INFORMATION BRIEF (RAPID REVIEW)

[redacted] (POINT OF CARE MOLECULAR TESTING FOR TUBERCULOSIS)

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
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Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
Level 4, Block E1, Precinct 1
Government Office Complex
62590, Putrajaya
Tel: 603 8883 1229

Available online via the official Ministry of Health Malaysia website: http://www.moh.gov.my

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TITLE: [redacted] (Point of Care Molecular Testing for Tuberculosis)

PURPOSE

To provide evidence on safety, effectiveness and cost effectiveness of [redacted] (Point of care molecular testing for Tuberculosis) upon the request from Office of the Deputy Director-General of Health (Research & Technical Support), Ministry of Health (MOH) Malaysia following proposal from a company to introduce the technology in MOH facilities.

BACKGROUND

Tuberculosis (TB), a human disease caused by *Mycobacterium tuberculosis* (Mtb), remains a major global public health problem and progress to reduce the burden of disease falls far short of 2030 targets in most parts of the world. Globally in 2024, an estimated 10.7 million people (95% uncertainty interval [UI]: 9.9–11.5 million) fell ill with TB (incident cases) and 1.23 million died from the disease (95% UI: 1.13–1.33 million). The TB incidence rate (new cases per 100 000 population per year) was 131 (95% UI:122–141) and the case fatality rate was 11.5%, underscoring the urgent need for accessible, accurate diagnostic tools to close the persistent gap between estimated and notified cases.[1] In 2024, WHO recommended rapid diagnostics for TB available in less than half of TB diagnostic units in 23 of 30 high burden countries and were used as the initial test in less than half of people diagnosed with TB. Missed or delayed diagnosis of TB remains common despite the availability and scale-up of World Health Organisation (WHO) recommended rapid molecular tests since 2010. Among the reason that current molecular tests cannot be deployed at lower-level health facilities in high burden countries due to infrastructure constraints, human resource requirements and prohibitive costs.[2]

Diagnostic tests for TB disease have improved substantially in recent years. A point-of-care (POC) lateral-flow test performed on urine is also recommended by WHO (2025) and its main use is to assist with diagnosis of TB in people with advanced HIV disease, in combination with rapid molecular tests. There are additional rapid molecular tests which has the ability to detect resistance to a variety of first- and second-line anti-TB drugs. The older method of sputum smear microscopy (developed more than 100 years ago) is still used for TB diagnosis in low and middle-income countries but is increasingly being replaced with rapid tests.[1,2]

Leveraging technological advances from the COVID-19 pandemic, swab-based platforms are emerging to meet the urgent need for simpler molecular tests for TB. Unlike conventional sputum-based testing, swab-based methods eliminate the requirements for homogenisation, nucleic acid extraction, and purification, thereby reducing both cost and complexity. [redacted] replaces DNA extraction with a simple sonication-based automated mechanical lysis step ([redacted]) followed by DNA amplification using an existing automated real-time quantitative microPCR (Polymerase Chain Reaction) analyser [redacted].[3]

The [redacted] is a novel point-of-care testing (POCT) system that employs an automated heat-based mechanical lysis step ([redacted]), followed by isothermal amplification originally developed for SARS-CoV-2

(Severe Acute Respiratory Syndrome Coronavirus 2) testing. [redacted] targets *Mycobacterium tuberculosis* complex (MTBC), a specific regions of IS6110 and gyrB, and utilises the proprietary RNase hybridization-assisted amplification (RHAM) technology developed by [redacted] to detect MTBC DNA from paired tongue swab and sputum specimens in presumptive pulmonary TB patients.[4]

Technical Features

[redacted] is a portable, battery-operated, employs an automated heat-based mechanical lysis step ([redacted] followed by isothermal amplification using a method originally developed for SARS-CoV-2 testing. According to the company submitted documents, it has dimensions of 101 × 91 × 65 mm and weighs 240 g, making it a very compact and lightweight instrument suitable for portable or near-point-of-care use. It connects via USB Type-C or Wi-Fi, can be stored between −20°C and 55°C, and is designed to operate reliably within an ambient temperature range of 15°C to 30°C. The [redacted] assay detects MTBC DNA, with a reported limit of detection of ≤25 colony-forming units per millilitre. Results are available in 30 minutes or less. Test cards remain stable for 13 months when stored between 0°C and 40°C, and the assay is validated for use with both sputum and tongue swab specimens. (Figure 1)[9,10]

The [redacted] test follows a simplified four-step process, as shown in Figure 2, to enable rapid detection of MTBC. Sample collection involves either sputum or a tongue swab, with the latter requiring 30 seconds and mixed thoroughly using a pipette, typically repeated ten times to ensure proper homogenization. In the third step, the sample undergoes a single-step pretreatment in the [redacted] device, where it is heated and vortexed at 3000 rpm and 75°C for five minutes. Finally, the prepared sample is loaded into the test system, which generates results and the entire workflow is completed within 30 minutes.[11]

[redacted]

Figure 1: [redacted][9,10]

a) [redacted]

b) [redacted]

c) [redacted]

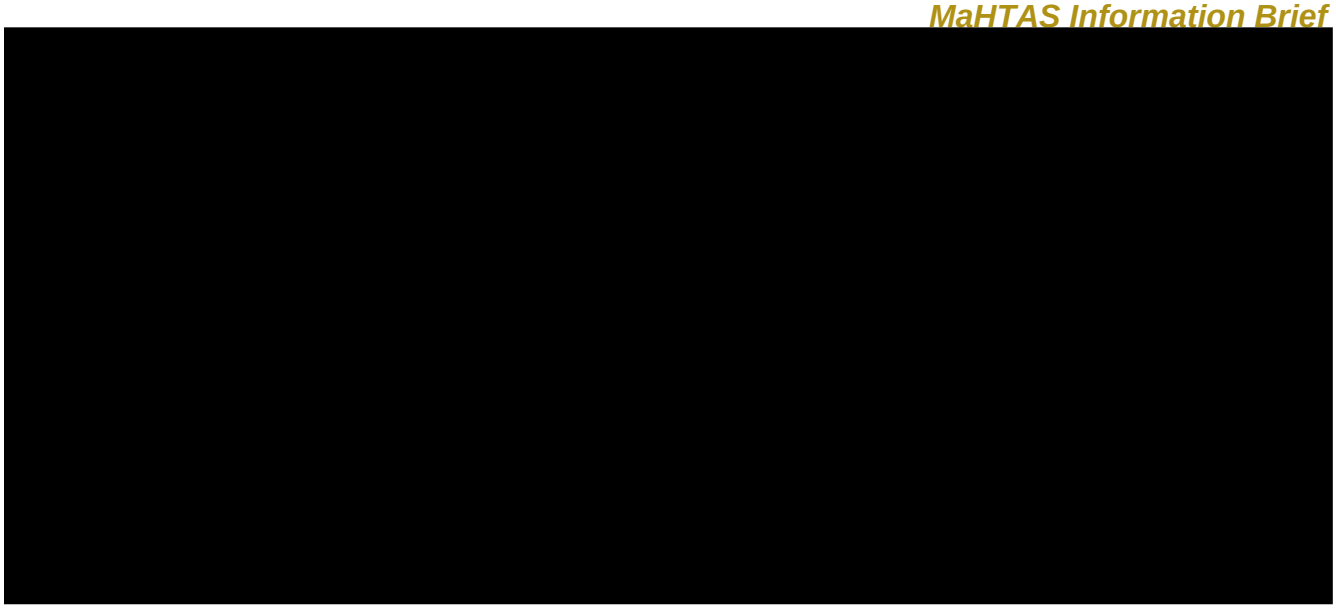

Figure 2: Sample processing workflow for [redacted][11]

EVIDENCE SUMMARY

A total of 1365 articles were retrieved from the scientific databases, including Ovid, PubMed, and Embase. Google was used to search for additional web-based materials and information. Search was limited to human and English language and the last search was conducted on 1st December 2025.

Four studies were included in this review, comprising a cross-sectional study, a prospective multicentre evaluation, a laboratory-based assessment, and a retrospective comparative study evaluating the diagnostic accuracy of the [redacted], together with evidence from the WHO Consolidated Guidelines on tuberculosis.

EFFECTIVENESS

There were four studies reported on the effectiveness of [redacted].

A prospective, cross-sectional, multi-country diagnostic accuracy study was conducted by Steadman A et al. (2025) at outpatient health centres in India, Uganda, and Vietnam. The study evaluated the diagnostic accuracy of two swab-based molecular tests including [redacted] and [redacted], using both sputum swabs and non-invasive tongue swabs, with results compared against conventional sputum culture and existing molecular diagnostics. Between January and September 2017, a total of 1,127 participants were enrolled including 1,050 for the tongue swab [redacted], 197 for the sputum swab [redacted] and 322 for the [redacted]. Table 1 simplified the Diagnostic Accuracy of Swab-Based Molecular Tests for Tuberculosis.

Table 1: Diagnostic Accuracy of Swab-Based Molecular Tests for Tuberculosis[3]

Test & Sample Type	Sensitivity (95% CI)	Specificity (95% CI)
[redacted] Tongue Swab	77.9% (70.3 to 84.2)	98.2% (97.0 to 99.0)
[redacted] MTB Tounge Swab	85.7% (75.3 to 92.9)	100.0% (98.4 to100.0)
MTB [redacted] Sputum Swab	91.7% (80.0 to 97.7)	97.7% (93.5 to 99.5)
[redacted] Sputum Swab	89.9% (80.2 to 95.8)	98.2% (95.5 to 99.5)
[redacted] Sputum	92.8% (87.2 to 96.5)	99.1% (98.2 to 99.7)
Smear Microscopy Sputum	59.1% (50.7 to 67.0)	99.6% (98.9 to 99.9)

The swab-based molecular tests, [redacted] and [redacted] MTB demonstrated significant effectiveness by meeting or exceeding the minimum World Health Organisation (WHO) accuracy targets for both sputum-based and non-sputum-based near-point-of-care (POC) TB diagnostics. The WHO minimum accuracy targets for near POC sputum-based tests are greater than 85% sensitivity and greater than 98% specificity. Both [redacted] and [redacted] showed comparable sensitivity to sputum [redacted] (approximately 90% to 92%) and achieved high specificity (~98%), with only minor differences in sensitivity compared to sputum [redacted] (−6.4%, p=0.25 for [redacted]; −3.0%, p=0.50 for [redacted]). Non-invasive tongue swabs demonstrated sensitivities of 77.9% ([redacted] and 85.7% ([redacted]), significantly higher than sputum smear microscopy (59.1%, p<0.001 for both). While both [redacted] and [redacted] MTB showed similar sensitivity to sputum[redacted], tongue swab testing was less sensitive than sputum [redacted]. These platforms align with near-POC goals by being affordable, portable, requiring minimal hands-on time, and delivering rapid results (≤45 minutes for [redacted]; ≤30 minutes for [redacted]), making them practical for decentralized molecular testing. The authors concluded that [redacted] and [redacted]MTB met WHO accuracy targets, offer flexible sputum and non-sputum based testing options particularly for PLHIV and young children and further validation and implementation to maximise their impact in expanding TB diagnosis worldwide.[3]

Wu Z et al. (2025) conducted prospective multicentre diagnostic accuracy study of the [redacted]MTB Test ([redacted]), an innovative POCT molecular system that targets MTBC specific regions of IS6110 and gyrB using RHAM technology, in detecting MTBC DNA from paired tongue swab and sputum specimens obtained from presumptive patients with pulmonary TB between 1 May 2024 and 30 November 2024. The study included 594 participants adults (aged >18 years) presenting with symptoms suggestive of pulmonary TB. The diagnostic performance of the [redacted] test was compared against the sputum [redacted] assay, smear microscopy, mycobacteria growth indicator tube (MGIT) culture, and a composite microbiological reference standard (MRS). Table 1, 2 and 3 simplified the diagnostic accuracy of the [redacted] test on sputum and tongue specimens compared with sputum [redacted] and MRS.

Table 1: Diagnosis accuracy of the MiniDock test on sputum specimens compared with the sputum Xpert MTB/RIF (Xpert) and the composite microbiological reference standard [4]

Parameter	Sputum Xpert	MRS
Sensitivity % (95% CI)	98.2 (95.7-99.2)	94.2 (90.9-96.6)
Specificity % (95% CI)	90.4 (86.7-93.2)	93.7 (90.3-96.1)
PPV % (95% CI)	89.5 (85.5-92.5)	93.6 (90.2-96.1)
NPV % (95% CI)	98.3 (96.1-99.3)	94.3 (91.2-96.6)
Overall concordance (95% CI)	93.9 (91.7-95.6)	93.9 (91.7-95.7)

PPV: Positive Predictive Value; NPV: Negative Predictive Value

Table 2: Diagnostic accuracy of tongue swabs MiniDock compared with the sputum Xpert MTB/RIF assay and composite microbiological reference standard [4]

Parameter	Sputum Xpert	MRS
Sensitivity % (95% CI)	80.0 (74.8-84.3)	74.5 (69.1-79.4)
Specificity % (95% CI)	95.4 (92.5-97.2)	96.0 (93.1-97.9)
PPV % (95% CI)	93.5 (89.6-96.0)	94.8 (91.1-97.3)
NPV % (95% CI)	85.1 (81.1-88.4)	79.3 (74.8-83.4)
Overall concordance (95% CI)	88.4 (85.6-9.07)	85.4 (82.3-88.1)

Table 3: Sensitivity of sputum and tongue swabs MiniDock MTB Test compared with sputum semiquantitative results [4]

Sputum Xpert		Sputum MiniDock		Tounge swab Minidock	
Xpert Semiquantitative results	Sputum Xpert	Positive sputum MiniDock results	Agreement % (95%CI)	Positive tongue swab MiniDock results	Agreement, % (95% CI)
High	54	54	100.0 (93.4-100.0)	53	98.2 (90.2-99.7)
Medium	98	98	100.0 (96.2-100.0)	87	88.8 (81.0-93.6)
Low	95	93	97.9 (92.7-99.4)	65	68.4 (58.5-76.9)
Very Low	23	20	87.0 (67.9-95.5)	11	47.8 (29.2-67.0)

Negative	324	31	90.4 (86.7-93.2)	15	95.4 (92.5-97.2)
Overall Concordance			93.9 (91.7-95.6)		88.4 (85.6-90.7)

MTB; Mycobacterium tuberculosis; Xpert: Xpert MTB/RIF assay; Minidock Minidock MTB Test

The MiniDock test demonstrated high diagnostic accuracy with sputum specimens, showing sensitivity 98.2% (95% CI: 95.7 to 99.2) and a specificity of 90.4% (95% CI: 86.7 to 93.2) against Xpert and sensitivity of 94.2% (95% CI: 90.9 to 96.6) with specificity of 93.7% (95% CI: 90.3 to 96.1) against the composite MRS, with overall concordance of 93.9% (95% CI: 91.7 to 95.6) (Table1). Tongue swab-based MiniDock demostrated a sensitivity of 80.0% (95% CI: 74.8 to 84.3) and a specificity of 95.4% (95% CI: 92.5 to 97.2) against Xpert and a sensitivity of 74.5% (95% CI: 69.1 to 79.4) with specificity of 96.0% (95% CI: 93.1 to 97.9) when compared with MRS. The sensitivity of 74.5% is close to the WHO's 2024 Target Product Profile (TPP) requirement for POC testing of non sputum samples (≥75%), while the specificity of 96.0% falls slightly below the TPP threshold of >98% for TB detection. Strong agreement was observed between the tongue swab MiniDock and both reference standards, with overall concordance higher for sputum Xpert (88.4%, 95% CI: 85.6 to 90.7) than for MRS (85.4%, 95% CI: 82.3 to 88.1) (Table 2). Agreement was consistently higher for sputum-based testing (93.9%) compared to tongue swabs (88.4%), with tongue swabs offering superior feasibility due to fewer unqualified samples (Table 3). Sputum-based MiniDock offers a quicker turnaround time (<1 hour) and greater portability than Xpert, making it suitable for low-resource settings. The authors concluded that the MiniDock test, particularly with non-invasive tongue swabs, offers a reliable and rapid diagnostic alternative for individuals unable to produce sputum, and further evaluation needed in community-based and high-risk, asymptomatic populations to establish its real-world effectiveness.[4]

A prospective laboratory-based evaluation conducted by Chen X et al (2025) at the Microbiology and Virology Department of AOU Sassari between August and October 2024 to evaluate the diagnostic accuracy of Point-of-Care Test (POCT) utilizing RNase Hybridization-Assisted Amplification (RHAM) technology for detecting MTBC and its alignment with the WHO's ASSURED (Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free, Deliverable to end-users) criteria. It is evaluated on consecutive clinical samples from suspected TB cases including sputum, bronchial aspiration, and non-tuberculous mycobacteria and benchmarked against Polymerase Chain Reaction (PCR), microscopy, and culture, RHAM based POCT demonstrated a sensitivity of 83.3% (95% CI: 50.9 to 97.1%) and specificity of 100% (95% CI: 83.4 to 100%) and with only two false negatives occurring in samples with very high PCR cycle threshold values (>36), indicating challenges in paucibacillary specimens. The authors concluded that RHAM-based POCT is rapid, user-friendly, and offering promising utility in resource-poor and field environments, though larger-scale studies are needed to validate its performance in low-bacterial-load cases such as pediatric TB, HIV-associated TB, and extrapulmonary TB where sensitivity remains a critical limitation.[5]

Herrmann L et al. (2024) conducted a retrospective comparative evaluation study to evaluate the diagnostic accuracy of the [redacted] (using RNase HII-assisted amplification, RHAM technology) against the [redacted] (Nicking Enzyme Amplification Reaction, NEAR technology) and the [redacted] (Real-Time PCR, RT-PCR) using SARS-CoV-2 as a model pathogen. The study included 319 residual nasopharyngeal swab samples, 137 RT-PCR confirmed positive and 104 negative samples and conducted at Pfützner Science & Health Institute (Mainz, Germany) + University for Digital Technologies in Medicine and Dentistry (Luxembourg) and DHS-Diagnostic HealthCare Solutions GmbH (Berlin, Germany) + Charité Universitätsmedizin Berlin. Table 4 simplified the comparative diagnostic accuracy.

Table 4: Comparative Diagnostic Accuracy for the three POCT devices [6]

Metric	[redacted] (RHAM)	[redacted] (NEAR)	[redacted] (RT-PCR)
Positive Percent Agreement (PPA/Sensitivity)	99.00%	100.00%	98.99%
Negative Percent Agreement (NPA/Specificity)	100.00%	98.90%	94.09%
Total Accuracy	99.68%	99.29%	95.42%
Overall Agreement	99.35%	89.35%	94.19%
Total Invalid Results	1 sample	31 samples	4 samples
Positive Percent Agreement (PPA/Sensitivity)	99.00%	100.00%	98.99%

[redacted] demonstrated the highest positive percent agreement (PPA) at 100.00% for valid results, while the [redacted] and [redacted] achieved PPA values of 99.00% and 98.99%, respectively. In terms of negative percent agreement (NPA), the [redacted] performed score of 100.00%. [redacted] showed slightly lower specificity at 98.90%, whereas [redacted] had the lowest NPA at 94.09%. [redacted] produced the highest number of invalid result with 31 samples, indicating reduced stability across specimens and [redacted] had only one invalid result, highlighting its robustness and consistency. Analytical accuracy was highest for the [redacted] at 99.68%, followed by [redacted] at 99.29%, and [redacted] demonstrated lower accuracy at 95.42%. The authors conclude that the [redacted], based on RHAM technology, outperformed [redacted] and [redacted] in detecting SARS-CoV-2 variants, highlighting RHAM-based point of care testing as a promising emerging approach for managing current infections and future infectious disease outbreaks.[6]

SAFETY

From the evidence search, there is no evidence retrieved on the safety, adverse events reported due to [redacted] MTB. As of today, there was no [redacted] MTB approved or cleared by United States Food and Drug Administration (US FDA). In Malaysia, [redacted] MTB has been approved for market use by the Medical Device Authority (MDA) ([redacted].[7]

COST-EFFECTIVENESS

There is no evidence retrieved on cost-effectiveness of [redacted]MTB. However, according to the Briefing Note: [redacted] – Advancing Affordable and Accessible Solutions for TB Diagnosis and Elimination, the prices are listed as follows: [redacted] MTB test cards at [redacted] per test (≈[redacted], ex works China), the [redacted] device at [redacted] (≈[redacted], ex works China), and the [redacted] sample pretreatment device at [redacted] (≈[redacted], ex works China). These prices are based on substantial procurement volumes and exclude taxes, shipping, and other related costs.[8]

ORGANISATIONAL IMPLICATION

The World Health Organization (WHO) consolidated guidelines on Tuberculosis (Module 3: Diagnosis), issued in 2025, strongly recommended the use of low-complexity automated nucleic acid amplification tests (LC-aNAATs) as the initial diagnostic method for adults and adolescents with signs, symptoms, or positive screening results for pulmonary TB, using respiratory samples such as sputum, tracheal aspirate, or bronchoalveolar lavage instead of smear microscopy or culture. This guidance is based on high-certainty evidence and specifically recommends [redacted]) and [redacted]MTB [redacted] for the diagnosis of TB and detection of rifampicin resistance. However, the data supporting the performance of [redacted] and [redacted] were noted to be more limited than those available for [redacted][2]. The [redacted] PoC device utilises RHAM technology, offering ease of use with minimal training and enhanced portability, removing the need for specialised laboratory infrastructure.[3,4,6] Participants had signed written informed consent and where approved the storage of their residual sample material and future use for laboratory evaluation projects in an anonymous.[3,4.]

CONCLUSION

Based on the above review, there is limited evidence retrieved on effectiveness and safety of [redacted]MTB. Evidence demonstrated that both [redacted] and [redacted]showed sensitivity comparable to sputum [redacted] (~90-92%) with high specificity (~98%). In addition, non-invasive tongue swabs demonstrated stronger diagnostic performance than sputum smear microscopy. Both [redacted] and [redacted]met WHO accuracy targets and provide flexible options for sputum and non-sputum based testing, particularly valuable for people living with HIV (PLHIV) and young children. [redacted] test, particularly with non-invasive tongue swabs, offers a reliable and rapid diagnostic alternative for individuals unable to produce sputum. RHAM-based POC testing as a promising emerging approach for managing current infections and future infectious disease outbreaks. As for now, the [redacted] MTB did not obtain clearance by the US FDA, but it has been approved for market use by the Medical Device Authority (MDA, Malaysia; [redacted]). More quality scientific evidence and further evaluation in community-based and high-risk, asymptomatic populations is encouraged to establish world effectiveness as a POC test for MTB.

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Prepared by

G. Anantharenu a/p Gopal
Principal Assistant Director
Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia

Reviewed by

Dr. Roza binti Sarimin
Public Health Physician
Head of HTA Unit
Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia

Dr. Syaqirah Akmal
Public Health Physician
Deputy Director
Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia

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