Not mentioned	Culture
L. Scott et al., 2011	Xpert MTB/RIF	86% (76-93)	>97%	Not mentioned	Not mentioned	Liquid culture
A. Bojang et al., 2016	TB-LAMP	99% (94.5-99.8)	94% (89.3-96.7)	Not mentioned	Not mentioned	Culture
A. Bojang et al., 2016	GeneXpert	99.1% (97.1-100)	96% (92.6-98.3)	Not mentioned	Not mentioned	Culture
G. Carriquiry et al., 2012	Xpert MTB/RIF	97.8% (88.4-99.6)	97.7% (91.9-99.4)	95.7% (85.5-98.8)	98.8% (93.6-99.8)	Composite culture (LJ/MGIT)
A. Penn-Nicholson et al., 2021	Truenat MTB Plus	80% (75-84)	High	Not mentioned	Not mentioned	Culture and phenotypic DST
N. Shah et al., 2011	MODS assay	85% (78-92)	97% (95-99)	Not mentioned	Not mentioned	Culture

Study	Diagnostic Test	Sensitivity (95% CI)	Specificity (95% CI)	Positive Predictive Value	Negative Predictive Value	Reference Standard
M. Shah et al., 2014	Xpert MTB/RIF	76% (66-84)	>97%	Not mentioned	Not mentioned	Culture
M. Shah et al., 2014	LF-LAM	49% (39-59)	>97%	Not mentioned	Not mentioned	Culture
Y. R. Ngangue et al., 2022	Truenat MTB Plus	91% (86-94)	96% (94-97)	Not mentioned	Not mentioned	Culture
Y. R. Ngangue et al., 2022	Xpert MTB/RIF	90% (86-93)	99% (97-99)	Not mentioned	Not mentioned	Culture
A. Esmail et al., 2023	GeneXpert	52%	Not mentioned	Not mentioned	Not mentioned	Culture
B. Saavedra et al., 2021	Xpert Ultra	95% (90-98)	98% (97-99)	Not mentioned	Not mentioned	Culture
P. Shete et al., 2019	TB-LAMP	80.3% (70.3-87.5)	98.1% (95.7-99.2)	Not mentioned	Not mentioned	Culture
G. Theron et al., 2011	Xpert MTB/RIF	95% (88-98) in smear-positive	94% (91-96)	Not mentioned	99.4% (for rifampicin resistance)	Culture

Study	Diagnostic Test	Sensitivity (95% CI)	Specificity (95% CI)	Positive Predictive Value	Negative Predictive Value	Reference Standard
C. Theron et al., 2011a	Xpert MTB/RIF	~98% (smear-positive), ~75% (smear-negative)	~99%	~97%	~96%	Liquid culture
K. Steingart et al., 2013a	Xpert MTB/RIF	88%	98%	Not mentioned	Not mentioned	Not mentioned
A. Rachow et al., 2012	Xpert MTB/RIF	66.6% (43.0-85.4) in smear-negative	100%	Not mentioned	Not mentioned	Culture
T. Balcha et al., 2014	Xpert MTB/RIF	66.4%	98.4% (97.0-99.2)	88.0% (79.2-93.6)	94.2% (92.1-95.8)	Liquid culture
C. Nikam et al., 2013	Truenat MTB	91.1% (86.1-94.7)	100% (90.0-100)	Not mentioned	Not mentioned	Composite reference standard
C. Hanrahan et al., 2013	Xpert MTB/RIF	66% (53-77)	99% (98-100)	Not mentioned	Not mentioned	Culture
Surabhi Lavania et al., 2018	Aptamer ALISA	94.1% (86.8-98)	100%	Not mentioned	Not mentioned	Culture

Study	Diagnostic Test	Sensitivity (95% CI)	Specificity (95% CI)	Positive Predictive Value	Negative Predictive Value	Reference Standard
R. Rakotoarivelo et al., 2018	Xpert MTB/RIF	82.4% (proven cases)	98.8% (proven cases)	98.3%	86.6%	Clinical classification
E. Walters et al., 2017	Xpert MTB/RIF (stool)	31.9% (21.8-44.5)	99.7% (98.2-100)	Not mentioned	Not mentioned	Bacteriologic confirmation
A. Muwonge et al., 2014	DZM microscopy	36.4% (24.9-49.1)	97.1% (94.4-98.7)	Not mentioned	Not mentioned	DFM microscopy
I. Mutingwende et al., 2015	NWU-TB test	80.8% (75-85.7)	75.6% (64.9-84.4)	Not mentioned	Not mentioned	MGIT culture
K. Reither et al., 2015	Xpert MTB/RIF	68% (50-82)	100% (97-100)	Not mentioned	Not mentioned	Culture
A. Raj et al., 2020	CB-NAAT	84.43%	94.93%	Not mentioned	Not mentioned	MGIT culture
I. Ullah et al., 2017	Xpert MTB/RIF	86%	88.4%	71.5%	95.1%	Culture
A. Gupta-Wright et al., 2020	Xpert MTB/RIF	70%	Not mentioned	Not mentioned	Not mentioned	Culture

Study	Diagnostic Test	Sensitivity (95% CI)	Specificity (95% CI)	Positive Predictive Value	Negative Predictive Value	Reference Standard
M. Kasaro et al., 2020	Xpert MTB/RIF	60.3% (48.4-71.1)	99.0% (97.4-99.6)	66.2%	94.5%	Culture
L. Nakiyingi et al., 2018	TB-LAMP	55.4% (44.1-66.3)	98.0% (94.3-99.6)	93.9% (83.1-98.7)	79.9% (73.4-85.4)	MTB culture
K. Myo et al., 2018	Xpert MTB/RIF	94.7% (80.9-99.1)	Not mentioned	Not mentioned	Not mentioned	Revised NIH classification
A. V. Khatawkar et al., 2019	CBNAAT	100%	79.31%	41.94%	100%	Sputum microscopy
Madhumathi Jayaprakasam et al., 2025	Quantiplus MTB FAST	86% (81-90)	96% (94-98)	93% (89-96%)	92% (89-94%)	MGIT culture
Gangarathna Krishna et al., 2019	TB-LAMP	98.3%	98.03%	98.3%	98.03%	Culture

Performance in Key Subpopulations

The diagnostic performance of RDTs varied across key subpopulations, particularly based on smear status and HIV co-infection. The distinction between smear-positive and smear-negative

TB is critical, as a key advantage of molecular RDTs is their ability to detect paucibacillary disease often missed by microscopy.

Across multiple studies, the sensitivity of Xpert MTB/RIF was consistently excellent in smear-positive, culture-positive patients, frequently reported as 98% or higher. In contrast, performance in smear-negative, culture-positive cases was substantially lower, though still representing a significant gain over microscopy. Reported sensitivities in this group ranged widely, from 55% to 76.9% for Xpert MTB/RIF. A systematic review found a pooled sensitivity of 68% (95% CI: 59% to 75%) for Xpert in smear-negative cases. Similar patterns were observed for other NAATs; Truenat MTB Plus had a sensitivity of 47% in smear-negative specimens, and TB-LAMP's sensitivity dropped to 24-42% in this subgroup.

Performance in people living with HIV (PLHIV) also showed variability, which is significant given the challenges of diagnosing TB in this population. Generally, assays trended toward lower sensitivity in PLHIV compared to HIV-negative individuals. One systematic review of Xpert reported a pooled sensitivity of 80% in PLHIV versus 89% in those without HIV. Another found a similar trend, with sensitivity at 79% in PLHIV and 86% in HIV-negative individuals. However, some studies found that Xpert's sensitivity was not significantly different based on HIV status. The urine LAM test is an exception, as its utility is primarily in HIV-positive individuals with advanced immunosuppression. Its sensitivity increases as CD4 counts decrease, reaching 66.7% for patients with CD4 counts below 50 cells/ μ L, whereas its performance is poor in patients with higher CD4 counts.

Study	Diagnostic Test	Subgroup	Sensitivity (95% CI)	Specificity (95% CI)	Sample Size
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Study	Diagnostic Test	Subgroup	Sensitivity (95% CI)	Specificity (95% CI)	Sample Size
C. Boehme et al., 2011	Xpert MTB/RIF	Smear-negative, culture-positive	76.9%	Not mentioned	385
C. Boehme et al., 2010	Xpert MTB/RIF	Smear-positive, culture-positive	98.2%	Not mentioned	561
C. Boehme et al., 2010	Xpert MTB/RIF	Smear-negative, culture-positive	72.5%	Not mentioned	171
K. Steingart et al., 2013	Xpert MTB/RIF	Smear-positive, culture-positive	98% (97-99)	Not mentioned	Not specified
K. Steingart et al., 2013	Xpert MTB/RIF	Smear-negative, culture-positive	68% (59-75)	Not mentioned	15 studies
K. Steingart et al., 2013	Xpert MTB/RIF	HIV-positive	80% (67-88)	Not mentioned	4 studies

Study	Diagnostic Test	Subgroup	Sensitivity (95% CI)	Specificity (95% CI)	Sample Size
K. Steingart et al., 2013	Xpert MTB/RIF	HIV-negative	89% (81-94)	Not mentioned	4 studies
K. Steingart et al., 2014	Xpert MTB/RIF	Smear-positive, culture-positive	98% (97-99)	Not mentioned	1936
K. Steingart et al., 2014	Xpert MTB/RIF	HIV-positive	79% (70-86)	Not mentioned	1789
K. Steingart et al., 2014	Xpert MTB/RIF	HIV-negative	86% (76-92)	Not mentioned	1470
S. Lawn et al., 2012	Determine TB-LAM	HIV-positive, CD4 <50	66.7% (41.0-86.7)	>98%	Not specified
S. Lawn et al., 2012	Determine TB-LAM	HIV-positive, CD4 <100	51.7% (32.5-70.6)	>98%	Not specified
L. Scott et al., 2011	Xpert MTB/RIF	Smear-negative, culture-positive	61%	>97%	18
L. Scott et al., 2011	Xpert MTB/RIF	HIV-positive	84% (69-93)	>97%	Not specified

Study	Diagnostic Test	Subgroup	Sensitivity (95% CI)	Specificity (95% CI)	Sample Size
A. Penn-Nicholson et al., 2021	Truenat MTB Plus	Smear-negative	47% (37-58)	High	Not specified
Y. R. Ngangue et al., 2022	Truenat MTB Plus	Smear-negative	55% (40-70)	Not mentioned	47
Y. R. Ngangue et al., 2022	Truenat MTB Plus	HIV-positive	85% (75-92)	Not mentioned	74
P. Shete et al., 2019	TB-LAMP	Smear-negative	42.2% (27.9-57.9)	Not mentioned	Not specified
P. Shete et al., 2019	TB-LAMP	HIV-positive	73.4% (51.9-87.6)	Not mentioned	Not specified
G. Theron et al., 2011	Xpert MTB/RIF	Smear-negative	55% (35-73)	Not mentioned	22
G. Theron et al., 2011	Xpert MTB/RIF	HIV-positive	Trend to reduced sensitivity (P=0.09)	Not mentioned	Not specified
T. Balcha et al., 2014	Xpert MTB/RIF	Smear-negative	57.4% (46.8-67.5)	Not mentioned	Not specified

Study	Diagnostic Test	Subgroup	Sensitivity (95% CI)	Specificity (95% CI)	Sample Size
T. Balcha et al., 2014	Xpert MTB/RIF	HIV-positive, CD4 ≤100	82.9%	Not mentioned	Not specified
M. Kasaro et al., 2020	Determine TB-LAM	HIV-positive, CD4 <50	81.8%	Not mentioned	Not specified
L. Nakiyingi et al., 2018	TB-LAMP	Smear-negative	24.4% (12.9-39.5)	98.6% (95.1-99.8)	Not specified
L. Nakiyingi et al., 2018	TB-LAMP	HIV-positive	52.3% (36.7-67.5)	97.1% (89.9-99.6)	113
B. Reeve et al., 2023	Xpert Ultra	HIV-positive	71% (61-80)	98% (96-100)	787
A. David et al., 2025	Cobas MTB	Smear-negative	85.0% (62.1-96.8)	100% (98.7-100)	Not specified
A. David et al., 2025	Cobas MTB	HIV-positive	88.2% (72.5-96.7)	100% (97.8-100)	Not specified

Drug Resistance Detection Performance

Rapid molecular tests offer a crucial advantage by enabling the prompt detection of drug resistance, which is critical for initiating appropriate treatment and curbing the spread of multidrug-resistant TB (MDR-TB). The Xpert MTB/RIF suite of assays was the most widely evaluated for this purpose, primarily for rifampicin (RIF) resistance.

The sensitivity of Xpert MTB/RIF for detecting RIF resistance was consistently high, with systematic reviews reporting pooled sensitivities of 94% (95% CI: 87% to 97%) and 95% (95% CI: 90% to 97%). Individual studies reported sensitivities ranging from 87.5% to 100%. Specificity for RIF resistance was also excellent, with pooled estimates of 98% and multiple studies reporting specificities of 98% or higher.

Positive predictive value (PPV) for RIF resistance was noted to be a concern, particularly in settings with a low prevalence of MDR-TB. Studies reported PPVs ranging from 66.7% in a low-prevalence setting in Peru to 97.9% in a high-burden setting in South Africa. One study noted that false-positive RIF resistance results were more common in samples with very low bacillary loads. Conversely, the negative predictive value (NPV) was consistently high, often at or near 100%, making the tests reliable for ruling out RIF resistance.

Newer assays, such as Xpert MTB/XDR, have expanded rapid testing capabilities to include isoniazid (INH) and second-line drugs. A multicenter study of Xpert MTB/XDR found a sensitivity of 94% for INH resistance and 94-95% for fluoroquinolone (FQ) resistance, with specificities of 98-100% for all drugs tested. Another study assessing the mflDx assay reported a sensitivity of 98.2% for RIF, 86.2% for INH, and 93.3% for FQ resistance, with specificities over 99%. Line probe assays also performed well, with one study showing 95.6% sensitivity for MDR-TB detection and another reporting 100% sensitivity for RIF and 85% for INH resistance. The reference standard for these evaluations was consistently phenotypic DST, sometimes supplemented with gene sequencing.

Study	Diagnostic Test	Resistance Detected	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	Reference Standard	DR Prevalence

Study	Diagnostic Test	Resistance Detected	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	Reference Standard	DR Prevalence
C. Boehme et al., 2011	Xpert MTB/RIF	Rifampicin	94.4%	98.3%	Not mentioned	Not mentioned	Drug-susceptibility testing	Not mentioned
C. Boehme et al., 2010	Xpert MTB/RIF	Rifampicin	97.6%	98.1%	Not mentioned	Not mentioned	Phenotypic DST	Not mentioned
K. Steingart et al., 2013	Xpert MTB/RIF	Rifampicin	94% (87-97)	98% (97-99)	Not mentioned	Not mentioned	Conventional culture-based DST	Not mentioned
M. Barnard et al., 2008	Line-probe assay	Rifampicin	98.9%	99.4%	97.9%	99.7%	Conventional DST	Not mentioned
M. Barnard et al., 2008	Line-probe assay	Isoniazid	94.2%	99.7%	99.1%	97.9%	Conventional DST	Not mentioned

Study	Diagnostic Test	Resistance Detected	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	Reference Standard	DR Prevalence
M. Barnard et al., 2008	Line-probe assay	MDR-TB	98.8%	100%	100%	99.7%	Conventional DST	Not mentioned
K. Steingart et al., 2014	Xpert MTB/RIF	Rifampicin	95% (90-97)	98% (97-99)	Not mentioned	Not mentioned	Phenotypic culture-based DST	15% / 5% (hypothetical cohorts)
G. Carriquiry et al., 2012	Xpert MTB/RIF	Rifampicin	100% (61.0-100.0)	91.0% (76.4-96.9)	66.7%	100%	Löwenstein-Jensen (LJ) proportion method	13.3%
K. Sachdeva et al., 2015	Xpert MTB/RIF	Rifampicin	Not mentioned	Not mentioned	94.7% (91.3-98.1)	Not mentioned	Conventional DST	Not mentioned

Study	Diagnostic Test	Resistance Detected	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	Reference Standard	DR Prevalence
A. Penn-Nicholson et al., 2021	Truenat MTB-RIF	Rifampicin	84% (62-95)	High	Not mentioned	Not mentioned	Phenotypic DST	15%
N. Shah et al., 2011	MODS assay	MDR-TB	100%	94%	Not mentioned	Not mentioned	1% proportion method DST	Not mentioned
A. Penn-Nicholson et al., 2021a	Xpert MTB/XDR	Isoniazid	94% (92-96)	98-100%	Not mentioned	Not mentioned	Composite (Phenotypic DST + WGS)	Not mentioned
A. Penn-Nicholson et al., 2021a	Xpert MTB/XDR	Fluoroquinolones	94% (90-96)	98-100%	Not mentioned	Not mentioned	Composite (Phenotypic DST + WGS)	Not mentioned

Study	Diagnostic Test	Resistance Detected	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	Reference Standard	DR Prevalence
N. Tukvadze et al., 2012	Genotype MTBDR plus	MDR-TB	95.6%	98.5%	95.6%	98.5%	Conventional DST	High
Youngwhan Kim et al., 2015	Xpert MTB/RIF	Rifampicin	100%	98.7%	86.2%	100%	Phenotypic DST	Low
V. Nikolayevsky et al., 2019	Xpert MTB/RIF	Rifampicin	93.4%	Not mentioned	Not mentioned	Not mentioned	Not mentioned	High
F. Saluzzo et al., 2024	Xpert MTB/XDR	Isoniazid	91.5%	99.5%	Not mentioned	Not mentioned	Phenotypic DST and NGS	High
F. Saluzzo et al., 2024	Xpert MTB/XDR	Fluoroquinolones	88.2%	97.7%	Not mentioned	Not mentioned	Phenotypic DST and NGS	High

Study	Diagnostic Test	Resistance Detected	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	Reference Standard	DR Prevalence
Faridath Massou et al., 2023	Xpert MTB/XDR	Fluoroquinolones	66.7%	99.7%	Not mentioned	Not mentioned	Composite (pDST and WGS)	Not mentioned
Faridath Massou et al., 2023	TrueNat XDR	Fluoroquinolones	47.4%	97.7%	Not mentioned	Not mentioned	Composite (pDST and WGS)	Not mentioned
T. Malaquias et al., 2020	Xpert MTB/RIF	Rifampicin	97%	94%	76%	99%	MGIT 960 DST	5.2%
T. Malaquias et al., 2020	LPA	Rifampicin	100%	98%	90%	100%	MGIT 960 DST	5.2%
T. Malaquias et al., 2020	LPA	Isoniazid	85%	99%	98%	96%	MGIT 960 DST	6.9%

Study	Diagnostic Test	Resistance Detected	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	Reference Standard	DR Prevalence
Gayathri Ramasubban et al., 2025	mfloDx pre-XDR-TB	Rifampicin	98.2%	99.7%	98.2%	99.7%	MGIT DST	Not mentioned
Gayathri Ramasubban et al., 2025	mfloDx pre-XDR-TB	Isoniazid	86.2%	99.2%	Not mentioned	Not mentioned	MGIT DST	Not mentioned

Comparative Performance Against Existing Diagnostic Methods

Numerous studies conducted head-to-head comparisons of RDTs against conventional methods, primarily sputum smear microscopy. A consistent finding was the superior sensitivity of molecular tests like Xpert MTB/RIF. Systematic reviews concluded that Xpert increased TB detection among culture-confirmed cases by 23% compared to smear microscopy. A large implementation study found that one-off Xpert testing detected 90.3% of culture-confirmed cases, compared to just 67.1% for microscopy. This incremental case detection is particularly significant for smear-negative TB, where Xpert consistently identified a substantial proportion of cases missed by microscopy. For example, one study reported that Xpert detected an additional 17 cases compared to smear microscopy, an 18% relative increase in the rapid TB case detection rate. Another study in Cameroon showed that Xpert detected TB in 90% of patients, whereas smear microscopy detected it in only 51%. While sensitivity was markedly higher, the specificity of Xpert

was found to be similar to or slightly lower than smear microscopy, which is known for its high specificity.

Other RDTs also demonstrated advantages over microscopy. The FASTPlaqueTB test showed significantly higher sensitivity than auramine smear microscopy (75.2% vs. 63.4%). The TB-LAMP assay was found to have higher sensitivity than microscopy (pooled difference +13.2%), with one study reporting it detected 1.7 times more cases. The main limitation noted for microscopy was its poor sensitivity, especially in paucibacillary disease and among PLHIV.

Compared to culture, the gold standard, RDTs offer the major advantage of speed. While molecular tests generally have lower sensitivity than liquid culture, they provide results in hours versus weeks or months. This allows for rapid diagnosis and the ability to detect drug resistance simultaneously, a capability that microscopy and culture alone do not possess. However, culture remains essential for comprehensive DST and for detecting cases missed by NAATs, particularly in smear-negative individuals where NAAT sensitivity is reduced. Some studies also highlighted performance limitations of RDTs, such as the lower sensitivity of urine LAM tests compared to sputum-based NAATs in outpatient settings and the suboptimal sensitivity of Xpert on non-respiratory samples like stool.

Study	Rapid Diagnostic Test	Comparator Method	Sensitivity of Rapid Test vs Comparator	Specificity of Rapid Test vs Comparator	Incremental Cases Detected	Key Advantages/Limitations
C. Boehme et al., 2011	Xpert MTB/RIF	Smear microscopy	90.3% vs 67.1%	Not mentioned	Increased detection of culture-confirmed cases	Advantage: Higher sensitivity, faster results.

Study	Rapid Diagnostic Test	Comparator Method	Sensitivity of Rapid Test vs Comparator	Specificity of Rapid Test vs Comparator	Incremental Cases Detected	Key Advantages/Limitations
G. Theron et al., 2014	Xpert MTB/RIF	Smear microscopy	83% vs 50%	95% vs 96%	More patients had same-day diagnosis and treatment	Advantage: Higher sensitivity, enables same-day treatment. Limitation: Did not reduce TB-related morbidity.
K. Steingart et al., 2014	Xpert MTB/RIF	Smear microscopy	Higher (89% vs ~60%)	Higher (99% vs lower)	Increased TB detection by 23%	Advantage: Substantially increases TB detection. Limitation: Expensive.

Study	Rapid Diagnostic Test	Comparator Method	Sensitivity of Rapid Test vs Comparator	Specificity of Rapid Test vs Comparator	Incremental Cases Detected	Key Advantages/Limitations
L. Scott et al., 2011	Xpert MTB/RIF	Smear microscopy	86% vs 59%	>97% vs >97%	Detected 61% of smear-negative, culture-positive cases vs. 28% for another NAAT	Advantage: Superior performance over microscopy and other molecular methods.
K. Myo et al., 2018	Xpert MTB/RIF	Smear microscopy	94.7% vs 31.6%	Not mentioned	Detected 36 cases vs. 12 for smear	Advantage: Improved bacteriological confirmation.
K. Myo et al., 2018	Xpert MTB/RIF	Solid culture	94.7% vs 42.1%	Not mentioned	Detected 36 cases vs. 16 for culture	Advantage: Much higher sensitivity than solid culture on gastric aspirates.

Study	Rapid Diagnostic Test	Comparator Method	Sensitivity of Rapid Test vs Comparator	Specificity of Rapid Test vs Comparator	Incremental Cases Detected	Key Advantages/Limitations
G. Theron et al., 2011	Xpert MTB/RIF	Smear microscopy	Higher	94% vs. Not mentioned	18% relative increase in rapid case detection	Advantage: Outperformed smear microscopy, detected culture-negative cases.
A. V. Rie et al., 2013	Xpert MTB/RIF	Smear microscopy	67% vs 27%	99% vs. Not mentioned	Not mentioned	Advantage: Higher diagnostic yield, faster turnaround.
C. Nikam et al., 2013	Truenat MTB	Nested PCR	91.1% vs 90.58%	100% vs 91.43%	Not mentioned	Advantage: Faster (1 hr vs 7 days), suitable for near-care.
C. Habeenzu et al., 2017	In-house LAMP	Xpert MTB/RIF	Lower in smear-negative (39.1% vs 73.9%)	96.5% vs 94.5%	Not mentioned	Advantage: Simpler equipment, 100% accessibility. Limitation: Lower sensitivity.

Study	Rapid Diagnostic Test	Comparator Method	Sensitivity of Rapid Test vs Comparator	Specificity of Rapid Test vs Comparator	Incremental Cases Detected	Key Advantages/Limitations
R. Yadav et al., 2017	TB-LAMP	Xpert MTB/RIF	100% vs 82.6%	99.2% vs 94.9%	Not mentioned	Advantage: Higher sensitivity and specificity, limited infrastructure needs.
S. Kaswabuli et al., 2022	GenoQuick MTB	Smear microscopy	81% vs 69%	92% vs 98%	Not mentioned	Advantage: Higher sensitivity. Limitation: Lower specificity.
Dwi Robbiardy Eksa et al., 2025	LF-LAM TB-Ag	Xpert MTB/RIF	79.59%	100%	Not mentioned	Advantage: Less invasive, simpler. Limitation: Lower sensitivity.
Madhumathi Jayaprakasam et al., 2025	Quantiplus MTB FAST	Xpert MTB/RIF	Comparable performance (kappa=0.83)	Comparable performance	Not mentioned	Advantage: Very low-cost, flexible open RT-PCR system.

Speed, Workflow, and Operational Characteristics

A defining advantage of rapid molecular tests is the substantial reduction in diagnostic turnaround time compared to conventional methods. Xpert MTB/RIF consistently delivered results in approximately two hours, a stark contrast to the days required for microscopy and the weeks to months needed for culture and conventional DST. One study reported a median time to TB detection of 0 days for Xpert, versus 1 day for microscopy, 16 days for liquid culture, and 30 days for solid culture. For drug resistance detection, the speed advantage was even more pronounced, with molecular tests like LPAs and Xpert providing results in 1-2 days or even hours, compared to a median of 20 days for an LPA, and up to 106 days for conventional DST.

This reduction in diagnostic delay directly translated to a shorter time to treatment initiation. Studies implementing RDTs reported significant decreases in the median time to starting treatment. For smear-negative TB, Xpert reduced the median time to treatment from 56 days to just 5 days. For MDR-TB, rapid tests shortened the time to treatment initiation from over 100 days to as few as 22 days, or from 64 days to 2 days in another study. Even for drug-sensitive TB, decentralized Xpert testing led to a median time to treatment of 1 day, compared to 11.5 days with smear microscopy.

Operationally, many molecular platforms like Xpert are fully automated, cartridge-based systems, which simplifies sample processing and requires minimal hands-on time. This reduces the need for extensive technical expertise and complex biosafety infrastructure compared to culture. However, throughput can be a limitation, with a standard 4-module GeneXpert instrument having a capacity of approximately 12-16 tests per day. Other technologies like LAMP are designed to be even simpler, requiring minimal equipment such as a heat block, making them suitable for peripheral health clinics with limited resources. The urine LAM test is a manual lateral flow assay that provides results in under 30 minutes with very simple processing.

Diagnostic Test	Time to Result	Hands-On Time	Throughput (samples/day)	Sample Processing Complexity	Automation Level	Comparison with Conventional Method Turnaround Time
Xpert MTB/RIF	< 2 hours	Minimal	12-16 (4-module system)	Low (integrated in cartridge)	Fully automated	0 days vs 16-30 days for culture; <2 hours vs weeks/months for DST
Line Probe Assay (e.g., MTBDRplus)	1-2 days	Not specified	2-8 samples per run	Moderate (requires PCR amplification and hybridization)	Semi-automated/ Manual	~4 days vs 22-67 days for culture-based DST
TB-LAMP	~1 hour	Not specified	Not specified	Low (isothermal amplification)	Manual	1 hour vs weeks for culture

Diagnostic Test	Time to Result	Hands-On Time	Throughput (samples/day)	Sample Processing Complexity	Automation Level	Comparison with Conventional Method Turnaround Time
Urine LAM (e.g., Determine TB-LAM)	< 30 minutes	Minimal	Not specified	Very low (direct urine application)	Manual	<30 minutes vs days/weeks for sputum-based tests
MODS Assay	7-10 days	Not specified	Not specified	Moderate (requires microscopy)	Manual	7 days vs 70 days for conventional DST
FASTPlaque TB	48 hours	Low (easy to perform)	Not specified	Low	Manual	2 days vs longer for culture
Truenat MTB	~1 hour	Not specified	Not specified	Low (chip-based PCR)	Semi-automated	Significantly faster than culture and smear

Implementation Feasibility and Cost Considerations

The feasibility of implementing RDTs in resource-limited settings is influenced by a combination of infrastructure requirements, costs, and human resource factors. Molecular tests like Xpert MTB/RIF, while automated, require a stable electricity supply, temperature control, and regular maintenance and calibration. Several studies noted the need for infrastructure renovations, air conditioning, and backup power to support these instruments. Simpler technologies, such as LAMP and urine LAM tests, have fewer infrastructure demands, with some LAMP assays operable using a battery-powered heat block and urine LAM requiring no equipment at all, making them more suitable for peripheral settings. Although training for automated systems is often minimal, basic computer literacy and technical support for troubleshooting and maintenance remain necessary. Equipment reliability can also be a challenge, with some studies reporting high rates of inconclusive or error results, particularly during the initial implementation phase of Xpert.

Cost is a major barrier to widespread implementation. The per-test cost of Xpert cartridges, while subsidized in high-burden countries to around US\$10, is still substantially higher than smear microscopy. An economic evaluation found the mean unit cost of point-of-care Xpert to be \$28.03, compared to \$23.00 for laboratory-based Xpert. Alternatives like LAMP, Truenat, and open-platform PCR assays are often presented as lower-cost molecular options. One study on an open RT-PCR assay reported a cost of less than US\$2 per test, while a novel nanoparticle-based assay cost an estimated \$0.10 per test. The urine LAM test is also a low-cost option, at approximately US\$3.50 per strip. Despite the higher upfront and per-test costs of molecular diagnostics, cost-effectiveness analyses generally suggest they offer good value for money by increasing case detection and enabling rapid treatment, particularly when targeted at high-risk populations. One study found point-of-care Xpert to be cost-effective at a willingness-to-pay of \$3,820 per treatment completion. Pooling sputum samples for Xpert testing has also been evaluated as a cost-saving strategy, with one study reporting a 48% savings in cartridges.

Diagnostic Test	Instrument Cost	Per-Test Cost	Infrastructure Requirements	Training Needs	Maintenance Considerations	Supply Chain Challenges	Cost-Effectiveness Findings
Xpert MTB/RIF	High (\$17,500 for 4-module)	~\$10 (subsidized)	Stable electricity, temperature control, AC	Minimal, basic computer skills	Annual calibration, module replacement	Cartridge stock-outs reported	Cost-effective vs microscopy, especially at POC
Truenat Assays	~\$4,000-\$6,000	~\$10-\$17	Portable, battery-operated; fewer needs than Xpert	Minimal	Not specified	Not specified	Likely favorable due to lower instrument cost

Diagnostic Test	Instrument Cost	Per-Test Cost	Infrastructure Requirements	Training Needs	Maintenance Considerations	Supply Chain Challenges	Cost-Effectiveness Findings
TB-LAMP	Low (requires heat block)	Not specified (low cost implied)	Minimal; no stable power required for some systems	Higher than automated systems	Minimal	Not specified	Favorable incremental cost-effectiveness vs Xpert in some settings
Urine LAM	None	~\$3.50	None	Minimal	None	Not specified	Cost-effective in hospitalized PLHIV, increased life expectancy

Diagnostic Test	Instrument Cost	Per-Test Cost	Infrastructure Requirements	Training Needs	Maintenance Considerations	Supply Chain Challenges	Cost-Effectiveness Findings
Line Probe Assay	Moderate	Not specified	Requires PCR capacity, biosafety cabinet	High technical expertise needed	Regular maintenance of PCR equipment	Not specified	Not specified
Open RT-PCR (Quantiplex)	Variable (uses existing RT-PCR machines)	<\$2	Standard molecular biology lab	Standard technical expertise	Standard equipment maintenance	Not specified	Presented as a very low-cost alternative to cartridge tests

Clinical and Public Health Impact

The implementation of rapid diagnostic tests has demonstrated a significant impact on TB case detection and programmatic indicators in resource-limited settings. Studies consistently report that replacing smear microscopy with a more sensitive molecular test like Xpert MTB/RIF increases the number of bacteriologically confirmed TB cases notified. One large-scale study in India found that upfront Xpert testing increased the case notification rate of bacteriologically confirmed TB by 39%. In Myanmar, using Xpert increased overall case detection by 40% and nearly doubled it among PLHIV compared to smear microscopy alone. Similarly, DR-TB case finding increased

substantially, with one study reporting a fivefold increase in rifampicin-resistant TB detection after introducing Xpert.

The most profound clinical impact observed was the reduction in time to treatment initiation. For drug-resistant TB, RDTs reduced the median time from diagnosis to treatment from months to days. One study in India documented a decrease from 130 days with conventional DST to 22 days with rapid molecular tests. Another in Indonesia showed a reduction in median time to diagnosis of 74 days and time to treatment start of 27 days. For drug-sensitive TB, particularly smear-negative cases, the impact was also substantial, with one trial showing a reduction in median time to treatment from 56 days to 5 days. Point-of-care implementation further accelerated this, enabling same-day treatment initiation for many patients. This speed can also reduce pre-treatment loss to follow-up.

Evidence for a direct impact on patient morbidity and mortality is more mixed. While some studies showed a mortality benefit, particularly with urine LAM testing in hospitalized, severely ill PLHIV or Xpert among HIV-positive populations, several large randomized trials of Xpert found no significant reduction in overall 6-month mortality compared to smear microscopy. This lack of mortality benefit has been attributed to high rates of empiric treatment in the smear microscopy arms and persistent challenges in linkage to care even after a rapid diagnosis is made. Nonetheless, the use of RDTs has shifted clinical practice away from empirical treatment toward bacteriologically confirmed diagnoses. The rollout of Xpert in Cape Town was associated with a halving of empirical TB treatment rates.

Study	Diagnostic Test	Change in Case Detection Rate	Time to Treatment Initiation (Before vs After)	Loss to Follow-up Rate	Patient Outcomes Reported	Other Clinical/Public Health Impacts
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Study	Diagnostic Test	Change in Case Detection Rate	Time to Treatment Initiation (Before vs After)	Loss to Follow-up Rate	Patient Outcomes Reported	Other Clinical/Public Health Impacts
C. Boehme et al., 2011	Xpert MTB/RIF	From 67.1% (microscopy) to 90.3% (Xpert) of culture-confirmed cases	56 days vs 5 days (smear-negative TB)	Not specified	Decreased morbidity associated with diagnostic delay	Simplifies access to early, accurate diagnosis
G. Theron et al., 2014	Xpert MTB/RIF	Higher sensitivity (83% vs 50%) than microscopy	Increased same-day treatment (23% vs 15%)	Reduced from 15% to 8%	No difference in morbidity scores	Not specified
K. Sachdeva et al., 2015	Xpert MTB/RIF	39% increase in bacteriologically confirmed TB; fivefold increase in DR-TB	Not specified	Not specified	Not specified	Increased bacteriologically confirmed diagnoses

Study	Diagnostic Test	Change in Case Detection Rate	Time to Treatment Initiation (Before vs After)	Loss to Follow-up Rate	Patient Outcomes Reported	Other Clinical/Public Health Impacts
A. Esmail et al., 2023	GeneXpert	Detected 52% of culture-positive TB; 94% of probably infectious cases	41 days (smear) vs 8 days (Xpert)	Not specified	100% of POC Xpert-positives on treatment at 60 days vs 46.5% of all culture-positives	Challenges paradigm of passive case finding
F. Haraka et al., 2021	Xpert MTB/RIF	Increased proportion with bacteriologically confirmed diagnosis	Not specified	Probably reduced	Probable mortality reduction in PLHIV; uncertain effect on overall mortality or treatment success	Not specified

Study	Diagnostic Test	Change in Case Detection Rate	Time to Treatment Initiation (Before vs After)	Loss to Follow-up Rate	Patient Outcomes Reported	Other Clinical/Public Health Impacts
Jae Hyoung Lee et al., 2022	Xpert (for DS-TB)	Not specified	Reduced by a median of 2.55 days	Not specified	Not specified	Not specified
Jae Hyoung Lee et al., 2022	LPA (for DR-TB)	Not specified	Reduced by a median of 45.32 days	Not specified	Not specified	Not specified
G. Churchyard et al., 2015	Xpert MTB/RIF	Not specified	Not specified	Not specified	No difference in mortality at 6 months	Better linkage to care is needed to improve outcomes
D. Nair et al., 2016	Rapid molecular tests	Not specified	130 days vs 22 days for MDR-TB treatment	>30% in both groups	Treatment success increased from 30% to 41%	Not specified

Study	Diagnostic Test	Change in Case Detection Rate	Time to Treatment Initiation (Before vs After)	Loss to Follow-up Rate	Patient Outcomes Reported	Other Clinical/Public Health Impacts
Jacob Creswell et al., 2015	Xpert MTB/RIF	+15.2% bacteriologically positive notifications; - 8.5% overall pulmonary TB notifications	Doubled DR-TB treatment initiations	Not specified	Not specified	Large reduction in empiric treatment of smear-negative disease
S. Hermans et al., 2017	Xpert MTB/RIF	Bacteriologically confirmed cases increased 1-3%; overall notification rate decreased 12-19%	Not specified	Not specified	Not specified	Halving of empirical treatment rate

Study	Diagnostic Test	Change in Case Detection Rate	Time to Treatment Initiation (Before vs After)	Loss to Follow-up Rate	Patient Outcomes Reported	Other Clinical/Public Health Impacts
V. Nikolayevsky et al., 2019	Xpert MTB/RIF	Not specified	Initiation within 1 week increased successful outcomes	Not specified	No significant improvement in overall treatment outcomes	Rapid testing may need other programmatic improvements
M. Kasaro et al., 2020	Xpert MTB/RIF	Not specified	Significantly shorter time to diagnosis and treatment	Not specified	No difference in all-cause mortality	Not specified
S. V. van Kampen et al., 2015	Xpert MTB/RIF	+15% TB positivity rate	Reduced time from registration to diagnosis by 74 days	Not specified	19% increase in second-line treatment initiation	Not specified

Synthesis of Evidence

The evidence overwhelmingly demonstrates that rapid molecular diagnostic tests, particularly Xpert MTB/RIF and similar NAATs, offer superior sensitivity for TB detection compared to sputum smear microscopy, the longstanding conventional method in many resource-

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limited settings. This advantage is most pronounced in the diagnosis of smear-negative pulmonary TB, a form of the disease that is common in PLHIV and children and represents a major diagnostic challenge. While the specificity of these molecular tests is high and generally comparable to microscopy, their primary value lies in the substantial increase in bacteriologically confirmed case detection. The ability to provide a result in hours, as opposed to the days or weeks required for microscopy and culture, represents a paradigm shift, enabling the possibility of same-day diagnosis and treatment initiation. Furthermore, the integration of rifampicin resistance detection into the primary diagnostic test is a critical advancement for MDR-TB control, drastically shortening the time to appropriate therapy from months to days.

However, the improved diagnostic accuracy and speed have not uniformly translated into improved patient outcomes, specifically mortality. Several large, well-conducted randomized trials comparing Xpert MTB/RIF to smear microscopy did not find a significant reduction in overall mortality. This apparent contradiction can be reconciled by examining the context of these trials. The lack of mortality benefit was often attributed to highly effective clinical algorithms and high rates of empirical treatment in the control (smear microscopy) arms, where clinicians did not wait for bacteriological confirmation to start treatment in highly suspicious cases. This suggests that in well-functioning health systems with aggressive clinical management, the incremental benefit of a better test on mortality may be diminished. In contrast, studies showing a clinical impact, such as reduced time to treatment and improved treatment success rates for MDR-TB, highlight the importance of the diagnostic test in contexts where empiric treatment is less common or where the correct treatment is critically dependent on a specific diagnosis (i.e., drug resistance). The mortality benefit observed with urine LAM testing in severely ill, hospitalized PLHIV further supports a context-dependent model; in this specific, high-risk population that is often unable to produce sputum and has high rates of disseminated disease, a rapid, non-sputum-based test that can be performed at the point of care can be life-saving.

The operational and economic data present a similar nuanced picture. While molecular platforms are expensive and have significant infrastructure requirements, their implementation leads

to a substantial reduction in empiric treatment, which has its own costs and risks (e.g., unnecessary drug exposure, delayed diagnosis of other conditions). Strategies such as targeting high-risk groups, using cheaper triage tests, or pooling samples are being explored to optimize cost-effectiveness. The evidence suggests that RDTs are most effective not as simple replacements for older tests, but as components of a strengthened diagnostic and clinical care cascade. Their full potential is realized only when rapid results are effectively linked to prompt and appropriate treatment, a step that remains a significant challenge in many resource-limited settings. Therefore, the effectiveness of RDTs depends heavily on which test is used, in which population it is applied, and the strength of the health system to act upon the results. For general TB screening, Xpert MTB/RIF significantly improves case detection over microscopy. For severely ill, immunosuppressed PLHIV, urine LAM offers a crucial, potentially life-saving tool. For drug resistance, rapid molecular DSTs are indispensable for timely and effective care.

DISCUSSION

This review synthesizes evidence from 126 studies conducted across diverse resource-limited settings, demonstrating that rapid diagnostic tests represent a substantial advancement in tuberculosis diagnosis, yet their effectiveness is context-dependent and requires nuanced interpretation. The discussion examines key findings in relation to diagnostic accuracy, subpopulation performance, drug resistance detection, comparative effectiveness, operational characteristics, implementation feasibility, clinical impact, and health system considerations.

Diagnostic Accuracy and Platform Performance

The consistently high specificity (>98%) of molecular RDTs across multiple platforms and settings provides reassurance that false-positive results are uncommon, supporting their use as rule-in tests (Steingart et al., 2014; Boehme et al., 2011). This finding has important programmatic implications, as the consequences of unnecessary TB treatment—including drug toxicity, stigma, and opportunity costs—are substantial in resource-limited settings. However, sensitivity

demonstrated considerable heterogeneity, ranging from 55% in smear-negative populations to over 98% in smear-positive cases (Boehme et al., 2010; Steingart et al., 2013). This variation reflects the fundamental challenge of detecting paucibacillary disease and underscores that molecular tests, while superior to microscopy, are not perfect substitutes for culture.

The comparative performance of different platforms warrants careful consideration. Xpert MTB/RIF, the most extensively evaluated assay, shows consistent performance across multiple systematic reviews (Steingart et al., 2014). Truenat assays demonstrate comparable accuracy, with the added advantage of lower instrument cost and portability, making them potentially more suitable for peripheral deployment (Penn-Nicholson et al., 2021; Ngangue et al., 2022). TB-LAMP offers simplicity and minimal infrastructure requirements, though sensitivity in smear-negative populations is lower than Xpert (Shete et al., 2019; Bojang et al., 2016). The choice between platforms therefore involves trade-offs between accuracy, cost, and operational suitability that must be contextualized to specific settings.

Performance in Key Subpopulations

The reduced sensitivity of all sputum-based molecular tests in PLHIV represents a persistent diagnostic challenge. Our finding of pooled sensitivity of 79-80% in PLHIV versus 86-89% in HIV-negative individuals (Steingart et al., 2013; Steingart et al., 2014) reflects the lower bacillary burden in HIV-associated TB, particularly among those with advanced immunosuppression. This has important implications for diagnostic algorithms in high-HIV settings, where negative molecular test results cannot reliably exclude TB and clinical judgment remains essential (Theron et al., 2011).

The urine lipoarabinomannan (LAM) assay addresses an important niche by detecting antigen in HIV-positive patients with disseminated disease who cannot produce sputum. The finding that sensitivity increases with declining CD4 count, reaching 66.7% in patients with CD4 <50 cells/ μ L (Lawn et al., 2012), supports targeted use in severely immunocompromised hospitalized patients. However, the poor performance in outpatients and HIV-negative individuals

limits its utility as a general screening test (Shah et al., 2014). This illustrates the principle that optimal test selection depends on the specific population and clinical context.

Pediatric TB diagnosis remains particularly challenging, with Xpert on respiratory samples showing modest sensitivity (57-68%) in children (Zar et al., 2013; Rachow et al., 2012). The use of stool samples, while convenient, showed only 31.9% sensitivity (Walters et al., 2017), indicating that novel approaches are needed for this vulnerable population. The development of non-sputum-based biomarkers and simplified sample processing methods should be prioritized for pediatric TB diagnostics research.

Drug Resistance Detection

The ability to simultaneously detect TB and rifampicin resistance within hours represents a paradigm shift in MDR-TB control. The pooled sensitivity of 94-95% for rifampicin resistance detection (Steingart et al., 2013; Steingart et al., 2014) enables rapid initiation of appropriate therapy, reducing the period of transmission of resistant strains and improving individual outcomes. However, the positive predictive value (PPV) concern in low-prevalence settings, with PPV as low as 66.7% reported (Carriquiry et al., 2012), necessitates confirmatory testing when prevalence is low. The finding that false-positive results are more common in samples with very low bacillary loads (Cuella-Martin et al., 2025) suggests that repeat testing or alternative specimens may be warranted in such cases.

The expansion of resistance detection to include isoniazid and second-line drugs through platforms like Xpert MTB/XDR represents further progress (Penn-Nicholson et al., 2021a). Sensitivity of 94% for isoniazid and 94-95% for fluoroquinolone resistance, with near-perfect specificity, approaches the performance needed for clinical decision-making. However, the lower sensitivity for some second-line drugs in field evaluations (Massou et al., 2023) highlights the need for ongoing surveillance of test performance as resistance patterns evolve.

Comparative Effectiveness and Incremental Value

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The consistent finding that molecular tests increase TB detection by 23-39% compared to smear microscopy (Steingart et al., 2014; Sachdeva et al., 2015) confirms their superior sensitivity and justifies their implementation. The incremental detection is most pronounced in smear-negative populations, where Xpert identifies cases that would otherwise be missed or diagnosed only after prolonged delay (Boehme et al., 2011; Theron et al., 2014). However, the comparison to culture reveals that molecular tests, while faster, have lower sensitivity, particularly in paucibacillary disease (Scott et al., 2011). Culture therefore remains essential as a back-up for smear-negative, Xpert-negative patients with high clinical suspicion, and for comprehensive drug susceptibility testing.

The head-to-head comparisons between different molecular platforms provide important guidance for technology selection. Truenat and Xpert showed comparable performance in a Cameroonian study (Ngangue et al., 2022), while TB-LAMP demonstrated similar accuracy to Xpert in The Gambia (Bojang et al., 2016) but lower sensitivity in Uganda (Nakiyingi et al., 2018). These discrepancies may reflect differences in study populations, specimen handling, or operator expertise, underscoring the importance of local validation before widespread deployment.

Speed, Workflow, and Operational Characteristics

The dramatic reduction in turnaround time from weeks to hours is the most unambiguous benefit of RDTs. The finding that Xpert reduces median time to TB detection from 16-30 days to 0 days, and time to MDR-TB treatment from months to 22 days (D. Nair et al., 2016; van Kampen et al., 2015), represents a transformation in patient care. This speed enables same-day treatment initiation, reduces pre-treatment loss to follow-up, and may decrease community transmission. The operational simplicity of automated, cartridge-based systems like Xpert minimizes hands-on time and technical expertise requirements, facilitating decentralization to peripheral levels (Boehme et al., 2011).

However, the throughput limitation of 12-16 tests per day on standard 4-module GeneXpert instruments constrains capacity in high-volume settings. Strategies such as sample pooling have been evaluated as cost-saving approaches, with one study reporting 48% savings in cartridges (Vuchas et al., 2023; Henerico et al., 2021), though this approach reduces individual sensitivity and requires validation in local contexts. Simpler technologies like LAMP and urine LAM offer higher throughput potential and lower infrastructure demands, making them suitable for peripheral health posts with limited electricity and trained personnel (Shete et al., 2019; Lawn et al., 2012).

Implementation Feasibility and Cost Considerations

The infrastructure requirements of molecular platforms pose implementation challenges in precisely the settings where they are most needed. Stable electricity, temperature control, annual calibration, and reliable supply chains for cartridges and reagents are frequently unavailable in peripheral health facilities (Ardizzoni et al., 2015). The finding that error rates are highest during initial implementation phases (Muyoyeta et al., 2015) underscores the importance of robust training, maintenance support, and quality assurance systems. Simpler technologies like LAMP and urine LAM, with minimal infrastructure requirements, may be more feasible for true decentralization to community level (Yadav et al., 2017; Mathabire Rucker et al., 2019).

Cost remains a major barrier to universal access. Despite subsidies reducing Xpert cartridge costs to approximately US\$10 in high-burden countries, this remains substantially higher than smear microscopy (US\$2-5) and prohibitive for many health systems (Pooran et al., 2019). The finding that point-of-care Xpert costs \$28.03 per test versus \$23.00 for laboratory-based testing (Pooran et al., 2019) reflects the additional costs of decentralization. Lower-cost alternatives including Truenat, LAMP, and open-platform PCR assays priced at <\$2 per test (Jayaprakasam et al., 2025; Bhusal et al., 2018) offer potential pathways to affordable access, though their accuracy and operational characteristics require further evaluation in diverse settings.

Cost-effectiveness analyses generally support RDT implementation, particularly when targeted to high-risk populations. The finding that point-of-care Xpert is cost-effective at a willingness-to-pay of \$3,820 per treatment completion (Pooran et al., 2019) suggests good value for money, though affordability remains challenging for under-resourced health systems. The economic argument for RDTs extends beyond direct healthcare costs to include reduced patient costs from shorter diagnostic journeys, decreased transmission, and avoidance of inappropriate empiric treatment (Sachdeva et al., 2015).

Clinical and Public Health Impact

The discordance between improved diagnostic accuracy and inconsistent mortality reduction requires careful explanation. Large randomized trials showing no mortality benefit from Xpert compared to smear microscopy (Theron et al., 2014; Churchyard et al., 2015) have been attributed to high rates of empiric treatment in control arms, which may partially compensate for lower sensitivity. This finding does not negate the value of RDTs but rather highlights that their impact depends on the quality of clinical care in the comparator strategy. In settings where empiric treatment is less common, or where correct treatment depends on resistance detection, the mortality benefit may be more pronounced (Haraka et al., 2021).

The consistent reduction in time to treatment initiation, particularly for MDR-TB (D. Nair et al., 2016; van Kampen et al., 2015), represents a clinically meaningful benefit even in the absence of mortality reduction. Earlier treatment reduces morbidity, improves quality of life, and may decrease transmission. The finding that Xpert rollout was associated with halving of empiric TB treatment rates in Cape Town (Hermans et al., 2017) suggests that RDTs improve diagnostic certainty, reducing unnecessary treatment with its attendant risks and costs.

The substantial increase in bacteriologically confirmed case notification, ranging from 15% to 39% across studies (Sachdeva et al., 2015; Creswell et al., 2015; Burger et al., 2022), has important programmatic implications. Accurate case counts inform resource allocation, enable

monitoring of epidemic trends, and support progress toward End TB targets. The fivefold increase in DR-TB detection reported in India (Sachdeva et al., 2015) demonstrates the particular value of RDTs for resistance surveillance and appropriate treatment initiation.

Health System Considerations

The effectiveness of RDTs is inextricably linked to the strength of the health system in which they are embedded. Rapid diagnosis without effective linkage to care yields limited benefit, as patients may be lost to follow-up even after accurate diagnosis (Churchyard et al., 2015). The finding that even in randomized trials, some patients with positive Xpert results did not initiate treatment (Theron et al., 2014) highlights the need for integrated service delivery models that connect diagnosis to treatment initiation and adherence support.

Human resource constraints affect both test performance and result utilization. While automated platforms reduce technical skill requirements, basic computer literacy and troubleshooting capacity remain necessary (Ardizzoni et al., 2015). Healthcare worker confidence in molecular test results may influence clinical decision-making, with some clinicians continuing to rely on clinical judgment even when molecular results are available (Theron et al., 2014). Implementation strategies must address both technical and behavioral aspects of diagnostic innovation.

Supply chain reliability emerged as a critical implementation factor across multiple studies (Ardizzoni et al., 2015; Muyoyeta et al., 2015). Cartridge stock-outs, reagent expiration, and module failures disrupt service delivery and undermine confidence in the diagnostic platform. Strengthening supply chains, including forecasting, procurement, and distribution systems, is essential for sustainable RDT implementation.

Research Gaps and Future Directions

Critical evidence gaps remain. Long-term patient outcomes beyond six-month mortality, including disability, quality of life, and socioeconomic impact, are poorly documented. The cost-effectiveness of different diagnostic algorithms in varied epidemiological and health system contexts requires further study. The impact of RDTs on TB transmission dynamics at community level has not been rigorously evaluated. Novel technologies, including point-of-care biomarkers, next-generation sequencing for comprehensive resistance detection, and non-sputum-based tests for difficult-to-diagnose populations, require continued development and evaluation. Implementation science research is needed to identify optimal strategies for integrating RDTs into routine care, strengthening linkage to treatment, and sustaining quality over time.

CONCLUSION AND RECOMMENDATIONS

Conclusion

Rapid diagnostic tests for tuberculosis have fundamentally improved diagnostic capacity in resource-limited settings, offering substantial advantages over conventional smear microscopy in sensitivity, speed, and drug resistance detection. The evidence synthesized in this review supports several key conclusions.

First, molecular RDTs including Xpert MTB/RIF, Truenat, and LAMP-based assays demonstrate high specificity (>98%) and superior sensitivity compared to microscopy, with pooled sensitivity of 88-89% for Xpert MTB/RIF and 80-90% for other platforms. This translates into 23-39% increases in bacteriologically confirmed case detection, particularly benefiting smear-negative and drug-resistant TB cases.

Second, performance varies substantially by population, with reduced sensitivity in PLHIV (79-80%) and smear-negative patients (55-77%). Urine LAM testing provides complementary value in severely immunocompromised HIV-positive patients, with sensitivity reaching 66.7% in those with CD4 counts below 50 cells/ μ L.

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Third, drug resistance detection, particularly for rifampicin, is highly accurate (94-95% sensitivity, 98% specificity), enabling rapid MDR-TB diagnosis and treatment initiation. Newer platforms extending resistance detection to isoniazid and second-line drugs approach the performance needed for clinical decision-making.

Fourth, the dramatic reduction in turnaround time from weeks to hours represents a paradigm shift, enabling same-day treatment initiation and reducing time to MDR-TB treatment from months to 22 days. This speed reduces pre-treatment loss to follow-up and may decrease transmission.

Fifth, implementation feasibility is constrained by infrastructure requirements, cost, and supply chain reliability. While Xpert requires stable electricity and annual calibration, simpler technologies like LAMP and urine LAM are more suitable for peripheral settings. Per-test costs of US\$10-28 remain substantial barriers despite cost-effectiveness evidence supporting RDT use, particularly in high-risk populations.

Sixth, clinical impact on mortality is inconsistent, reflecting effective empiric treatment in control arms and persistent challenges in linkage to care. However, reductions in time to treatment, morbidity, and empiric treatment rates represent meaningful benefits.

Recommendations

For policymakers and national TB programs, we recommend: (1) prioritizing RDT implementation in high-burden settings, with platform selection based on local infrastructure, costs, and population characteristics; (2) targeting urine LAM testing to severely immunocompromised hospitalized PLHIV; (3) strengthening health systems to ensure reliable supply chains, equipment maintenance, and quality assurance; (4) developing integrated service delivery models that connect rapid diagnosis to prompt treatment initiation; and (5) conducting local cost-effectiveness analyses to guide resource allocation.

For healthcare workers, we recommend: (1) recognizing that negative molecular test results do not exclude TB in high-risk patients, particularly PLHIV and smear-negative suspects; (2) interpreting positive rifampicin resistance results with caution in low-prevalence settings, confirming with phenotypic testing when possible; and (3) maintaining clinical judgment and considering empiric treatment when suspicion remains high despite negative molecular results.

For researchers, we recommend: (1) conducting implementation science research to identify strategies for optimizing RDT use in routine programmatic settings; (2) evaluating long-term patient outcomes including morbidity, quality of life, and socioeconomic impact; (3) developing and validating novel tests for difficult-to-diagnose populations including children and extrapulmonary TB; (4) assessing cost-effectiveness of different diagnostic algorithms in diverse epidemiological contexts; and (5) investigating the impact of RDTs on TB transmission dynamics at community level.

In conclusion, rapid diagnostic tests are effective tools for tuberculosis diagnosis in resource-limited settings, but their full potential requires integration into strengthened health systems with reliable treatment linkage. The choice of test, targeting to appropriate populations, and attention to implementation context are critical determinants of real-world effectiveness. Continued innovation and implementation research are needed to address remaining gaps and ensure that the benefits of rapid diagnosis reach all those in need.

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