INFORMATION BRIEF (RAPID REVIEW)

MYCOBACTERIA TUBERCULOUS (TB) ANTIGEN- BASED SKIN TEST (TBST)

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
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Rapid Review
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TITLE: Mycobacteria tuberculous (TB) antigen-based skin test (TBST)

PURPOSE

To provide evidence on safety, effectiveness and cost effectiveness of Mycobacteria tuberculous (TB) antigen-based skin test (TBST) upon the request from Disease Control Division, Ministry of Health (MOH) Malaysia.

BACKGROUND

Tuberculosis (TB), a human disease caused by Mycobacterium tuberculosis (Mtb), is a major challenge facing global public health.[1] It is estimated that about a quarter of the world's population is infected with Mycobacterium tuberculosis (Mtb), the bacterium that causes tuberculosis (TB) disease.[2] Progression to active disease can result in transmission of infection and the risk of progression to active disease is highest in young children (especially those <5 years old) and in people with immunosuppressive conditions. Strategies for tuberculosis control are anchored in screening at-risk populations and offering preventive therapy to those at highest risk of developing active tuberculosis disease.[3] Testing for TB infection can identify individuals who would benefit the most from TB preventive treatment (TPT). Without TPT, it is estimated that about 5–10% of people who are infected will develop TB disease over the course of their lives, usually within 5 years of the initial infection.[4]

The tuberculin skin test (TST) is a widely used point-of-care test that involves intradermal injection of purified protein derivative (PPD), a crude mixture of different mycobacterial antigens, which stimulates a delayed-type hypersensitivity response and causes induration at the injection site within 48–72 hours.[2] This test has relatively low specificity in those with recent bacille Calmette-Guérin (BCG) vaccination and low sensitivity in immunosuppressed individuals (e.g. people living with HIV [PLHIV]) and interpretive cut-offs must be adapted for these populations. IGRAs are in vitro tests that measure release of interferon-gamma (IFN-γ) by T-cells following stimulation by the early secretory antigenic target 6 kDa protein (ESAT-6) and culture filtrate protein 10 (CFP-10) antigens that are specific to Mtb.[2] Unlike the TST, IGRAs are not affected by prior BCG vaccination, or by infection with nontuberculous mycobacteria (NTM). However, IGRA platforms are more expensive to run and require specialized facilities and trained personnel.[6]

Newer skin-based tests based on antigen have been developed, which combine the simpler skin-test platform with the specificity of IGRA. These include the C-Tb (Serum Institute of India, Pune, India), Diaskintest (Generium, Moscow, Russia), and the EC-skintest (recently renamed Creative-TST or C-TST by Anhui Zhifei Longcom, Hefei, China), which, like Interferon-Gamma Release Assay (IGRA) using recombinant ESAT-6 and CFP-10 antigens (a recombinant protein based on amino acids from the N-terminus sequence). All tests use intradermal injection of antigen like the TST and are read as induration in mm after 48–72 h using the same method as Mantoux test (also called the Mendel–Mantoux test, tuberculin sensitivity test, or PPD test).[1]

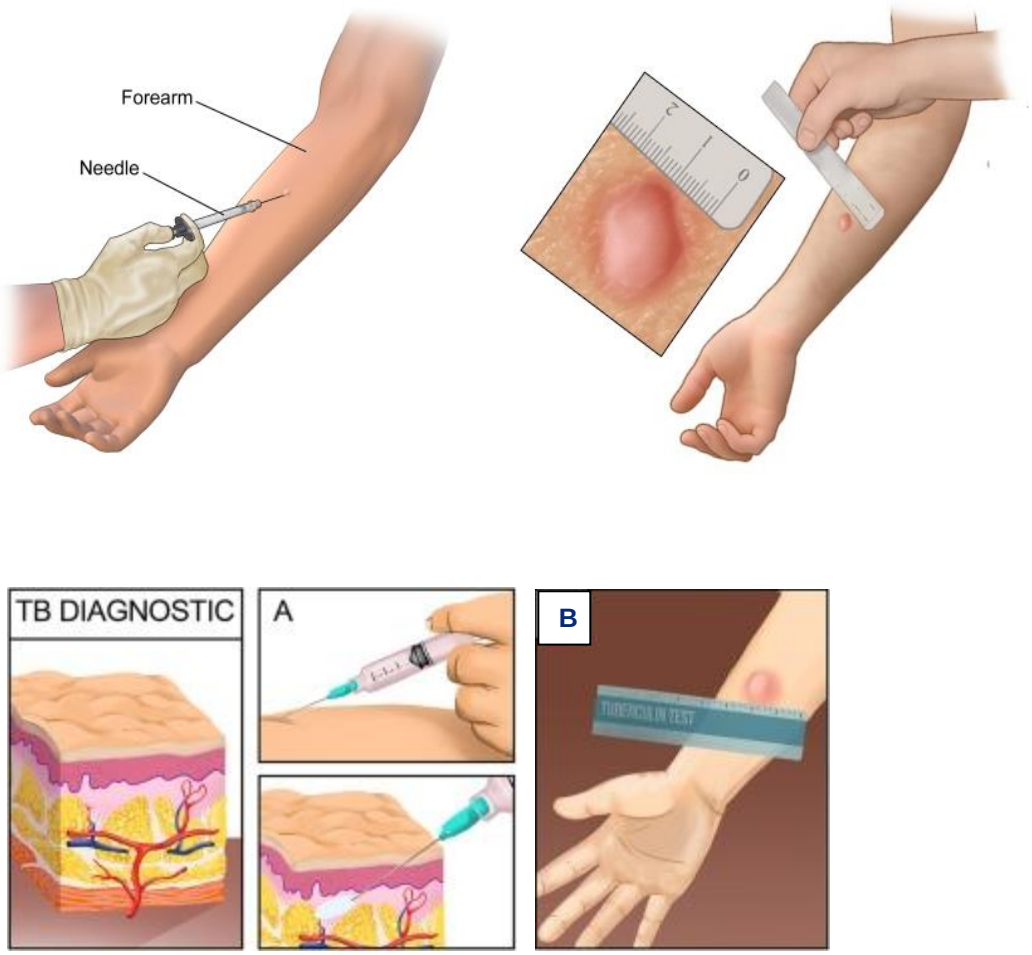

Figure 1: Mycobacterium Tuberculosis (TB) antigen-based skin test
(a) Intradermal injection involves the needle being inserted at a shallow angle, ensuring the fluid is deposited between the skin layers. (b) The size of the reaction is measured using a ruler.

EVIDENCE SUMMARY

A total of 1426 articles were retrieved from scientific databases, including Ovid, PubMed, And Embase. Google was used to search for additional web-based materials and information. There was language and human limitation in the search and the last search was conducted on 17 October 2025.

Six studies were included in this review, comprising systematic reviews (SR) and Meta-Analysis (MA) and economic evaluation study. Additionally, evidences from WHO Consolidated Guidelines on tuberculosis were also included.

EFFECTIVENESS

There were three studies reported on the effectiveness of Mycobacteria tuberculous (TB) antigen-based skin test (TBST).

A double blind randomised controlled trial (RCT) was conducted by L. Xia et al. (2025) at four hospitals in China evaluating the diagnostic accuracy and safety of the C-TST for detecting tuberculosis infection (TBI) in children and adolescents from September 2016 to June 2017. A total of 96 participants comprising 48 individuals diagnosed with tuberculosis and 48 with non-tuberculous pulmonary conditions were simultaneously administered three diagnostic tests including C-TST (recombinant ESAT6/CFP10 fusion protein), TST, and the T-SPOT.TB interferon-gamma release assay. Table 1 simplified the Diagnostic accuracy of C-TST, TST, and T-SPOT.TB for active TB.

Table 1: Diagnostic accuracy of C-TST, TST, and T-SPOT.TB for active TB [5]

Test	Sensitivity (95 % CI)	Specificity (95 % CI)	AUC
C-TST	83.0 % (68.7 % to 91.9 %)	100 % (91.9 % to 100 %)	0.92
TST	80.9 % (66.3 % to 90.4 %)	98.0 % (87.8 % to 99.9 %)	0.89
T-SPOT.TB	76.6 % (61.6 % to 87.2 %)	100 % (90.9 % to 100 %)	0.88

The C-TST was found to have comparable sensitivity at 83% (95% CI: 68.7 to 91.9) and specificity 100 % (95% CI:91.9 % to 100 %) compared with other assays, displaying strong diagnostic agreement with existing tests (kappa of 0.847 for C-TST and T-SPOT.TB and 0.827 for T-TST and TST). The C-TST shows no Bacillus Calmette-Guerin (BCG)-related false-positives because it utilizes the ESAT-6 and CFP-10 antigens, which are encoded by the Mycobacterium tuberculosis (MTB) complex genome's Region of Difference 1 (RD1), a region absent from all BCG vaccine strains. However, a limitation of the C-TST is its inability to distinguish between active TB and latent TB infection (LTBI), as it only detects general TB-specific immune responses, thus preventing definitive diagnosis of active disease. The authors concluded that C-TST, which mitigates false positives caused by BCG vaccination due to its use of TB-specific antigens and comparable diagnostic accuracy may be considered as an effective alternative for TBI screening in pediatric populations.[5]

Peng L et al. (2024) conducted a systematic review with meta analysis to evaluate the diagnostic accuracy of the Interferon-Gamma Release Assay (IGRA), Tuberculin Skin Test (TST), and Mycobacterium tuberculosis Antigen-Based Skin Tests (TBST). Systematic search across three databases including EMBASE, PubMed,and Cochrane until September 2024 and identified 49 relevant studies encompassing a total of 11 402 patients. Table 2 simplified the diagnostic performance using sensitivity, specificity, and Area Under the Curve (AUC).

Table 2: Diagnostic performance using sensitivity, specificity and Area Under the Curve (AUC)[1]

Diagnostic Method	Pooled Sensitivity (95% CI)	Pooled Specificity (95% CI)	AUC (95% CI)
All Methods Combined	77.9% (0.69 to 0.856)	80.3% (0.75 to 0.86)	0.89 (0.86 to 0.92)
IGRA (Alone)	82.1% (0.78 to 0.86)	81.1% (0.75 to 0.86)	0.90 (0.87 to 0.92)
TBST (Alone)	78.7% (0.68 to 0.88)	98.5% (0.96 to1.00)	N/A (Insufficient data)
TST (Alone)	75.5% (0.65 to 0.85)	73% (0.57 to 0.87)	0.83 (0.80 to 0.86)

The IGRA demonstrated superior diagnostic performance compared to TST, with higher sensitivity, specificity, and overall accuracy in detecting tuberculosis infection. TBST showed the highest specificity at 98.5%, indicating its strong ability to minimize false-positive results. Its sensitivity, at 78.7%, was intermediate between IGRA and TST. When TBST was combined with either TST or IGRA, diagnostic performance improved further. Specifically, the TST plus TBST combination maintained a sensitivity of 76% while increasing specificity to 84%, resulting in an area under the curve (AUC) of 0.85. The IGRA plus TBST combination achieved the highest diagnostic accuracy, with an AUC of 0.92, maintaining a sensitivity of 81% and enhancing specificity to 90%. The study showed that combining TBST with TST or IGRA provides a more accurate diagnostic method than using the traditional tests individually. However, the author concluded further research is needed in order to gain a deeper understanding of the utility and optimal implementation of these tests.[1]

A systematic review with meta-analysis conducted by Krutikov M et al. (2021) evaluated the diagnostic performance of novel skin-based tests for tuberculosis (TB) infection. The review included 37 studies (n=10915 individuals) and assessed the performance of skin-based recombinant antigen tests (C-Tb, Diaskintest, EC-skintest, and a DPPD) compared with currently available tests (TST and IGRA). Of these, Diaskintest demonstrated strong agreement with IGRA at 87.16% (95% CI: 79.47 to 92.24) in mixed populations, although its agreement with TST (5 mm cut-off) was notably lower at 55.45% (95% CI: 46.08 to 64.45). (Figure 2). The Diaskintest showed a sensitivity of 91.18% (95% CI: 81.72 to 95.98) among HIV-negative adults with active tuberculosis, showing performance comparable to TST (88.24%) and IGRA (89.66%). (Figure 3). However,specificity could not be reliably estimated due to the high TB burden in study settings and lack of confirmed TB-negative populations. For C-Tb test showed similar agreement with both IGRA of 79.80% (95% CI: 76.10 to 83.07) and stratified TST cut-offs (78.92%).(Figure 4) Its pooled sensitivity was 74.52% (95% CI: 70.39 to 78.25), aligning closely with TST5 mm/15 mm (78.18%) and IGRA (71.67%). Specificity showing a high pooled estimate of 97.85% (95% CI: 93.96 to 99.25), slightly exceeding TST 15 mm (93.31%) and comparable to IGRA (99.15%) (Figure 5).The EC-skintest showed a pooled sensitivity of 86.1% (95% CI: 82.39 to 89.07) at a threshold of 5 mm or more but data on specificity and agreement with other tests were not available. A recombinant protein based on the N-terminus sequence (DPPD) demonstrated 60.5% agreement with TST in one study (95% CI: 43.39 to 75.96). Sensitivity was 89% (95% CI: 75 to 97) in HIV-positive individuals and reached 100% (95% CI: 91 to 100) in HIV-negative participants. Despite finding that the diagnostic performance of novel skin tests was similar to IGRA and TST in terms of concordance and

accuracy, the author concluded the need for further high-quality research to support the implementation of these potentially accessible diagnostic alternatives in clinical practice.[3]

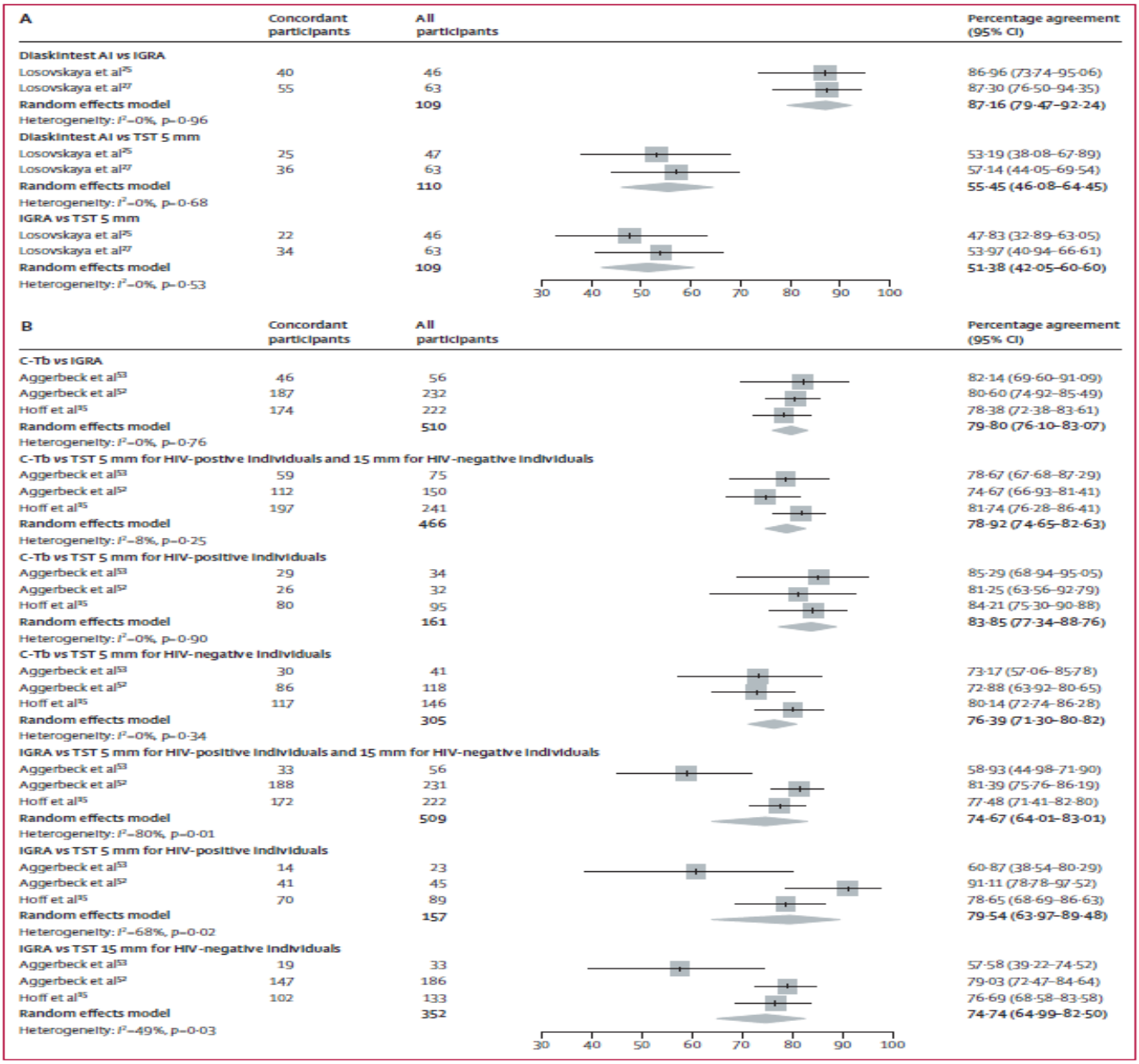

Figure 2: Test agreement in head-to-head studies comparing all three tests
Source: Krutikov M et al. (2021)

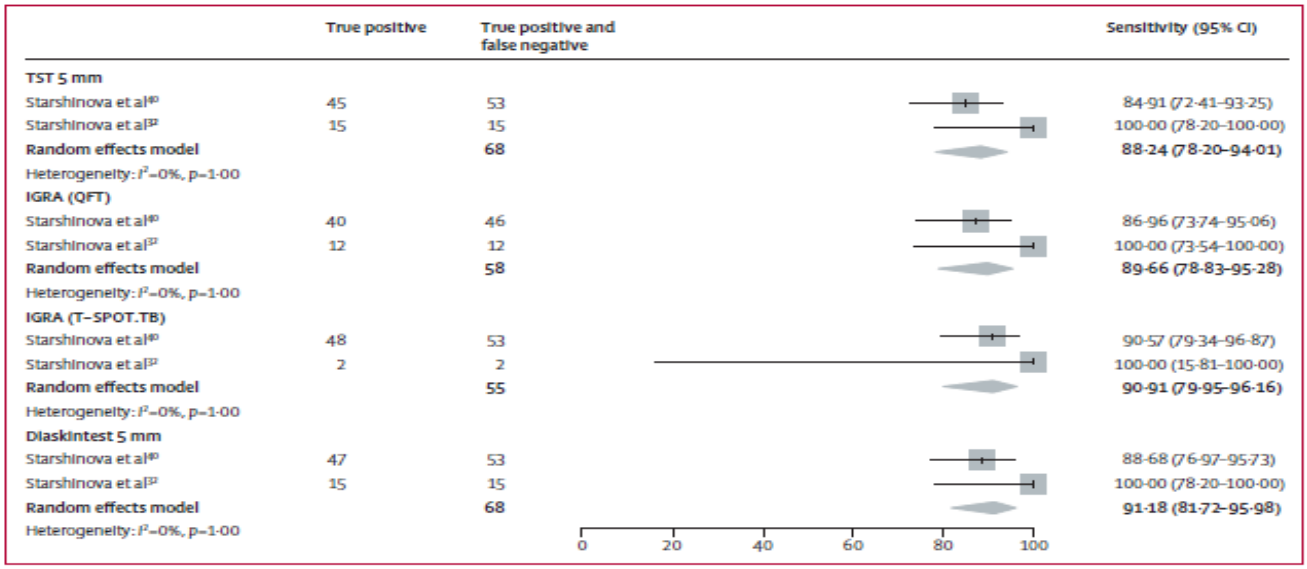

Figure 3: Test sensitivity in three -way- head-to-head studies comparing Diaskintest, IGRA, and TST
Source: Krutikov M et al. (2021)

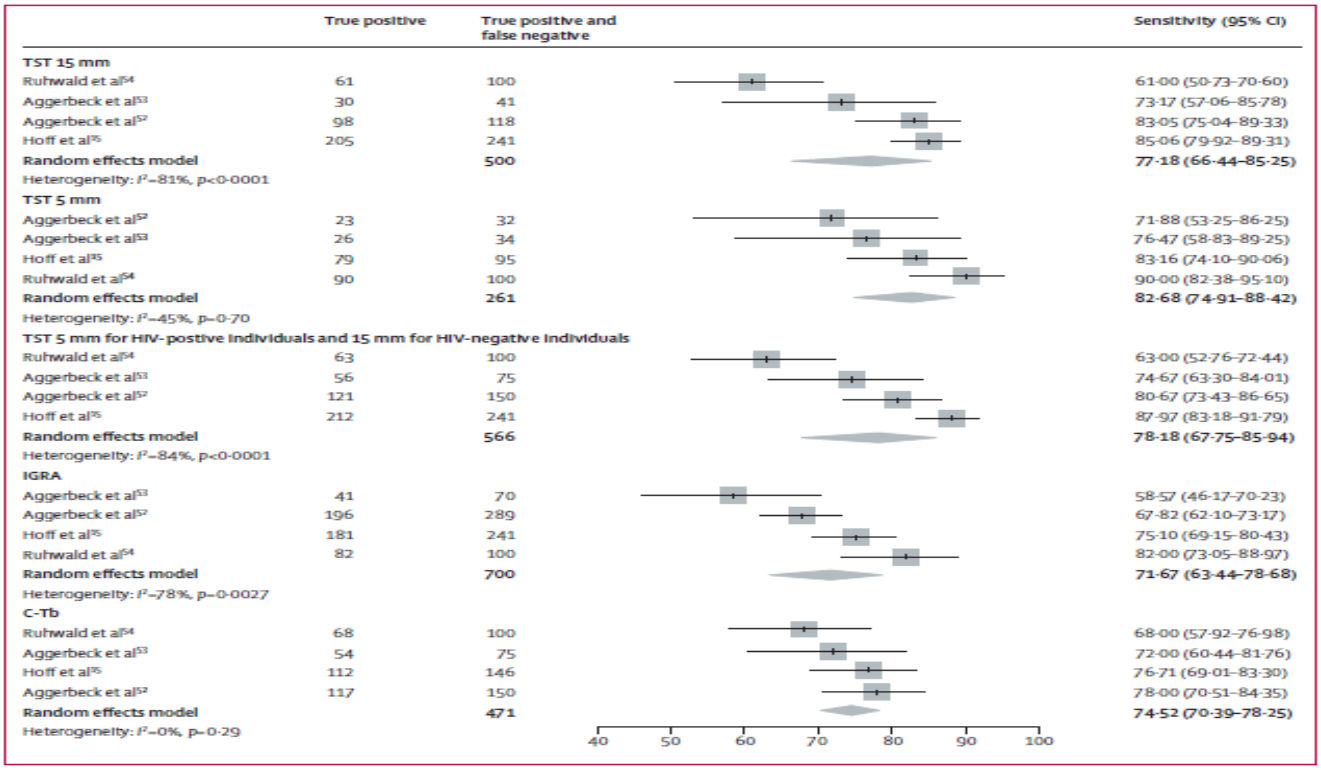

Figure 4: Test sensitivity in head-to-head studies comparing C-Tb, IGRA, and TST
Source: Krutikov M et al. (2021)

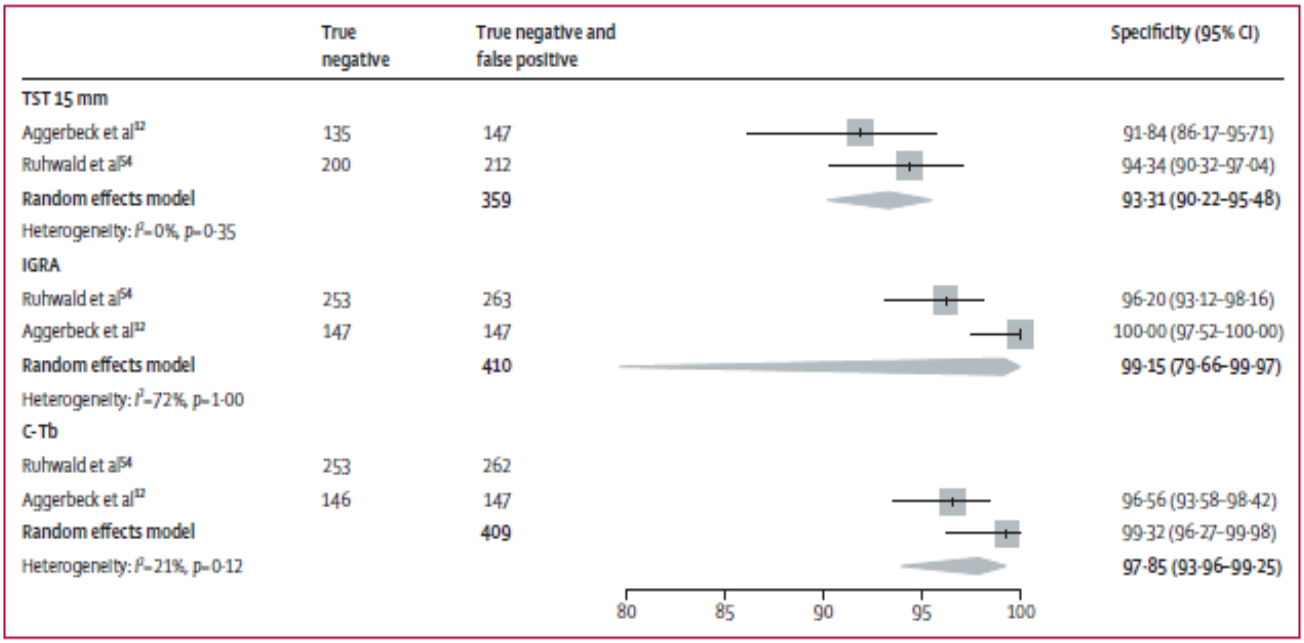

Figure 5: Test specifity in head-to-head studies comparing C-Tb, IGRA, and TST
Source: Krutikov M et al. (2021)

SAFETY

There were three studies reported on the safety of Mycobacteria tuberculous (TB) antigen-based skin test (TBST).

In the systematic review and Meta Analysis by L. Xia et al. (2025), it was reported that C-TST demonstrated a favorable safety profile throughout the trial, with no serious adverse events (AEs) reported. Overall, 32 adverse events (AEs) were noted among 13 participants, resulting in an AE incidence rate of 13.54%. The most frequent AEs were mild, localized skin reactions at the injection site, primarily pruritus (itching, 8.33%) and petechiae (small spots, 4.17%), followed by pain (1.04%). Systemic adverse event (SAEs) were less common, including general complaints like headache or body aches (3.13%), fever (2.08%), and fatigue (1.04 %). One participant also experienced transient proteinuria, which resolved without intervention. Table 3 simplified the intervention -related to AEs.[5]

Table 3: Intervention-related AEs of all 96 participants [5]

Intervention-related AEs of all 96 participants

AEs	Frequency	Total case	Incidence (%)
Abnormal laboratory examination			
Urine protein positive	1	1	1.04
Systemic AEs			
Fever (≥37.2°C)	4	2	2.08
Fatigue	1	1	1.04
Headache/body aches	5	3	3.13
Local AEs			
Petechiae at the injection site	7	4	4.17
Pain at the injection site	2	1	1.04
Pruritus at the injection site	12	8	8.33
Total	32	13	13.54

AEs: adverse events

A systematic review (SR) conducted by Hamada et al. (2023) evaluated the safety of three TBSTs including Cy-Tb, C-TST, and Diaskintest are compared with the traditional TST for diagnosing tuberculosis infection.This SR included data from 29 studies, from July 2021 to November 2022. Of these, injection site reaction (ISRs) were the most common adverse events across all tests. For Cy-Tb, pooled data from five studies (n = 2,931) showed no significant difference in ISR frequency compared to TST (Risk Ratio 1.05, 95% CI: 0.70 to1.58). The rate over 95% of reactions were mild or moderate, with common symptoms like pain, itching, and rash. Cy-Tb had slightly fewer cases of itching and erythema than TST but showed a higher risk of large indurations and mild hematomas. For C-TST, a large RCT (n = 14,579) found ISR rates similar to or lower than TST. Pain and itching were comparable, while TST had more bleeding, discoloration, and swelling. In a split-body RCT (n = 1,090), itching occurred in 9.7% of C-TST recipients vs. 9.5% for TST; pain was 2.3% vs. 1.4%, respectively. Diaskintest data were less reliable due to inconsistent reporting. However, one study reported hyperallergic reactions in 11.3% of participants, including vesicles and lymphangitis, compared to 3.8% for TST. Other safety outcomes, particularly SAEs showed that Cy-Tb was associated with reactions such as fever, headache, and dizziness in 28.5% to 53.0% of participants, though severe cases were rare. Fever occurred in only 2.6% and headache in 11.3%. One comparative study found similar SAE rates between Cy-Tb (32%) and TST (37.6%). C-TST demonstrated low systemic reaction rates, with mild symptoms like fatigue and headache affecting around 1% of participants in a phase 3 trial, while earlier studies reported fever in up to 7.1%. Fever associated with Diaskintest was reported in 0% to 7% of cases, with a pooled average of 2.6%. In a study involving adults co-infected with HIV and tuberculosis, 4.5% experienced symptoms including fever, weakness, chills, and headache. Despite a lack of specific evaluation in Diaskintest studies, no serious adverse events were documented for it or reported in large studies of Cy-Tb (n=2,924) and C-TST (n=8,491). The study indicated one Cy-Tb study of HIV-positive individuals found that over

75% of local reactions were mild, showing no significant difference compared to HIV-negative participants. Furthermore, a single Diaskintest study in pregnant women (n=267) reported no embryo toxicity, although it lacked comprehensive safety details.The author concludes that despite the less standardized Diaskintest data, the overall safety profile suggests that TB skin tests (TBSTs) are a viable alternative to current diagnostic methods.[6]

In the systematic review and meta analysis by Krutikov M et al.(2021), it was reported that only six (16%) of the 37 studies reported safety data, and adverse events (AEs) were not classified consistently. For the C-Tb test, injection site reactions occurred in 30.9% of participants (853 out of 2764), closely resembling the rate observed with the TST (29.3%). Additional reported AEs for C-Tb included injection-site itching (20.3%), pain (8.4%), rash (4.5%), and vesicle formation (2.5%). In studies of the EC-skintest, mild pain was reported by 4.9% of participants and mild itching by 12.5%. No safety data were reported in the studies evaluating Diaskintest or DPPD.[3]

As of today, there was no TB antigen based skin test registered with Malaysian Medical Device Authority (MDA) or United States Food and Drug Administration (US FDA). [9,10]

COST-EFFECTIVENESS

There were three studies reported on the cost effectiveness of Mycobacteria tuberculous (TB) antigen-based skin test (TBST).

Goscé L et al (2024) conducted two systematic reviews to compare the evidence, costs, and cost-effectiveness of novel Tuberculosis Skin Tests (TBST) like Diaskintest and C-TST against the established TST and IGRA. Evidence for TBST including Diaskintest and C-TST, limited, with only eight studies, primarily from Russia and one from Brazil. Diaskintest demostrated a low average kit cost of $1.60 (RM 6.71) and a full unit cost of $5.07 (RM21.28), while C-TST cost $9.96 (RM 41.80). Despite the limited scope and quality of the studies, all papers reported strategies involving these novel tests as cost-effective or cost-saving with one showing Diaskintest saved $1,375 (RM 5770.19) per quality-adjusted life year (QALY) compared to older tests. Thirty-two studies evaluated traditional tests like TST and IGRA and showed average unit costs of $37.88 (RM158.96) for TST and $87.81 (RM368.49) for IGRA, and staff costs were a major source of variation. The study showed that any testing (TST or IGRA) was generally cost-effective compared to no testing, though no clear economic consensus existed between TST and IGRA, with IGRA often preferred for patient living with HIV (PLHIV) and migrants. TBST showed significantly lower costs tests and may offer a valuable alternative, especially in settings where TST is commonly used and IGRA is less feasible due to cost and infrastructure. However, more research is required in high-burden, low- and middle-income countries to fully assess their cost-effectiveness.[7]

Souza FM et al. (2025) conducted a cost-effectiveness analysis of three newer tuberculosis (TB) antigen-based skin tests (Diaskintest, C-TST, and Cy-TB) and QFT-Plus (IGRA) for TB infection diagnosis, compared to the current standard of care, PPD Rt-23 TST, among healthcare workers in Brazil. This study utilized a state-transition Markov model for testing and treating TB infection with three months of weekly doses of rifapentine and isoniazid (3HP) under the Brazilian public health system perspective. Table 2 simplified the 5-year simulation for 10,000 healthcare workers compared to TST.

Table 2: 5-year simulation for 10,000 healthcare workers compared to TST.[8]

Strategy	Total Cost (USD)	TB Disease Cases Averted	ICER (USD per TB case averted)
TST (Reference)	334,619	—	—
Diaskintest	298,236	5	-7,239 (Cost Saving)
Cy-TB	286,640	1	-62,388 (Cost Saving)
C-TST	434,984	4	25,917
QFT-Plus	801,727	6	84,038

Diaskintest and Cy-TB were showed as the most cost-saving strategies for diagnosing TB infection compared to the traditional TST. The QFT-Plus strategy's total cost was significantly higher at USD 801,727 due to the high costs of equipment, labor, and the test kit itself, compared to only USD 298,236 for Diaskintest and USD 286,640 for Cy-TB. Although QFT-Plus showed slightly greater effectiveness by averting six TB cases compared to five with Diaskintest and one with Cy-TB, the incremental cost per TB case averted was USD 84,038. Sensitivity analysis of Diaskintest showed the highest net benefit in 92.9% of simulations at the willingness-to-pay threshold of USD 7,752 per TB case averted, followed by Cy-TB at 7.1%. Diaskintest and Cy-TB are the most cost-effective strategies, primarily because the QFT-Plus test requires equipment, laboratory infrastructure, sample transportation from health facilities to the laboratory, and labor-intensive processes despite having slightly higher effectiveness. The results showed newer testing methods may offer valuable alternatives to the QFT-Plus approach, with the potential to support broader implementation of TB prevention strategies and strengthen global efforts to control tuberculosis.[8]

ORGANISATIONAL ISSUES

The World Health Organization (WHO) consolidated guidelines on Tuberculosis (Module 3: Diagnosis), issued in 2025, were based on a systematic review of the new class of tests for TB infection, which includes Cy-Tb (Serum Institute of India, India), Diaskintest (Generium, Russian Federation), and C-TST (Anhui Zhifei Longcom, China). WHO recommendations were conditional for the intervention due to very low certainty of evidence. The studies evaluating the new-generation TBSTs focused only on their diagnostic accuracy (sensitivity, specificity, and concordance) and lack of evidence concerning the tests' utility in clinical practice, such as their predictive value for progression to active disease, the efficacy of subsequent TB Preventive Treatment (TPT), or the actual rate of TPT initiation. The criteria for interpreting a positive result differed across tests. Cy-Tb and C-TST uniformly used a ≥5 mm induration threshold, but Diaskintest lacked consistency—some sources adopted the same cut-off even though the manufacturer recommends considering any induration as positive. The safety profile of these novel TBSTs is comparable to that of the traditional TST, with both being associated with predominantly mild injection site reactions (ISRs) such as itching and pain. Current evidence does not indicate a safety signal that would influence the choice between TBSTs and the TST. Furthermore, the safety review was not comprehensive, as it did not cover product safety, animal, or preclinical studies and regulatory assessment is therefore required before any TBST product can be implemented. Written informed consent was obtained after discussion of advantages, risks, and trial requirements, in accordance with

the Declaration of Helsinki and Good Clinical Practice guidelines, with protocol approval by the ethics committee of the Shanghai Public Health Clinical Center (No. 2016-E012-07)[5k]. Although Diaskintest has demonstrated potential cost savings and greater health gains (measured in QALYs per patient) compared with the TST and IGRA particularly in high-burden, resource-limited settings such as Brazil and South Africa,more high-quality evidence is needed to support definitive policy recommendations.[2]

CONCLUSION

Based on the above review, there is limited evidence retrieved on effectiveness and safety of Mycobacteria tuberculous (TB) antigen-based skin test (TBST). Evidence demonstrated that TBSTs have comparable diagnostic accuracy to other assays, with 83% sensitivity and 100% specificity and mitigates false positives results caused by BCG vaccination due to its use of TB-specific antigens. Combining TBST with TST or IGRA provides a more accurate diagnostic method than using the traditional tests individually. TBSTs had lower incidence of adverse effects and mostly mild ISR such as itching and pain. No TBST registered with Malaysian Medical Device Authority (MDA) and United States Food and Drug Administration (US FDA). WHO recommendations were conditional for the intervention due to very low certainty of evidence. Thus, high quality scientific evidence is warranted to support the safety and implementation of these potentially accessible diagnostic alternatives in clinical practice.

REFERENCES

1. Peng L, Ma W, Zhong L, Yang J, Wu H, Zhu L, Huang X, Yang R, Li B, Ma W, Wu X, Song J, Luo S, Bao F, Liu A. Diagnostic Accuracy of Mycobacterium tuberculosis Antigen-Based Skin Tests (TBSTs) for Tuberculosis Infection Compared with TST and IGRA: A Network Meta-Analysis. Pathogens. 2024 Nov 29;13(12):1050
2. WHO consolidated guidelines on tuberculosis. Module 3: diagnosis. Geneva: World Health Organization;2025.
3. Krutikov M, Faust L, Nikolayevskyy V, Hamada Y, Gupta RK, Cirillo D, Mateelli A, Korobitsyn A, Denkinger CM, Rangaka MX. The diagnostic performance of novel skin-based in-vivo tests for tuberculosis infection compared with purified protein derivative tuberculin skin tests and blood-based in vitro interferon-γ release assays: a systematic review and meta-analysis. Lancet Infect Dis. 2022 Feb;22(2):250-264. doi: 10.1016/S1473-3099(21)00261-9. Epub 2021 Oct 1. Erratum in: Lancet Infect Dis. 2022 Feb;22(2):e41. doi: 10.1016/S1473-3099(21)00651-4. Erratum in: Lancet Infect Dis. 2022 Apr;22(4):e101.
4. WHO consolidated guidelines on tuberculosis: Module 3: Diagnosis – Tests for tuberculosis infection. Geneva: World Health Organization; 2022. 1, Use of Mycobacerium tuberculosis antigen-based skin tests for the diagnosis of TB infection NEW. Available from: https://www.ncbi.nlm.nih.gov/books/NBK586680/
5. Lu Xia, Xu-hui Liu, Miao Xu, Ting Zhang, Guo-zhi Wang, Bao-dong Yuan, Feng Li, Guo-xi Chen, Xi-rong Wu, Yan Guo, Ting Song, A-dong Shen, Tao Li, Shui-hua Lu, Recombinant fusion ESAT6-CFP10 immunogen as a skin test reagent for tuberculosis diagnosis in children and adolescents: An open-label, randomized, multicenter phase III trial,LabMed Discovery,Volume 2, Issue 2,2025,

6. Hamada Y, Kontsevaya I, Surkova E, Wang TT, Wan-Hsin L, Matveev A, Ziganshina LE, Denkinger CM, Korobitsyn A, Ismail N, Abubakar I, Rangaka MX. A Systematic Review on the Safety of Mycobacterium tuberculosis-Specific Antigen-Based Skin Tests for Tuberculosis Infection Compared With Tuberculin Skin Tests. Open Forum Infect Dis. 2023 May 2;10(5):ofad228.
7. Goscé L, Allel K, Hamada Y, Surkova E, Kontsevaya I, Wang TT, Liu WH, Matveev A, Ziganshina LE, Korobitsyn A, Ismail N, Bashir S, Denkinger CM, Abubakar I, White PJ, Rangaka MX. Systematic review of the economic impact of novel Mycobacterium tuberculosis specific antigen-based skin tests for detection of TB infection compared with tuberculin skin test and interferon-gamma release assays. PLOS Glob Public Health. 2024 Oct 14;4(10):e0003655.
8. Souza FM, Steffen RE, Pinto MFT, Prado TND, Maciel ELN, Trajman A. TB antigen-based skin tests and QFT-Plus for Mycobacterium tuberculosis infection diagnosis in Brazilian healthcare workers: a cost-effectiveness analysis. Cad Saude Publica. 2025 Feb 24;41(1):e00178623.
9. Registered Medical Device Search https://mmdr.mda.gov.my/
10. U.S Food and Drug Administration. Device Approval and Clearances. Available at https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-and-clearances
11. https://en.wikipedia.org/wiki/Mantoux_test

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