INFORMATION BRIEF (RAPID REVIEW)

SPUTUM TUBERCULOSIS LOOP-MEDIATED ISOTHERMAL AMPLIFICATION (TB-LAMP) FOR DETECTION OF TUBERCULOSIS

Malaysian Health Technology Assessment Section (MaHTAS)
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SPUTUM TUBERCULOSIS LOOP-MEDIATED ISOTHERMAL AMPLIFICATION (TB-LAMP) FOR DETECTION OF TUBERCULOSIS

PURPOSE

To outline the effectiveness, safety parameters and cost implications of TB-LAMP for tuberculosis detection in sputum.

BACKGROUND

Tuberculosis (TB), caused primarily by members of the *Mycobacterium tuberculosis* complex (MTBC) remains a grave global health threat. Despite being preventable and curable, TB has recently re-emerged as the leading cause of death from a single infectious agent worldwide. The complex pathogenesis of TB is characterised by its slow growth, capacity for latency and resistance to standard antimicrobials. It necessitates rapid, accurate diagnostic tools and lengthy, multi-drug treatment regimens to effectively curb transmission and minimise disease progression. Delays in diagnosis amplify the risk of infectious spread and significantly worsen patient outcomes.[1]

The global burden of TB remains substantial, with an estimated 10.8 million new cases and 1.25 million TB-related deaths reported worldwide in 2023, as detailed in the World Health Organization (WHO) Global Tuberculosis Report 2024.[1] The Southeast Asian region continues to face high TB prevalence, particularly in countries such as Indonesia and the Philippines, which rank among the world's highest-burden nations. Within Malaysia, the Ministry of Health recorded 26,183 TB cases in 2024, reflecting a marginal increase of 0.1% from the previous year. The national incidence rate stood at 76.9 per 100,000 populations, while TB-related mortality was reported at 2,580 deaths, corresponding to a fatality rate of 7.6 per 100,000 populations. High-risk groups in Malaysia include individuals living with human immunodeficiency virus (HIV), patients undergoing dialysis, diabetics, the elderly and smokers. These figures underscore the persistent challenges in TB control across global and regional contexts, reinforcing the need for resilient, infrastructure-independent diagnostic platforms that can sustain rapid case detection, particularly in resource-limited and crisis-affected settings.[2-4]

Regarding currently implemented intervention, effective TB control hinges on timely and accurate diagnosis, yet global efforts are hindered by conventional diagnostic methods that are either slow or insufficiently sensitive. Acid-fast bacilli smear microscopy, though widely used in resource-limited settings due to its low cost and simplicity, requires a high bacterial load for detection and often fails to identify smear-negative cases, particularly in children, extra-pulmonary TB and HIV co-infected individuals. Mycobacterial culture, the gold standard for diagnosis of TB detects low bacterial loads but suffers from prolonged time-to-detection; averaging over 33 days and resulting in delayed treatment and increased transmission. Meanwhile, molecular diagnostics like [redacted]Xpert *Mycobacterium tuberculosis*/ Rifampicin resistance (MTB/RIF) assay offer rapid and accurate results but remain inaccessible in many high-burden areas due to prohibitive costs and infrastructure demands. These limitations collectively underscore the urgent need for high-sensitivity, infrastructure-independent diagnostic platforms to close the equity gap and accelerate global TB case detection.[5,6]

In 2016, the World Health Organization (WHO) recommended TB-LAMP as a replacement for smear microscopy in adults with suspected pulmonary TB, particularly in resource-limited settings. It offers rapid results within one hour, requires minimal infrastructure and enables visual detection without the need for real-time polymerase chain reaction equipment. While it

does not detect drug resistance, its operational simplicity and improved sensitivity over smear microscopy make it suitable for decentralised laboratories. Commercially available as the [redacted] MTBC Detection Kit, TB-LAMP supports the WHO End TB Strategy by enhancing early diagnosis and expanding access to molecular testing in high-burden areas.[7]

Looking at present international uptake, the TB-LAMP has been implemented across multiple regions as part of WHO-endorsed rapid diagnostic strategies, with uptake varying by country context. It is deployed in several high-burden countries as pilot implementations in Asia and Africa, including India, Indonesia, the Philippines, Thailand and Vietnam, where it is integrated into national TB programs as an alternative to smear microscopy for decentralised settings.[1] Japan continues to use TB-LAMP domestically, while African nations such as Uganda, Tanzania and Zambia have adopted TB-LAMP through WHO and Foundation for Innovative New Diagnostics (FIND)-supported initiatives to expand access to rapid molecular diagnostics. Advocacy updates in 2025 further confirm that TB-LAMP remains part of WHO's diagnostic toolbox, particularly in low- and middle-income countries, where its lower infrastructure requirements compared to [redacted]Xpert make it suitable for peripheral laboratories.[8]

As shown in **Figure 1**, TB-LAMP is known as an emerging nucleic acid amplification tests (NAATs), designed to detect MTBC deoxyribonucleic acid (DNA) using a strand-displacement mechanism under isothermal conditions, primers targeting six distinct DNA regions, enabling rapid and efficient amplification. Operationally, TB-LAMP offers simplified DNA extraction via kits and allows for easy result interpretation through ultraviolet fluorescence or turbidity, bypassing costly real-time detection systems. Its streamlined workflow and minimal infrastructure requirements yield definitive results within one to two hours, making it a practical alternative to conventional NAATs.[9] **Table 1** shows comparative summary of key characteristics of conventional and molecular TB diagnostic methods and the TB-LAMP assay.

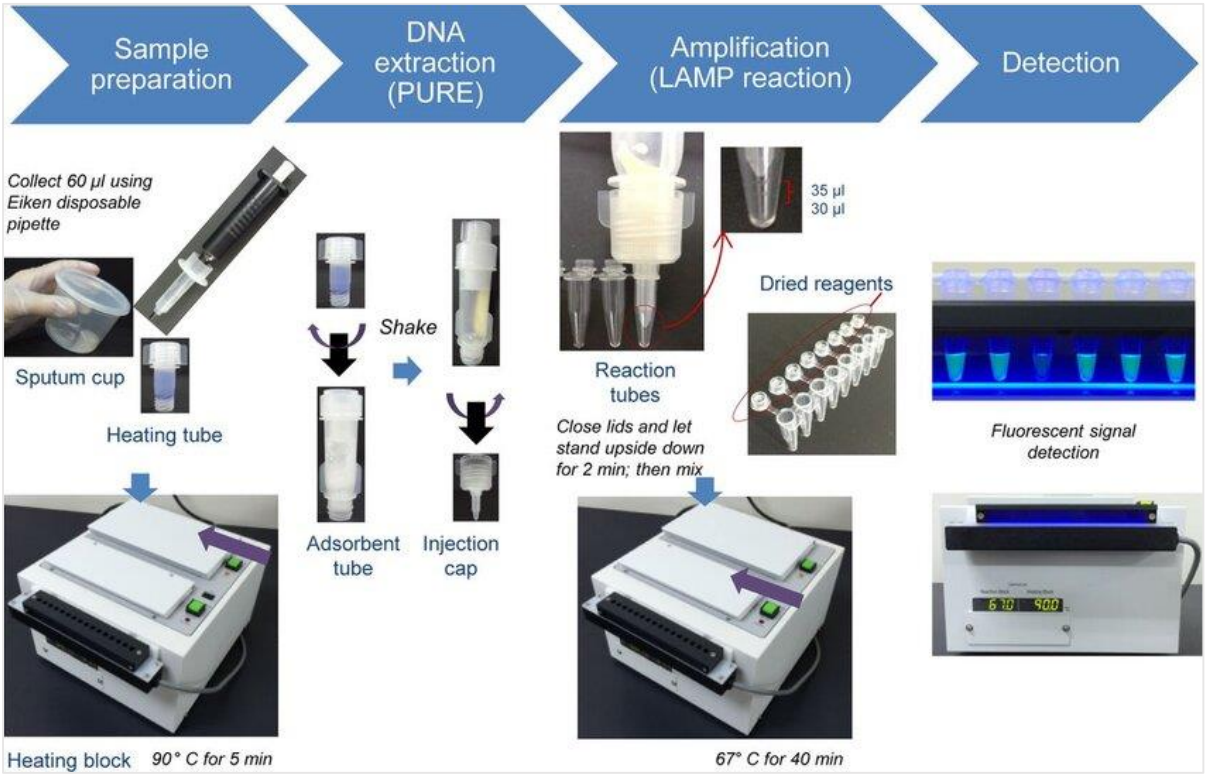

Figure 1: In the TB-LAMP procedure, 60 µL of sputum is added to an extraction tube and heated at 90°C for five minutes to lyse and inactivate mycobacteria. After cooling, the sample is mixed with an adsorbent powder to remove inhibitors, then 30 µL to 35 µL of the processed

solution is transferred into a reaction tube containing primers for amplification. All steps are designed to minimise contamination and simplify workflow.[10]

Table 1: Summary comparison of key features of conventional and molecular tuberculosis diagnostic approaches.[5-7]

Diagnostic Method	Sensitivity	Time to Result	Infrastructure Requirement	Cost (Relative)	Key Limitations
AFB Smear Microscopy	Low (requires ≥5,000 bacilli/mL)	~1–2 hours	Minimal (basic microscopy)	Very low	Low sensitivity; misses smear-negative, paediatric, and extrapulmonary TB cases
Mycobacterial Culture	High (10–100 CFU/mL)	7–42 days	Moderate to high (lab setup needed)	Moderate	Long turnaround time; delays treatment initiation
[redacted]Xpert MTB/RIF	High (detects MTBC + RR)	~2 hours	High (power, climate control)	High (10–20× smear)	Costly; infrastructure-dependent; limited scalability in remote settings
TB-LAMP	Moderate to high (comparable to [redacted]Xpert in some settings)	~60–90 minutes	Low to moderate (no thermocycler)	Moderate	Requires basic training; not yet universally adopted or scaled

AFB, acid-fast bacillus; TB, tuberculosis; CFU, colony-forming unit; MTB, Mycobacterium tuberculosis; RIF, rifampicin; MTBC, Mycobacterium tuberculosis complex, RR, rifampicin-resistant; LAMP, loop-mediated isothermal amplification

A comprehensive review of TB-LAMP is essential to inform evidence-based decision-making in healthcare and policy, particularly in the context of strengthening TB diagnostic capacity. Given its potential to overcome key limitations of conventional methods, such as low sensitivity in smear microscopy and infrastructure dependence in molecular platforms like [redacted]Xpert, TB-LAMP is claimed to offer a promising alternative for decentralised, rapid case detection. Evaluating its diagnostic accuracy, operational feasibility, cost-effectiveness and scalability within local health systems will enable policymakers to determine its suitability for national implementation, especially in resource-limited or high-burden settings. This review is critical to guide strategic investments, optimise diagnostic algorithms and align with national and global TB elimination goals.

EVIDENCE SUMMARY

A systematic review was conducted. A total of 255 titles were retrieved through the Embase, PubMed and United States of Food and Administration (US FDA). Google was used to search for additional web-based materials and information. There was no language limitation in the search and the last search was conducted on 29 October 2025. Six systematic reviews, with or without meta-analysis and four economic studies were included. The studies were primarily conducted in Asia (India, Thailand, Indonesia, China, Japan), followed by the Canada and United States.

EFFECTIVENESS

Six studies evaluated the effectiveness of TB-LAMP as a screening tool for detecting TB in sputum.

Inbaraj LR et al. (2025; India) conducted a systematic review and meta-analysis to assess the diagnostic accuracy of low-complexity, manual NAATs, specifically TB-LAMP for detecting *Mycobacterium tuberculosis* in adults and adolescents (aged ≥10 years) with presenting presumptive pulmonary or extrapulmonary TB. This procedure was compared against microbiological or composite reference standards and considered an alternative to both smear microscopy and more resource-intensive automated molecular NAATs, such as [redacted]Xpert MTB/RIF and [redacted] MTB. The primary meta-analysis focused on pulmonary TB detection from respiratory specimens, including 26 studies involving 18,297 participants and found a summary sensitivity of 84.1% (95% CI 78.3 to 88.6) and a summary specificity of 96.1% (95% CI 94.2 to 97.4). Furthermore, for extrapulmonary TB, three studies involving 95 participants assessed TB-LAMP for detecting lymph node TB, showing a summary sensitivity of 94.3% (95% CI 79.8 to 98.6) and a summary specificity of 90.0% (95% CI 79.5 to 95.4).[11, level I]

In the systematic review, eight diagnostic studies (2,991 participants; including 460 individuals with pulmonary TB) assessed the diagnostic performance of TB-LAMP in people living with HIV (PLWH). Sensitivity ranged from 52.0% to 100.0%, with a pooled estimate of 77.1% (95% CI 60.8 to 87.9), while specificity ranged from 27.0% to 100.0%, with a pooled estimate of 95.9% (95% CI 84.9 to 99.0). In HIV-negative populations, based on three studies with 1,541 participants, TB-LAMP showed a summary sensitivity of 76.7% and specificity of 98.9%. Among 690 participants with CD4 count data, those with CD4 <200 cells/μL had reduced sensitivity (60.9%) but maintained high specificity (96.2%), indicating diagnostic limitations in immunocompromised individuals. **These findings highlighted TB-LAMP's variable sensitivity across subgroups, with consistently high specificity**.[11, level I]

Another **systematic review and meta-analysis conducted by Bumbrah GS et al. (2023; India)** aimed to assess the diagnostic efficiency of the LAMP assay for detecting a panel of *Mycobacterium spp.*, with the goal of identifying a rapid alternative to conventional diagnostics, such as smear microscopy, culture assay and polymerase chain reaction in low-resource settings. The methods involved searching diverse scientific databases from the year 2000 until March 2022, to identify articles utilising LAMP technology on clinical samples for detection of mycobacterial species. The results were based on a detailed meta-analysis of 30 eligible studies. Although the source stated that most included articles did not mention specific patient details, the studies examined various specimens with sputum being the most common (used in 21 studies). The accuracy and precision rates for the included studies on TB-LAMP varied, ranging between 37.73% and 99.33% for accuracy and between 39.47% and 100.00% for precision, while pooled sensitivity values **(see Figure 2)** ranged from 0.26 to 1.00 and specificity values ranged from 0.67 to 1.00.[12, level I]

Habiburrahman M et al. (2021; Indonesia) also conducted a systematic review to investigate the performance and applicability of LAMP, particularly when combined with Au-Nanoprobe (Au-Np) as an alternative molecular diagnostic tool for detecting *Mycobacterium tuberculosis*, and its resistance to isoniazid (INH) and rifampicin (RIF). The search identified three studies directly evaluating LAMP-Au-Np for detecting INH-RIF resistance, along with 25 additional articles examining the effectiveness of LAMP, Au-Np or their combination compared to other diagnostic methods. The available evidence on LAMP-based diagnostics for antibiotic resistance from limited studies demonstrated consistently high accuracy. Three small-scale studies; using sample sizes of 25, 12 and 46 reported 100.0% sensitivity and specificity for detecting RIF and INH resistance, with one study benchmarking against the Genotype multi-

drug resistance TB (MDR-TB) Plus assay. For general TB detection, LAMP combined with Au-Np yielded 98.2% sensitivity and 88.2% specificity, indicating strong diagnostic potential. Broader systematic reviews evaluating LAMP as a standalone tool across 14 to 59 studies showed pooled sensitivities ranging from 77.7% to 93.0% and specificities between 88.0% and 99.0%, reinforcing its reliability across diverse settings. **These findings suggested that LAMP particularly when enhanced with Au-Np, might offer a robust, scalable alternative for TB and drug resistance detection**.[13, level I]

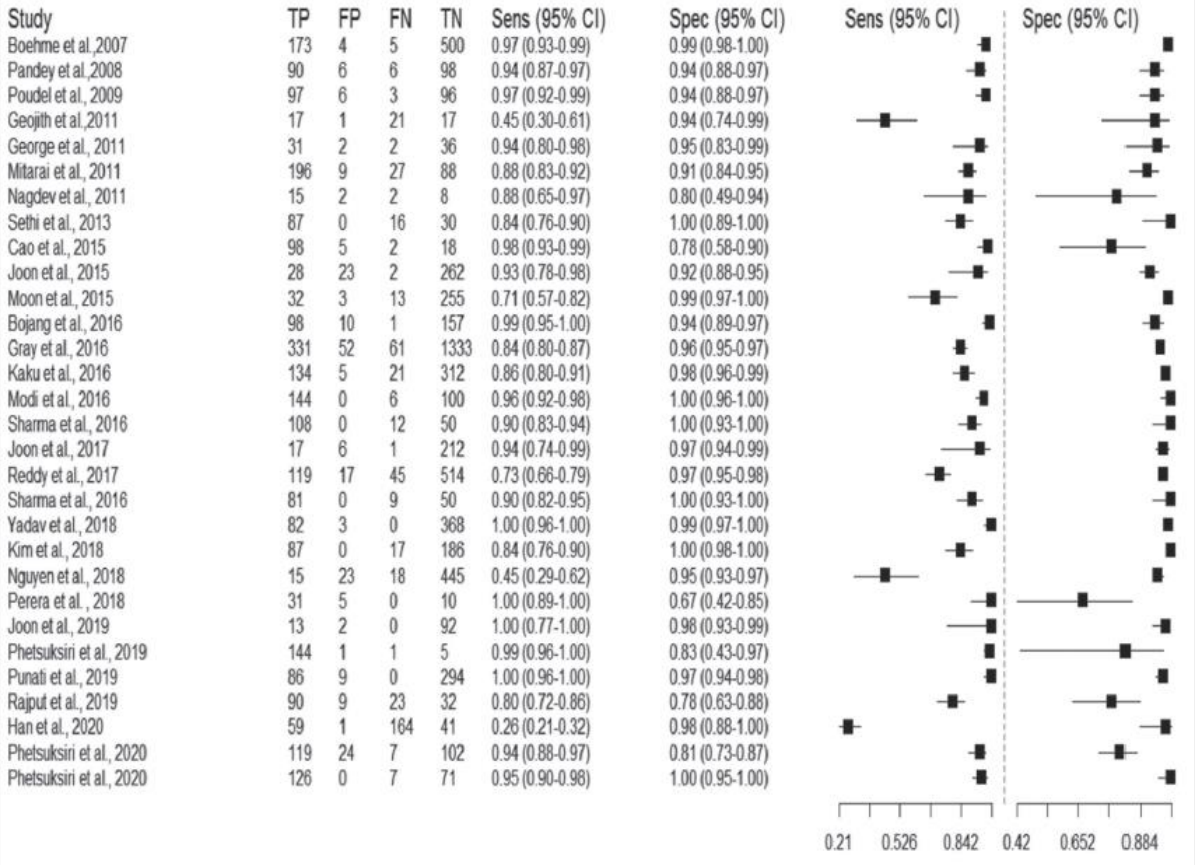

Figure 2: The forest plot of sensitivity and specificity of included studies (n=30) on the diagnostic performance of LAMP technique.[12, level I]

The next **systematic review and meta-analysis was explored by Shete PB et al. (2019; United States).** The review assessed the diagnostic accuracy for detecting *Mycobacterium tuberculosis* and included 13 studies (4,760 participants) that was conducted from January 2012 to October 2015. The TB-LAMP's accuracy was compared against smear microscopy and [redacted]Xpert MTB/RIF using three hierarchical culture-based reference standards; to classify TB status based on the number and results of cultures. Patients were considered TB-positive if at least one culture confirmed MTB complex. The TB-negative classification depended on progressively less stringent criteria: Standard 1 (n=1,810) required two negative cultures from different sputum samples, Standard 2 (n=3,110) required two negatives from one sample and Standard 3 (n=4,596) required only one negative culture. These standards balanced diagnostic yield (highest with Standard 1) and study inclusion (highest with Standard 3).[14, level I]

The findings showed that TB-LAMP possessed higher sensitivity than sputum smear microscopy (pooled sensitivity difference +13.2% [95% CI 4.5 to 21.9]) and similar sensitivity to GeneXpert MTB/RIF (pooled sensitivity difference -2.5% [95% CI -8.0 to +2.9]) when using the most stringent reference standard. Using this same standard (Standard 1), the pooled sensitivity of TB-LAMP was 77.7% (95% CI 71.2–83.0) and pooled specificity was 98.1% (95%

CI 95.7–99.2). When used as an alternative to smear microscopy in HIV-infected adults, TB-LAMP demonstrated lower pooled sensitivity compared to the general adult population, ranging from 63.8% (95% CI 49.0 to 76.4) under Standard 2 to 73.4% (95% CI 51.9 to 87.6) under Standard 3. Specificity varied more markedly, with high performance under Standard 2 (98.8%, 95% CI 85.1 to 99.9) but reduced precision under Standard 3 (95.0%, 95% CI 64.0 to 99.5). Substantial heterogeneity was observed in both sensitivity and specificity estimates with Standard 3 (I^2=86.0%, p<0.001), indicating variability across studies, whereas Standard 2 showed moderate heterogeneity in sensitivity (I^2=54.0%) and none in specificity (I^2=0.0%). **These findings suggested that while TB-LAMP maintained high specificity, its sensitivity in HIV-infected populations was modest and variable, warranting cautious interpretation in clinical and policy contexts**.[14, level I]

Comparative analysis of TB-LAMP and [redacted]Xpert revealed that both assays demonstrated high diagnostic accuracy, though [redacted]Xpert generally performed better in terms of sensitivity:[14, level I]

a. For sensitivity comparison:

- [redacted]Xpert sensitivity ranged from 65.0% to 97.0% across studies and reference standards.
- TB-LAMP sensitivity ranged from 48.0% to 93.0%, showing slightly lower performance overall.
- Difference in sensitivity between TB-LAMP and [redacted]Xpert:
    - Standard 1: −14.0% to +3.0%; pooled difference −2.5% (95% CI −8.0 to +2.9).
    - Standard 2: −15.0% to +3.0%.
    - Standard 3: −36.0% to +3.0%; pooled difference −6.9% (95% CI −12.8 to −1.0).

b. For specificity comparison:

- [redacted]Xpert specificity ranged from 90.0% to 100.0%.
- TB-LAMP specificity ranged from 94.0% to 100.0%.
- Difference in specificity between TB-LAMP and [redacted]Xpert:
    - Standard 1: −1.0% to +3.0%.
    - Standard 2: −1.0% to +4.0%.
    - Standard 3: −3.0% to +5.0%.

- No significant difference in pooled specificity between TB-LAMP and [redacted]Xpert across all standards.

Another **systematic review and meta-analysis was carried out by Deng S et al. (2019; China)** to assess the diagnostic accuracy of molecular diagnostic methods, including the LAMP assay, for the detection of pulmonary TB in studies performed in China. The study involved 41 articles published between January 2000 and September 2017, utilising *Mycobacterium tuberculosis* culture methods (either solid or liquid media) as the reference standard for comparison. Across 20 studies involving over 10,000 participants, [redacted]Xpert MTB/RIF demonstrated high diagnostic accuracy with pooled sensitivity of 91.0% (95% CI 87 to 94) and specificity of 92.0% (95% CI 89 to 94). In smear-positive TB cases, sensitivity reached 98.0% to 100.0%, even though specificity was not reported due to limited interpretive value. For smear-negative TB, pooled sensitivity dropped to 75.0% (95% CI 52 to 90) while specificity remained high at 94.0% (95% CI 81 to 98).[15, level I]

In comparison, six studies evaluating LAMP across 4,653 participants showed pooled sensitivity of 90.0% (95% CI 78 to 95) and specificity of 93.0% (95% CI 85 to 97). Subgroup analyses revealed LAMP sensitivity of 92.0% (95% CI 87 to 96) to 97.0% (95% CI 93 to 99) in

smear-positive TB, and 67.0% (95% CI 49 to 81) in smear-negative TB, with specificity at 96.0% (95% CI 86 to 99). **These findings suggested that while both tests performed well in smear-positive cases, [redacted]Xpert maintained superior sensitivity in smear-negative populations, whereas LAMP offered comparable specificity and operational advantages in decentralised settings**.[15, level I]

Nagai K et al. (2016; Japan) also implemented a systematic review and meta-analysis to clarify the diagnostic test accuracy of the LAMP assay for culture-proven *Mycobacterium tuberculosis*. The methods involved included cohort and case-control studies that provided sufficient data of sensitivity and specificity, using any LAMP assay (commercialised kits or in-house assays) as the index test, and *Mycobacterium tuberculosis* culture as the positive reference test. The results from the systematic review included 27 studies focusing on sputum samples, which totalled 9,645 sputum specimens (consisting of 3,099 TB culture-positive specimens and 6,546 culture-negative specimens). Across the 26 studies that evaluated a total of 9,330 sputum samples (3,069 were culture-positive specimens, while 6,261 were culture-negative specimens), which evaluated LAMP's diagnostic accuracy for pulmonary TB, yielded a summary sensitivity of 89.6% (95% CI 85.6 to 92.6) and a summary specificity of 94.0% (95% CI 91.0 to 96.1), demonstrating a very good overall diagnostic accuracy with an area under curve of 0.962.[16, level I]

There was an analysis comparing the diagnostic performance of commercialised [redacted] MTBC and in-house LAMP assays across multiple studies. [redacted] MTBC was evaluated in nine studies using 5,283 sputum samples, while in-house LAMP assays were assessed in 17 studies with 4,047 samples. Although diagnostic odds ratio values were similar between both assay types, in-house LAMP showed a significantly higher area under the curve, suggesting better overall diagnostic accuracy. The in-house LAMP assays achieved higher sensitivity (93.0%) but lower specificity (91.8%) compared to [redacted] MTBC (sensitivity 80.9%, specificity 96.5%).[16, level I]

Subgroup analysis of [redacted] MTBC revealed strong performance in smear-positive specimens, with sensitivity of 96.6% and specificity of 71.3%, yielding a positive likelihood ratio of 3.4 and a negative likelihood ratio of 0.05. In smear-negative specimens, sensitivity dropped to 54.3%, but specificity increased to 98.6%, with a positive likelihood ratio of 38.8 and negative likelihood ratio of 0.46. **These figures indicated that [redacted] MTBC was highly specific in smear-negative cases but less sensitive, while it was highly sensitive but less specific in smear-positive cases**.[16, level I]

Overall findings: Across multiple high-quality systematic reviews and meta-analyses, TB-LAMP demonstrated consistently high diagnostic accuracy for detecting *Mycobacterium tuberculosis*, with pooled sensitivities generally ranging from 77.0% to 94.0% and specificities exceeding 90.0% across diverse populations and specimen types. Its performance was comparable to [redacted]Xpert in many settings, although sensitivity was slightly lower, particularly among HIV-positive patients and those with low CD4 counts. Several studies confirmed TB-LAMP's strong specificity and utility as an alternative to smear microscopy and a viable option for decentralised or resource-limited settings. Moreover, innovations like LAMP-Au-Np showed potential for detecting both TB and drug resistance (INH-RIF) with near-perfect accuracy in early studies. Overall, the accumulated evidence positioned TB-LAMP as a rapid and reliable molecular diagnostic tool, particularly suitable for low- and middle-income countries where affordability and scalability are critical to TB control efforts.

Table 4 delineates the diagnostic efficacy metrics of TB-LAMP in the detection of *Mycobacterium tuberculosis*, showcasing its analytical robustness across studies.

Table 4: Diagnostic performance of TB-LAMP for detecting *Mycobacterium tuberculosis*.

Study	*Study Characteristics*	*Intervention*		*Findings*
		Treatment	**Control**	
Inbaraj LR et al./2025/SRMA India[11]	26 studies N=18,297 TB patients; Adults and adolescents ≥10 years old	TB-LAMP	Smear microscopy, [redacted]Xpert MTB/RIF, [redacted] MTB	**Pulmonary TB detection (respiratory specimens via TB-LAMP):** • 26 studies, 18,297 participants • Summary sensitivity: 84.1% (95% CI: 78.3–88.6) • Summary specificity: 96.1% (95% CI: 94.2–97.4) **Extrapulmonary TB detection (lymph node TB via TB-LAMP):** • 3 studies, 95 participants • Summary sensitivity: 94.3% (95% CI: 79.8–98.6) • Summary specificity: 90.0% (95% CI: 79.5–95.4) **TB-LAMP in people living with HIV:** • 8 studies, 2,991 participants (460 with pulmonary TB) • Sensitivity range: 52.0%–100.0%; pooled estimate: 77.1% (95% CI: 60.8–87.9) • Specificity range: 27.0%–100.0%; pooled estimate: 95.9% (95% CI: 84.9–99.0) **TB-LAMP in HIV-negative populations:** • 3 studies, 1,541 participants • Summary sensitivity: 76.7% • Summary specificity: 98.9% **Subgroup analysis by CD4 count:** • 690 participants with CD4 data • CD4 <200 cells/μL: sensitivity reduced to 60.9%, specificity remained high at 96.2% Remarks: TB-LAMP demonstrated strong diagnostic performance for pulmonary and extrapulmonary TB, with consistently high specificity across populations, though sensitivity was notably reduced in HIV-positive individuals with low CD4 counts.
Bumbrah GS et al./2023/SRMA India[12]	30 studies N=9,250 TB patients	TB-LAMP	Smear microscopy, culture assay, PCR	**Diagnostic performance across studies:** • Accuracy ranged from 37.73% to 99.33% • Precision ranged from 39.47% to 100.00% • Pooled sensitivity ranged from 0.26 to 1.00 • Pooled specificity ranged from 0.67 to 1.00 Remarks: TB-LAMP studies showed wide variability in diagnostic performance across settings, indicating inconsistent sensitivity and specificity outcomes influenced by study design and population characteristics.

Habiburrahman M et al./2021/SR Indonesia[13]	28 studies TB patients + INH-RIF resistance	TB-LAMP + Au-Np	TB-LAMP alone, Au-Np alone, combination with other methods	**Detection of RIF and INH resistance:** • Three small-scale studies (sample sizes: 25, 12 and 46) • All reported 100.0% sensitivity and specificity • One study benchmarked against Genotype MDR-TB Plus assay **General TB detection using LAMP + Au-Np:** • Sensitivity: 98.2% • Specificity: 88.2% **TB-LAMP as standalone tool:** • 14 to 59 studies • Pooled sensitivity: 77.7% to 93.0% • Pooled specificity: 88.0% to 99.0% Remarks: TB-LAMP demonstrated high diagnostic potential across diverse study settings, variable accuracy and precision, consistently strong performance in drug resistance detection and enhanced sensitivity when combined with Au-Np.

Shete PB et al./2019/SRMA United States[14]	13 studies
	N=4,760
	TB patients
		TB-LAMP	Smear microscopy, [redacted]Xpert MTB/RIF	**TB-LAMP vs. smear microscopy**: Higher sensitivity (+13.2%, 95% CI 4.5–21.9)
				
				TB-LAMP vs. [redacted]Xpert MTB/RIF: Comparable sensitivity (−2.5%, 95% CI −8.0 to +2.9)
				
				Standard 1 performance:
				• Sensitivity: 77.7% (95% CI 71.2–83.0)
				• Specificity: 98.1% (95% CI 95.7–99.2)
				
				In HIV-infected adults:
				• Sensitivity lower than general population:
				  ○ Standard 2: 63.8% (95% CI 49.0–76.4)
				  ○ Standard 3: 73.4% (95% CI 51.9–87.6)
				• Specificity:
				  ○ Standard 2: 98.8% (95% CI 85.1–99.9)
				  ○ Standard 3: 95.0% (95% CI 64.0–99.5)
				
				Heterogeneity:
				• Standard 3: High heterogeneity in sensitivity and specificity (I^2=86.0%, p<0.001)
				• Standard 2: Moderate heterogeneity in sensitivity (I^2=54.0%), none in specificity (I^2=0.0)
				
				Remarks: TB-LAMP showed high specificity but variable and modest sensitivity in HIV-infected populations, requiring cautious use in clinical and policy settings.

Deng S et al./2019/SRMA China[15]	20 studies N= >10,000 TB patients	TB-LAMP	[redacted]Xpert MTB/RIF	**Overall diagnostic accuracy**: • [redacted]Xpert: Sensitivity 91.0%, Specificity 92.0% • TB-LAMP: Sensitivity 90.0%, Specificity 93.0% **Smear-positive TB**: • [redacted]Xpert: Sensitivity 98.0%–100.0% • TB-LAMP: Sensitivity 92.0%–97.0% • Specificity not reported for [redacted]Xpert; TB-LAMP specificity at 96.0% **Smear-negative TB**: • [redacted]Xpert: Sensitivity 75.0%, Specificity 94.0% • TB-LAMP: Sensitivity 67.0%, Specificity 96.0% Remarks: [redacted]Xpert demonstrated superior sensitivity in smear-negative cases, while TB-LAMP provided comparable specificity and operational benefits.
Nagai K et al./2016/SRMA Japan[16]	27 studies N=9,645 TB patients	In-house TB-LAMP	Commercial TB-LAMP	**Overall LAMP performance (26 studies, 9,330 sputum samples)**: • High diagnostic accuracy for pulmonary TB • Sensitivity: 89.6%; Specificity: 94.0%; AUC: 0.962 **Commercial [redacted] MTBC) vs. in-house LAMP assays**: • [redacted] MTBC (9 studies): Lower sensitivity, higher specificity • In-house LAMP (17 studies): Higher sensitivity, slightly lower specificity • In-house assays showed better overall diagnostic accuracy (higher AUC) [redacted] **MTBC subgroup analysis**: • **Smear-positive specimens**: High sensitivity, lower specificity • **Smear-negative specimens**: Lower sensitivity, high specificity • Diagnostic trade-off observed between sensitivity and specificity across smear status Remarks: LAMP assays showed high accuracy for pulmonary TB, with in-house formats offering better sensitivity and [redacted] MTBC providing higher specificity, especially in smear-negative cases.

TB, tuberculosis; LAMP, loop-mediated isothermal amplification; [redacted]Xpert, Cepheid [redacted]Xpert System; MTB, Mycobacterium tuberculosis; RIF, rifampicin; CI, confidence interval; HIV, human immunodeficiency virus; PCR, polymerase chain reaction; INH, isoniazid; Au-Np, Au-Nanoprobe; MDR, multidrug-resistant

SAFETY

There was no study retrieved on assessing the safety on the use of TB-LAMP in detecting TB in sputum.

The TB-LAMP was considered safe for use in routine TB diagnosis, particularly in decentralised and resource-limited settings. According to WHO's 2016 policy guidance, the assay required only basic biosafety precautions similar to those used in smear microscopy. It included a 90°C heat inactivation step that effectively neutralised *Mycobacterium tuberculosis*, reducing the risk of laboratory-acquired infection. The closed-tube amplification format minimised contamination and environmental exposure to amplified DNA. The device did not require complex equipment or aerosol-generating procedures, making it suitable for biosafety level two laboratories. With proper training in sputum handling and reagent disposal, TB-LAMP could be safely implemented without additional biosafety infrastructure. This safety profile supported its use in peripheral laboratories and aligns with WHO's goal of expanding access to rapid TB diagnostics.[7]

Nucleic acid amplification tests (such as the [redacted]Xpert MTB/RIF assay, the [redacted]TB and [redacted]TB [redacted] tests) have been approved by the US FDA for the detection of *Mycobacterium tuberculosis* and latent TB infection. However, the TB-LAMP assay (including [redacted] MTBC Detection Kit), despite being endorsed by the WHO since 2016 for use in decentralised settings, has not yet received US FDA approval and is therefore not authorised for clinical use in the United States.[17] In Malaysia, only the brand [redacted] has been registered with Medical Device Authority (MDA), as of December 2025.[21]

Several NAATs have received CE Mark certification in Europe, confirming their compliance with European Union safety and performance standards for in vitro diagnostics. However, despite the broad CE-mark coverage for infectious disease detection, there is currently no publicly available CE-marked LAMP assay specifically indicated for the detection of TB.[18-20]

Although TB-LAMP was not approved by the US FDA and did not received CE Mark certification, it was approved for clinical use in Japan, where its domestic commercialisation indicated regulatory clearance under the Pharmaceuticals and Medical Devices Agency, in accordance with standard procedures governing in vitro diagnostic products marketed within Japan.[26] Additionally, its adoption remains concentrated in countries that align more closely with WHO guidance, particularly in settings where regulatory frameworks prioritise global health recommendations over FDA-specific approvals.[17]

ECONOMIC IMPLICATION

Four studies to date have assessed the cost-effectiveness of TB-LAMP in detecting TB.

Ibrahim HU et al. (2025; Nigeria) conducted an economic evaluation using a decision tree model combined with cost-effectiveness analysis to compare three TB diagnostic algorithms tailored for PLWH in Nigeria; (1) [redacted]Xpert MTB/RIF [redacted]ollowing chest radiography (chest X-ray; CXR), (2) TB-LAM following CXR and (3) TB-LAMP following CXR. The methods involved parameterising the model with data on test accuracy and costs obtained from systematic reviews and meta-analyses. Specifically related to TB-LAMP for detecting *Mycobacterium tuberculosis*, the model used a sensitivity of 0.64 and a specificity of 0.95, derived from external sources. While the exact number of included studies and patients used to establish these input parameters was not detailed within the source material, the study

simulated the effectiveness of the TB-LAMP algorithm in a hypothetical cohort of 10,000 PLWH with presumptive TB. Given an assumed TB prevalence of 22.0% (approximately 2,200 true TB cases), the TB-LAMP algorithm was projected to detect 1,404 pulmonary TB cases (63.8%) and miss 796 cases. Overall, the TB-LAMP strategy was found to be the least cost-effective option among those tested, having a model-derived average cost of USD 20.11 per TB case detected.[22, level I]

Chitpim N et al. (2025; Thailand) implemented an economic evaluation using a cost-utility analysis and a dynamic transmission model approach to assess the cost-effectiveness of five TB diagnostic algorithms, including the TB-LAMP used as an initial test or an add-on test, compared to conventional diagnosis (sputum smear microscopy with culture and drug susceptibility testing) in the general Thailand population. The methods involved calibrating a dynamic mathematical model over a 15-year horizon, informed by input parameters for TB diagnostic test accuracy (e.g., sensitivity and specificity) extracted from systematic reviews of randomised controlled trials and meta-analyses. Although the exact number of included studies and participants used in these underlying systematic reviews to derive the TB-LAMP parameters was not detailed in the source material, the cost-effectiveness analysis simulated outcomes for the general Thailand population encompassing approximately 57 million individuals.[23, level I]

The efficiency frontier approach was applied to assess the cost-effectiveness of the conventional diagnostic method compared to alternative molecular diagnostic strategies, including [redacted]Xpert MTB/RIF Add-On, TB-LAMP Add-On, [redacted]Xpert MTB/RIF Initial and TB-LAMP Initial algorithms in the general population. As illustrated in **Figure 3**, the [redacted]pert MTB/RIF Initial algorithm emerged as the most economically favourable option, primarily due to its cost-saving potential. This was followed by the [redacted]Xpert MTB/RIF Add-On strategy, which also demonstrated strong economic value relative to the conventional diagnostic pathway.

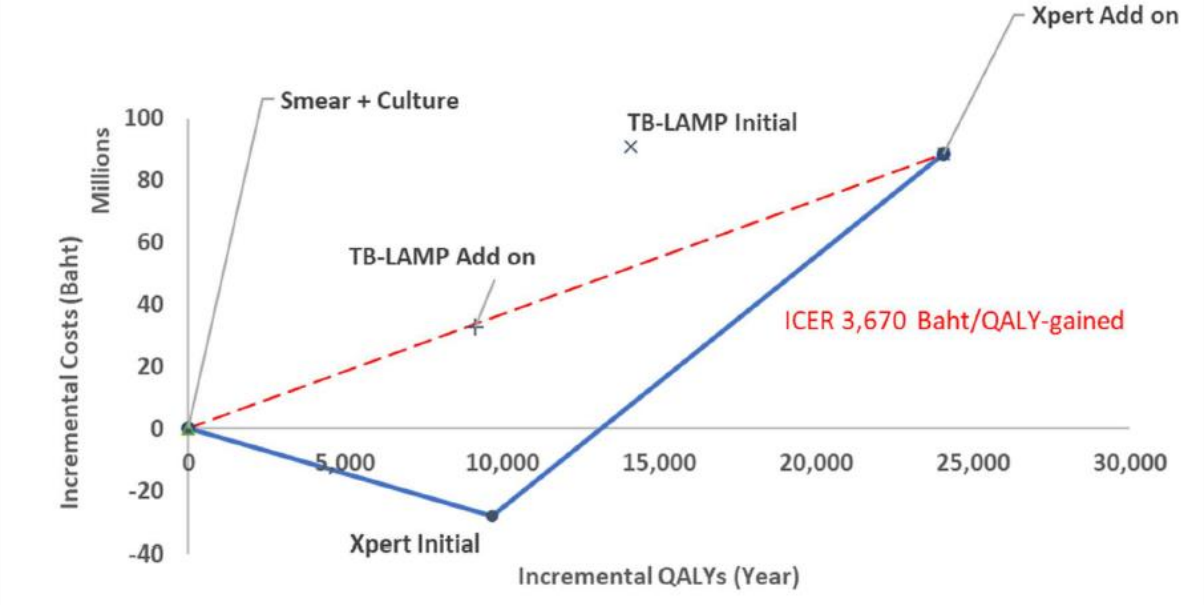

Figure 3: Efficiency frontier of molecular testing alternatives compared to conventional testing in general population.[23, level I]

Related to the diagnosis of pulmonary TB, which was predominantly caused by *Mycobacterium tuberculosis*, the dynamic model predicted that the TB-LAMP Add-On algorithm identified 57,372 cases over the time horizon, while the TB-LAMP Initial algorithm identified 50,338 cases. Compared to the conventional method, the TB-LAMP Add-On method showed a 2.78% reduction in TB incidence rate, and the TB-LAMP Initial method showed a

more significant 14.67% reduction. Furthermore, compared to sputum smear microscopy with culture/ drug susceptibility testing, the incremental cost-effectiveness ratios (ICERs) for TB-LAMP Add-On were THB 3,563 per quality-adjusted life year (QALY) gained, and for TB-LAMP Initial were THB 6,429 per QALY gained, indicating both TB-LAMP strategies were cost-effective based on the Thai societal willingness-to-pay threshold (THB 160,000).[23, level I]

A **cost-effectiveness analysis was carried out by Chitpim N et al. (2022; Thailand)**, utilising a hybrid decision tree Markov model with a one-month cycle length over a lifetime period. The analysis evaluated the cost-effectiveness of five TB diagnostic algorithms, including the TB-LAMP and [redacted]Xpert MTB/RIF test, in Thailand general population (>15 years old) suspected of having pulmonary TB. The methods involved comparing sputum smear microscopy with culture and drug susceptibility testing (conventional approach) against molecular testing algorithms like TB-LAMP Add-on (used as a secondary diagnostic for smear-negative patients) and TB-LAMP Initial (used as an initial test). Input parameters for the model, such as the sensitivity (0.8030 for all smear; 0.4030 for smear negative) and specificity (0.9770 for both) of TB-LAMP, were obtained from a systematic review and meta-analysis by Shete PB et al. (2019). Although the exact number of included studies and patients in the meta-analysis was cited as the source for the test performance data, this specific study did not detail the total number of underlying studies or patients used to calculate those mean parameters.[24, level I]

The baseline cost of sputum smear microscopy combined with culture and drug susceptibility testing was THB 6,845. Molecular testing options varied in cost: [redacted]Xpert MTB/RIF Add-on was the most expensive at THB 8,924 Baht, while TB-LAMP Initial was the least costly at THB 6,565 Baht, a 4.0% reduction compared to the conventional method. Overall, initial testing algorithms [redacted]Xpert MTB/RIF Initial at THB 7,010 and TB-LAMP Initial at THB 6,565) were more cost-efficient than add-on strategies.[24, level I]

In terms of health outcomes, molecular algorithms yielded greater clinical benefit, increasing life years by 0.64 to 0.85 and QALY by 0.53 to 0.94 compared to conventional. The TB-LAMP Initial emerged as the dominant strategy, offering both lower cost and improved effectiveness. Among all options, [redacted]Xpert MTB/RIF Initial had the lowest ICER at THB 197 per QALY gained, followed by TB-LAMP Add-on (THB 993/QALY). **Figure 4** presents the cost-effectiveness plane comparing molecular diagnostic strategies against the conventional method, with the green line denoting Thailand's willingness-to-pay threshold. The analysis revealed that nearly all simulations for TB-LAMP, whether implemented as an initial test or as an add-on fell below the threshold, indicating strong cost-effectiveness. Among all evaluated algorithms, TB-LAMP Initial demonstrated the highest probability of being cost-effective, with an estimated likelihood of 83.4% at the specified threshold.[24, level I]

Sohn H et al. (2019; Canada) conducted a cost and affordability analysis using a bottom-up costing method to compare the economic costs and affordability of the TB-LAMP, for detecting *Mycobacterium tuberculosis* against [redacted]Xpert MTB/RIF in peripheral laboratories in Malawi and Vietnam. The methods involved collecting empiric cost data using a time-and-motion study to directly observe and quantify all resource use for laboratory procedures.[25]

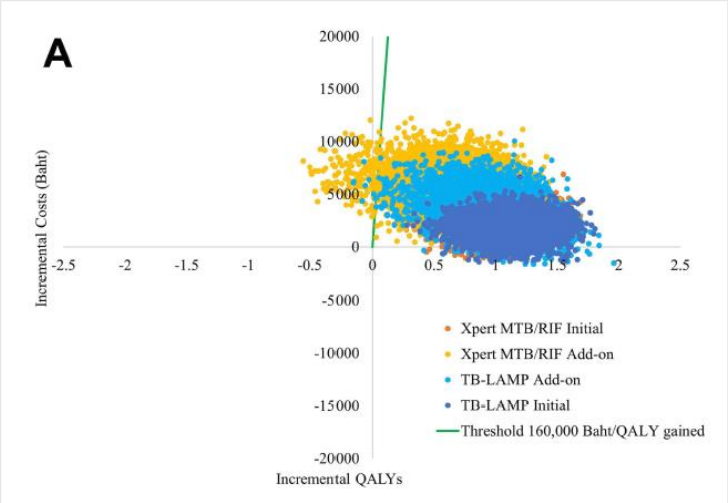

Figure 4: Cost-effectiveness plane.[24, level I]

A comparative cost analysis revealed that TB-LAMP was consistently more cost-efficient, particularly in low-volume laboratory settings. Per-test costs for TB-LAMP ranged from USD 10.39 to USD 19.25 in Malawi and USD 10.08 to USD 17.55 in Vietnam, depending on daily sample throughput. In contrast, [redacted]Xpert exhibited wider cost variability due to its dependence on equipment utilisation: per-test costs ranged from USD 13.40 to USD 48.01 in Malawi and USD 13.49 to USD 30.60 in Vietnam. Nationally, the weighted average per-test cost for [redacted]Xpert was approximately USD 11 higher than TB-LAMP in Malawi, representing a 70.0% increase. This disparity was driven by overheads linked to equipment, space and staffing, particularly when daily test volumes exceeded the [redacted]Xpert IV system's 4-sample capacity per run. Both assays identified reagents (TB-LAMP kits and [redacted]Xpert cartridges) as the dominant cost drivers.[25]

As shown in **Table 3**, the first-year implementation costs further underscored the economic advantage of TB-LAMP. At low, medium and high-volume laboratories, TB-LAMP incurred costs of USD 8,427, USD 14,170 and USD 26,348, respectively, while [redacted]Xpert costs were more than triple at USD 27,627, USD 40,621 and USD 57,775. When scaled nationally, TB-LAMP roll-out consumed 34.0% of Malawi's 2014 TB program budget and exceeded Vietnam's budget by over 50.0%. [redacted]Xpert's roll-out at low-volume sites alone accounted for 47.0% of Malawi's TB budget and surpassed Vietnam's budget by more than 100.0%. Even when restricted to high-volume laboratories, TB-LAMP would still consume over 30.0% of Vietnam's TB budget, while [redacted]Xpert would require 73.0%, highlighting the substantial fiscal burden associated with [redacted]Xpert deployment in resource-constrained settings. These findings supported TB-LAMP as a more scalable and economically sustainable option for national TB programs.[25]

Table 3: Total cost and affordability of national roll-out of TB-LAMP compared to [redacted]Xpert assay in Malawi and Vietnam.[25]

Workload categories	Malawi					Vietnam				
	No. of labs	TB-LAMP		Xpert		No. of labs	TB-LAMP		Xpert	
		Total 1st yr cost	National TB budget (%)	Total 1st yr cost	National TB budget (%)		Total 1st yr cost	National TB budget (%)	Total 1st yr cost	National TB budget (%)
Low (≤ 4 tests per day)	96	$808,994	14	$2,652,200	47	460	$4,651,715	64	$15,250,150	209
Medium (> 4 and < 10 tests per day)	48	$680,167	12	$1,949,850	34	280	$3,910,963	54	$11,211,638	154
High (≥ 10 tests per day	16	$421,584	7	$924,400	16	180	$2,424,106	33	$5,315,300	73
Total	160	$1,910,745	34	$5,526,450	97	920	$10,986,784	151	$31,777,088	435
Total national TB program budget (reported to WHO in 2014)	$5,700,000					$7,300,000				

TB, tuberculosis; WHO, World Health Organization; Lab, laboratory; TB-LAMP, loop-mediated isothermal amplification assay for tuberculosis; Xpert, Xpert MTB/RIF

Table 4 summarises key economic evaluations that assessed the cost-effectiveness and diagnostic performance of the TB-LAMP assay for detecting *Mycobacterium tuberculosis* across various populations and settings, highlighting its comparative performance, costs and outcomes relative to other molecular and conventional diagnostic algorithms.

Table 4: Summary of economic evaluations assessing the cost-effectiveness of TB-LAMP for detecting tuberculosis.

Study	Study Design & Model	Population/ Setting	Comparators/ Diagnostic Algorithms	Key TB-LAMP Parameters	Main Findings Related to TB-LAMP	Cost-Effectiveness/ Economic Outcome
Ibrahim HU et al. 2025 Nigeria[22]	Decision tree model + CEA	10,000 PLWH with presumptive TB	[redacted]Xpert MTB/ RIF Ultra + CXR; TB-LAM + CXR; TB-LAMP + CXR	Sensitivity 0.64, Specificity 0.95	Detected 1,404 TB cases (63.8%) out of 2,200 true TB cases	Least cost-effective: USD 20.11 per TB case detected
Chitpim N et al. 2025 Thailand[23]	CUA + dynamic transmission model (15-year horizon)	General Thailand population (~57 million)	Conventional; [redacted]Xpert MTB/RIF (Initial/Add-on); TB-LAMP (Initial/Add-on)	Not specified; derived from meta-analyses	TB-LAMP Add-On: 57,372 TB cases; TB-LAMP Initial: 50,338 TB cases; Reduced TB incidence by 2.78% (Add-on) and 14.67% (Initial)	TB-LAMP Add-On: ICER THB 3,563/QALY TB-LAMP Initial: THB 6,429/QALY Both cost-effective (below WTP THB 160,000)
Chitpim N et al. 2022 Thailand[24]	Decision tree + Markov model (lifetime horizon)	Adults >15 years with suspected pulmonary TB	Conventional; TB-LAMP (Initial/Add-on); [redacted]Xpert MTB/RIF	Sensitivity: 0.803 (overall), 0.403 (smear-negative); Specificity: 0.977	TB-LAMP Initial: dominant strategy (lower cost, higher effectiveness)	TB-LAMP Initial cost THB 6,565 (4.0% less than conventional): ICER THB 993/QALY (Add-on) TB-LAMP Initial most cost-effective (83.4% probability)
Sohn H et al. 2019 Canada[25]	Cost and affordability analysis (bottom-up costing, time-and-motion study)	Peripheral labs in Malawi & Vietnam	TB-LAMP; [redacted]Xpert MTB/RIF	Not applicable (empirical cost comparison)	TB-LAMP cheaper, especially in low-volume labs	TB-LAMP: USD 10.08–19.25/ test [redacted]Xpert: USD 13.40–48.01/ test [redacted]Xpert ~70.0% costlier TB-LAMP roll-out consumed 34.0% of Malawi TB budget vs. 47.0% for [redacted]Xpert

CEA, cost-effectiveness analysis, PLWH, people living with human immunodeficiency virus, TB, tuberculosis; MTB, Mycobacterium tuberculosis; RIF, rifampicin; CXR, chest X-ray; LAMP, loop-mediated isothermal amplification; USD, United States Dollar; CUA, cost-utility analysis; ICER, incremental cost-effectiveness ratio; THB, Thai Bhat; QALY, quality-adjusted life year; WTP, willingness-to-pay;

CONCLUSION

The high level of evidence showed that TB-LAMP consistently demonstrates high diagnostic accuracy across diverse settings, with slightly lower sensitivity than [redacted]Xpert, especially in HIV-positive individuals. Its strong specificity, operational simplicity and emerging formats like LAMP-Au-Np support its role as a scalable diagnostic tool for TB control. TB-LAMP is also

regarded as a low-risk diagnostic method, requiring only basic biosafety measures due to its integrated heat-inactivation step that effectively neutralises *Mycobacterium tuberculosis*. It is cost-effective diagnostic tool, with lower implementation costs than [redacted]Xpert and proven economic viability in multiple settings, making it particularly advantageous for decentralised and resource-limited healthcare environments.

REFERENCE

1. World Health Organization. Global tuberculosis report 2024. Global report. Geneva: World Health Organization; 2024:68.
2. Goletti D et al. Insights from the 2024 WHO Global Tuberculosis Report - More Comprehensive Action, Innovation, and Investments required for achieving WHO End TB goals. Int J Infect Dis. 2024;150:107325.
3. World Health Organization. Tuberculosis - South-East Asia Region. WHO Regional Office for South-East Asia. c2025. Available from: https://www.who.int/southeastasia/health-topics/tuberculosis. Accessed on 27.10.2025.
4. ASEAN Public Health Emergency Response Innovation Network. Tuberculosis in the ASEAN Region: Focus Report 2025. Available from: https://asean-phe.org/asean/data-publications/abvc/download/tuberculosis-in-the-asean-region-focus-report-2025-1740387299. Accessed on 27.10.2025.
5. O'Shea MK, Koh GCKW, Munang M et al. Time-to-detection in culture predicts risk of mycobacterium tuberculosis transmission: a cohort study. Clin Infect Dis. 2014;59(2):177–185.
6. Junaid M, Alam MB, Khan RA et al. Accuracy of sputum ZN smear microscopy for the diagnosis of pulmonary tuberculosis: a retrospective cross-sectional study. J Pak Med Assoc. 2020;70(12):2155–2158.
7. World Health Organization. The use of loop-mediated isothermal amplification (tb-lamp) for the diagnosis of pulmonary tuberculosis: policy guidance. Geneva: World Health Organization; 2016.
8. Treatment Action Group. 2025 pipeline: TB diagnostics: Treatment Action Group. Available from: https://www.treatmentactiongroup.org/wp-content/uploads/2025/11/2025_pipeline_TB_Diagnostics_final.pdf. Accessed on 18.11.2025.
9. Shete PB, Farr K, Strnad L et al. Diagnostic accuracy of TB-LAMP for pulmonary tuberculosis: a systematic review and meta-analysis. BMC Infect Dis. 2019;19(1):268.
10. Gray C, Katamba A, Narang P et al. Feasibility and operational performance of TB LAMP in decentralized settings - results from a multi-center study. J Clin Microbiol. 2016;54(8). doi:10.1128/JCM.03036-15.
11. Inbaraj LR, Srinivasalu VA, SathyaNarayanan MK et al. Diagnostic accuracy of low-complexity, manual nucleic acid amplification tests for the detection of pulmonary and extrapulmonary tuberculosis in adults and adolescents: a systematic review and meta-analysis. Lancet Microbe. 2025;6(10).
12. Bumbrah GS, Jain S, Fatima Z et al. Efficacy of LAMP assay for Mycobacterial spp. detection to prevent treatment delays and onset of drug resistance: a systematic review and meta-analysis. Drug Target Insights. 2023;17:78-89.
13. Habiburrahman M, Ariq H, Handayani RRD. Combining LAMP and Au-Nanoprobe to detect INH-RIF resistance accurately in tuberculosis: an evidence-based review. J Infect Dev Ctries. 2021;15(11):1555-1568. doi:10.3855/jidc.15188.
14. Shete PB, Farr K, Strnad L et al. Diagnostic accuracy of TB-LAMP for pulmonary tuberculosis: a systematic review and meta-analysis. BMC Infect Dis. 2019;19:268.
15. Deng S, Sun Y, Xia H et al. Accuracy of commercial molecular diagnostics for the detection of pulmonary tuberculosis in China: a systematic review. Sci Rep. 2019;9:4553.
16. Nagai K, Horita N, Yamamoto M et al. Diagnostic test accuracy of loop-mediated isothermal amplification assay for *Mycobacterium tuberculosis*: a systematic review and meta-analysis. Sci Rep. 2016;6:39090.
17. U.S. Food and Drug Administration. Tuberculin testing products. Available from: https://www.fda.gov/vaccines-blood-biologics/vaccines/tuberculin-testing-products. Accessed on 28.10.2025.
18. Cepheid Inc. Molecular diagnostic test menu. Available from: https://www.cepheid.com/en-US/tests.html. Accessed on 28.10.2025.
19. LumiraDx Limited. LumiraDx obtains CE mark for two molecular tests. Medical Device Network. 2022. Available from: https://www.medicaldevice-network.com/news/lumiradx-ce-mark-two-molecular-tests/. Accessed on 28.10.2025.
20. Sansure Biotech Inc. The TSure Nucleic Acid Analysis Device from Sansure Obtained CE Mark. 2022. Available from: https://www.sansureglobal.com/the-tsure-nucleic-acid-analysis-device-from-sansure-obtained-ce-mark/. Accessed on 28.10.2025.
21. Medical Device Authority (MDA), Ministry of Health Malaysia. Available from: https://www.mda.gov.my. Accessed on 28.10.2025.
22. Ibrahim HU, Garba RM, Ahmad JI et al. Cost-effectiveness of different tuberculosis diagnostic approaches in Nigeria based on decision analytical modelling. BMJ Glob Health. 2025;10:e019270. doi:10.1136/bmjgh-2025-019270.
23. Chitpim N, Praditsitthikorn N, White LJ et al. Economic evaluation of diagnostic tests for Thai patients with tuberculosis: A dynamic transmission model approach. PLoS ONE. 2025;20(3):e0315772. doi:10.1371/journal.pone.0315772
24. Chitpim N, Jittikoon J, Udomsinprasert W et al. Cost-utility analysis of molecular testing for tuberculosis diagnosis in suspected pulmonary tuberculosis in Thailand. ClinicoEconomics and Outcomes Research. 2022;14:61–73.
25. Sohn H, Puri L, Nguyen NAT et al. Cost and affordability analysis of TB-LAMP and Xpert MTB/RIF assays as routine diagnostic tests in peripheral laboratories in Malawi and Vietnam. Glob Health Sci. 2019;1(1):e22.

26. Eiken Chemical Co., LTD. TB LAMP Operation. EIKEN, Available from https://www.eiken.co.jp/en/ourfields/infection/lamp_operation. Accessed on 31.10.2025.

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