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| RESEARCH ARTICLE

Diagnostic Accuracy of the GeneXpert MTB/RIF Ultra for Tuberculous Meningitis: A Systematic Review and Meta-Analysis

Rafi Aliefiyanto [1]✉, Ni Made Mertaniasih[2], Ariani Permatasari[3] , and Abdullah Machin[4]
[1]*Medical Student, Faculty of Medicine, Universitas Airlangga, Surabaya, Indonesia*
[2]*Department of Microbiology, Faculty of Medicine, Universitas Airlangga / Universitas Airlangga Hospital, Surabaya, Indonesia*
[3]*Department of Pulmonology, Faculty of Medicine, Universitas Airlangga / Universitas Airlangga Hospital, Surabaya, Indonesia*
[4]*Department of Neurology, Faculty of Medicine, Universitas Airlangga / Universitas Airlangga Hospital, Surabaya, Indonesia*
Corresponding Author: Rafi Aliefiyanto **E-mail**: rafialiefiyanto2022@gmail.com

| ABSTRACT
Tuberculous meningitis (TBM) is the most severe form of extrapulmonary tuberculosis and remains difficult to diagnose because conventional methods are either insensitive or time-consuming. This study aimed to evaluate the diagnostic accuracy of GeneXpert MTB/RIF Ultra for TBM through a systematic review and meta-analysis. A literature search was conducted in PubMed, Scopus, ScienceDirect, and ProQuest, and eligible studies were assessed using the QUADAS-2 tool. Pooled estimates of sensitivity, specificity, diagnostic odds ratio (DOR), and summary receiver operating characteristic (SROC) curves were generated using Meta-DiSc 2.0. Thirteen studies met the inclusion criteria. Using culture as the reference standard, GeneXpert MTB/RIF Ultra demonstrated high pooled sensitivity (91.01%), specificity (78.66%), and an area under the curve (AUC) of 0.88. When evaluated against the Composite Reference Standard (CRS), pooled sensitivity decreased to 58.88%, whereas specificity remained excellent at 98.52%, with an AUC of 0.90. Publication bias analysis showed no significant evidence of bias for the culture-based studies. Overall, GeneXpert MTB/RIF Ultra demonstrated strong diagnostic performance and represents a rapid, highly specific diagnostic tool for TBM, supporting its clinical use, particularly in high TB-burden and resource-limited settings.

| KEYWORDS

Tuberculous Meningitis; GeneXpert MTB/RIF Ultra; Diagnostic Accuracy; Cerebrospinal Fluid; Systematic Review; Meta-Analysis.

| ARTICLE INFORMATION

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1. Introduction

Tuberculosis (TB) remains a major global health problem, with an estimated 10.8 million cases and 1.25 million deaths reported in 2023 (WHO, 2024). Among extrapulmonary tuberculosis (EPTB), tuberculous meningitis (TBM) is the most severe form due to its high mortality, diagnostic difficulty, and risk of long-term neurological complications (Olmesdahl, 2023). Early diagnosis is challenging because TBM presents with nonspecific clinical manifestations, while conventional methods such as smear microscopy and culture have limited sensitivity or require prolonged incubation (Navarro-Flores et al., 2022). GeneXpert MTB/RIF Ultra is a rapid molecular assay that improves the detection of Mycobacterium tuberculosis and rifampicin resistance, demonstrating higher sensitivity than conventional methods, particularly in paucibacillary and cerebrospinal fluid specimens (Patel et al., 2023). However, evidence regarding its diagnostic accuracy for TBM remains fragmented. Therefore, this systematic review and meta-analysis aimed to evaluate the diagnostic accuracy of GeneXpert MTB/RIF Ultra for TBM using culture and composite reference standards.

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2. Methodology

2.1 Literature Search Strategy

A comprehensive literature search was conducted in PubMed, Scopus, ScienceDirect, and ProQuest. The search combined terms related to tuberculous meningitis and GeneXpert MTB/RIF Ultra, including "tuberculous meningitis," "TB meningitis," "meningeal tuberculosis," "GeneXpert MTB/RIF Ultra," and "Xpert Ultra." Medical Subject Headings (MeSH) and database-specific syntax were applied where appropriate.

2.2 Selection of Studies

All retrieved records were imported into Rayyan.AI for duplicate removal and screening. Titles and abstracts were screened based on predefined eligibility criteria, followed by full-text assessment of potentially relevant articles. Reasons for exclusion were documented, and the study selection process was summarized using a PRISMA flow diagram.

2.3 Eligibility Criteria

Studies were included if they involved patients with suspected or confirmed tuberculous meningitis, evaluated GeneXpert MTB/RIF Ultra, used culture and/or Composite Reference Standard as the reference standard, and reported sufficient data to calculate diagnostic accuracy outcomes. Eligible designs included randomized controlled trials, cohort studies, cross-sectional studies, and diagnostic accuracy studies. Reviews, conference abstracts, case reports, case series, letters, protocols, duplicate publications, non-English articles, unavailable full texts, and studies without extractable diagnostic data were excluded.

2.4 Quality Assessment

Study quality was assessed using the Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) tool. Four domains were evaluated: patient selection, index test, reference standard, and flow and timing. Risk of bias was assessed in all domains, while applicability concerns were assessed in the first three domains.

2.5 Data Extraction

Data were extracted using a standardized form. Extracted variables included author, year, country, study design, population characteristics, sample size, specimen type, GeneXpert MTB/RIF Ultra method, reference standard, and diagnostic accuracy data. When available, true positive, false positive, true negative, and false negative values were extracted to construct 2 × 2 diagnostic tables.

2.6 Statistical Analysis

Pooled sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, diagnostic odds ratio, and AUC were calculated. Summary receiver operating characteristic curves were generated to assess overall diagnostic performance. Heterogeneity was evaluated using Higgins' I^2 statistic, with values above 50% indicating substantial heterogeneity. Subgroup analyses explored risk of bias, HIV status, CSF processing, centrifugation, and reference standard type. Analyses were performed using Meta-DiSc 2.0. Publication bias was assessed using Begg's funnel plot and Egger's regression test where applicable.

3. Results

3.1 Study Selection

The study selection process was conducted and reported according to the PRISMA flow diagram. The database search identified 1,247 records from PubMed, Scopus, ScienceDirect, and ProQuest. After removing 382 duplicate records, 865 records were screened by title and abstract, of which 780 were excluded. A total of 82 full-text reports were assessed for eligibility, and 73 were excluded due to irrelevant PICO, inappropriate publication type, or foreign language. Four additional studies were identified through citation searching. Finally, 13 studies were included in the systematic review and meta-analysis.

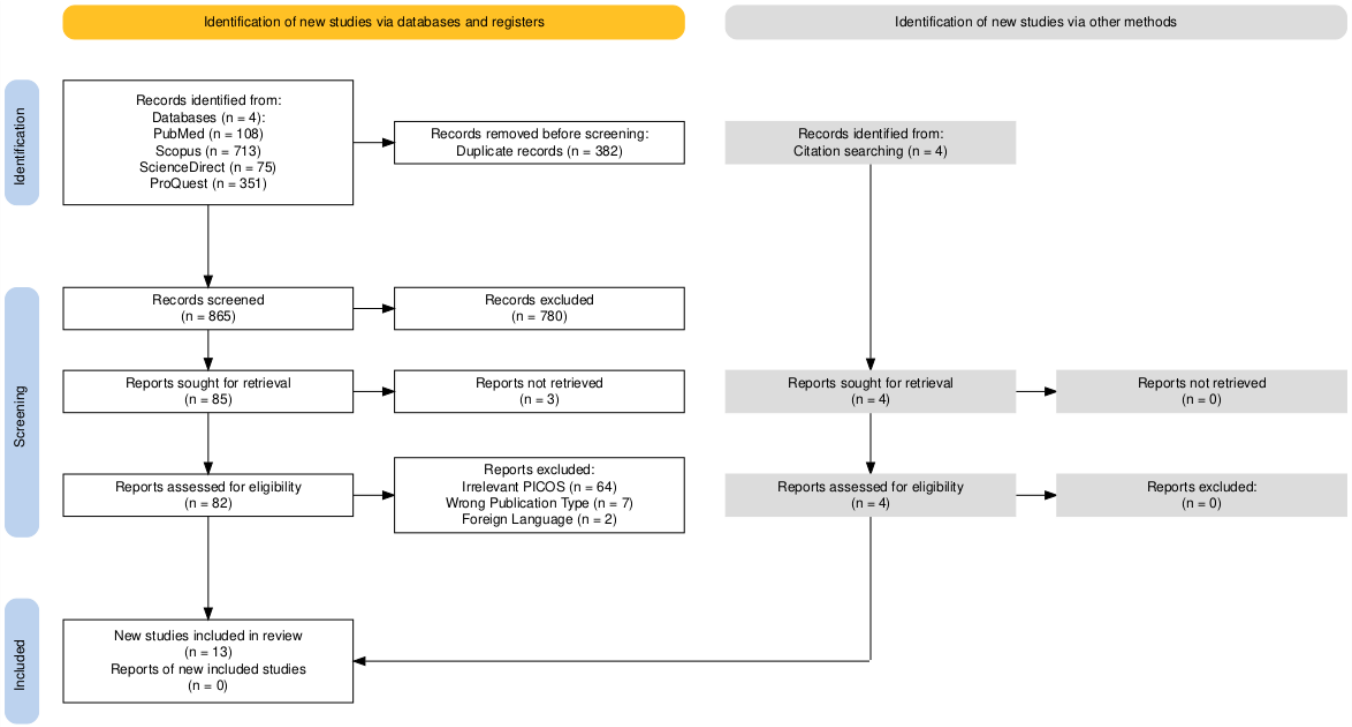

Figure 1. PRISMA flow diagram of study selection.

3.2 Quality Assessment

The methodological quality of the 13 included studies was assessed using the QUADAS-2 tool across four domains: patient selection, index test, reference standard, and flow and timing. Overall, the included studies showed variable but generally acceptable methodological quality. Five studies were judged to have high risk of bias in at least one domain, mainly due to issues related to patient selection, index test interpretation, or flow and timing. The reference standard domain showed the greatest number of unclear judgments, largely because of insufficient reporting on blinding and classification procedures. However, applicability concerns were generally low, indicating that most included studies were relevant to the review question.

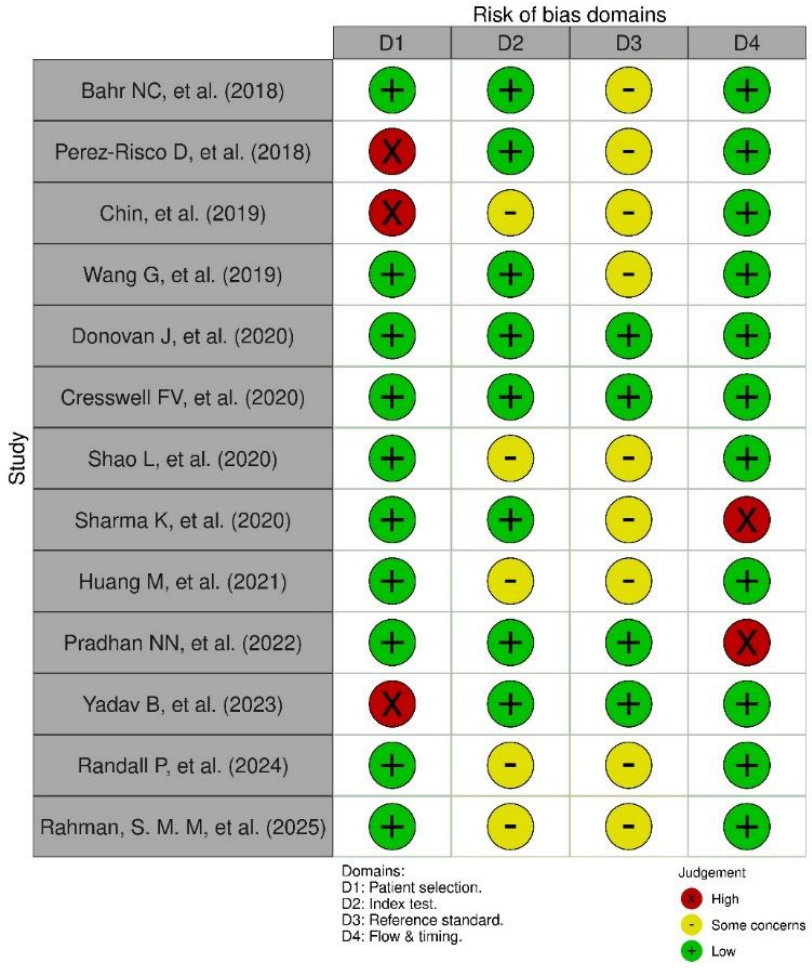

Figure 2. QUADAS-2 risk of bias summary per study.

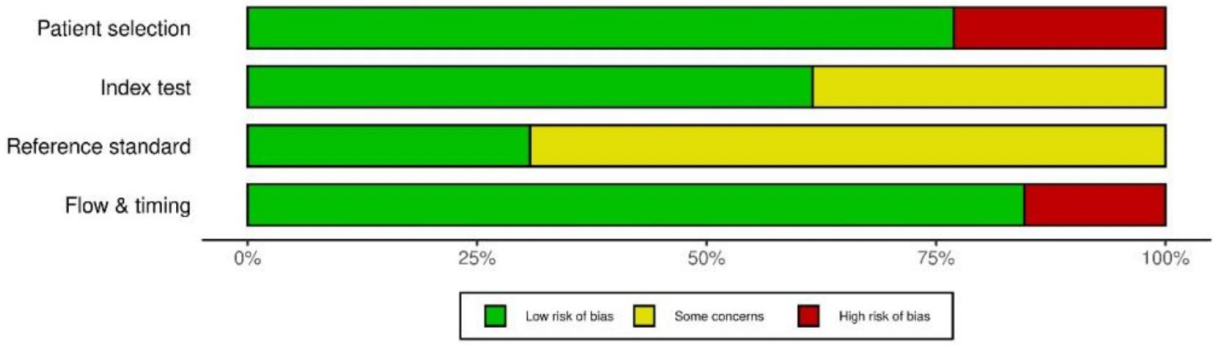

Figure 3. QUADAS-2 risk of bias summary by domain.

3.3 Characteristics of Included Studies

A total of 13 studies were included in this systematic review and meta-analysis. The included studies were conducted across several countries, including Uganda, Spain, China, Vietnam, India, Zimbabwe, and Bangladesh. Most studies used prospective cohort or diagnostic accuracy designs, while a smaller number used retrospective data. Sample sizes varied considerably across studies. Most studies evaluated GeneXpert MTB/RIF Ultra using cerebrospinal fluid specimens from patients with suspected or confirmed tuberculous meningitis. Culture was used as a reference standard in 11 studies, while CRS was used in 9 studies. Seven studies reported diagnostic data using both reference standards, allowing comparison across microbiological and clinical definitions of TBM.

No.	Study	Study Design	Country	Reference Standard	Sample Size	CSF Condition	HIV Status
1.	Bahr NC, 2018	Prospective cohort	Uganda	CRS, culture	129	Frozen at −80°C	HIV-positive
2.	Perez-Risco D, 2018	Retrospective	Spain	culture	4	Frozen at −80°C	Not reported
3.	J.H. Chin, 2019	Prospective observational	Uganda	culture	11	Fresh	2 HIV-positive
4.	Wang G, 2019	Prospective cohort study	China	CRS, culture	60 (CRS), 39 (culture)	Frozen at −80°C	HIV-negative
5.	Donovan J, 2020	Prospective, diagnostic accuracy	Vietnam	CRS, culture	103	Fresh	31 HIV-positive
6.	Cresswell FV, 2020	Prospective validation	Uganda	CRS, culture	204	Fresh	41 HIV-positive
7.	Shao L, 2020	Prospective multicentre study	China	CRS, culture	84	Frozen at −80°C	All were HIV-negative
8.	Sharma K, 2020	Diagnostic Accuracy Study	India	CRS, culture	244	Fresh (195), Frozen (49)	Not reported
9.	Huang M, 2021	Diagnostic Accuracy Study	China	CRS	121	Frozen and Fresh	All were HIV-negative
10.	Pradhan NN, 2022	Randomized Controlled Trial	India	culture	145	Fresh	4 HIV-positive
11.	Yadav B, 2023	Prospective, diagnostic accuracy	India	CRS, culture	300	Fresh	Not reported
12.	Randall P, 2024	Prospective cohort study	Zimbabwe	CRS	431	Frozen at −20°C	8 HIV+ TBM; 261 HIV+ non-TBM
13.	Rahman S. M. M., 2025	Prospective cohort study	Bangladesh	Culture	187	Fresh	Not reported

Table 1. Characteristics of Included Studies

3.4 Diagnostic Accuracy of GeneXpert MTB/RIF Ultra

GeneXpert MTB/RIF Ultra demonstrated strong overall diagnostic performance for the diagnosis of tuberculous meningitis across both reference standards (Figure 4). The SROC analysis showed excellent discriminatory ability, with an area under the curve (AUC) of 0.88 using culture and 0.90 using the Composite Reference Standard (CRS). Although the AUC values were comparable, the diagnostic profiles differed between the two reference standards. Compared with culture, GeneXpert MTB/RIF Ultra demonstrated higher pooled sensitivity, whereas evaluation against CRS resulted in lower sensitivity but consistently high specificity. These findings suggest that the assay performs well for confirming TBM while its diagnostic performance varies according to the reference standard used, reflecting the broader clinical definition of TBM incorporated within the CRS. Overall, the SROC analysis supports the clinical utility of GeneXpert MTB/RIF Ultra as a rapid and reliable diagnostic tool for TBM.

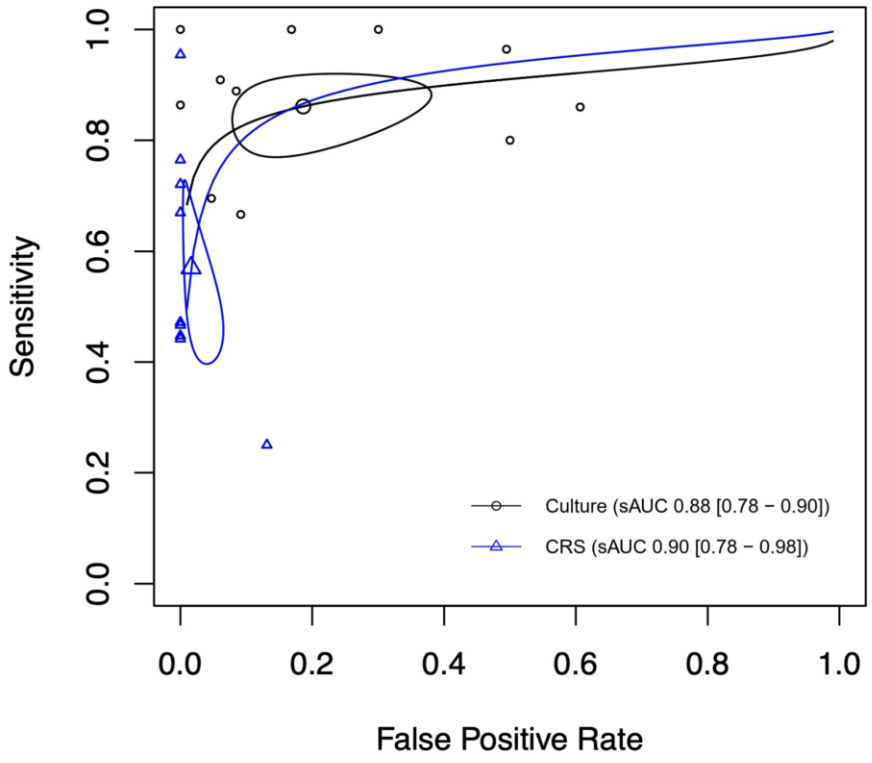

Figure 4. Summary receiver operating characteristic (SROC) curves of GeneXpert MTB/RIF Ultra for the diagnosis of tuberculous meningitis using culture and Composite Reference Standard (CRS).

3.4.1 Diagnostic Performance

GeneXpert MTB/RIF Ultra demonstrated strong diagnostic performance, although its accuracy profile differed according to the reference standard used. When evaluated against the Composite Reference Standard (CRS), the assay showed a pooled sensitivity of 58.88% (95% CI: 45.21–72.56) and specificity of 98.52% (95% CI: 95.61–100.00), indicating strong rule-in performance but limited ability to exclude clinically defined TBM following a negative result. In contrast, the culture-based analysis demonstrated a higher pooled sensitivity of 91.01% (95% CI: 85.72–96.31) but lower specificity of 78.66% (95% CI: 65.49–91.82). This difference may partly reflect the limitations of culture in paucibacillary TBM, whereby Xpert Ultra-positive but culture-negative cases may be classified as false positives, whereas CRS includes clinically probable cases that may have bacterial loads below the assay's detection threshold. The pooled diagnostic odds ratio was 96.70 (95% CI: 20.63–453.29) against CRS and 31.82 (95% CI: 12.19–78.43) against culture, demonstrating strong discriminatory ability under both reference standards. The test for subgroup differences showed no statistically significant difference in DOR between CRS and culture ($p = 0.22$). Substantial heterogeneity was observed, particularly for CRS sensitivity and specificity and culture specificity, suggesting variability in study populations, specimen processing, and diagnostic definitions. Because several studies contributed data to both reference-standard analyses, the combined overall pooled estimate across CRS and culture was not interpreted. Overall, GeneXpert MTB/RIF Ultra appears most useful as a rapid rule-in test for TBM, while negative results should be interpreted together with clinical assessment, cerebrospinal fluid findings, imaging, and microbiological evidence.

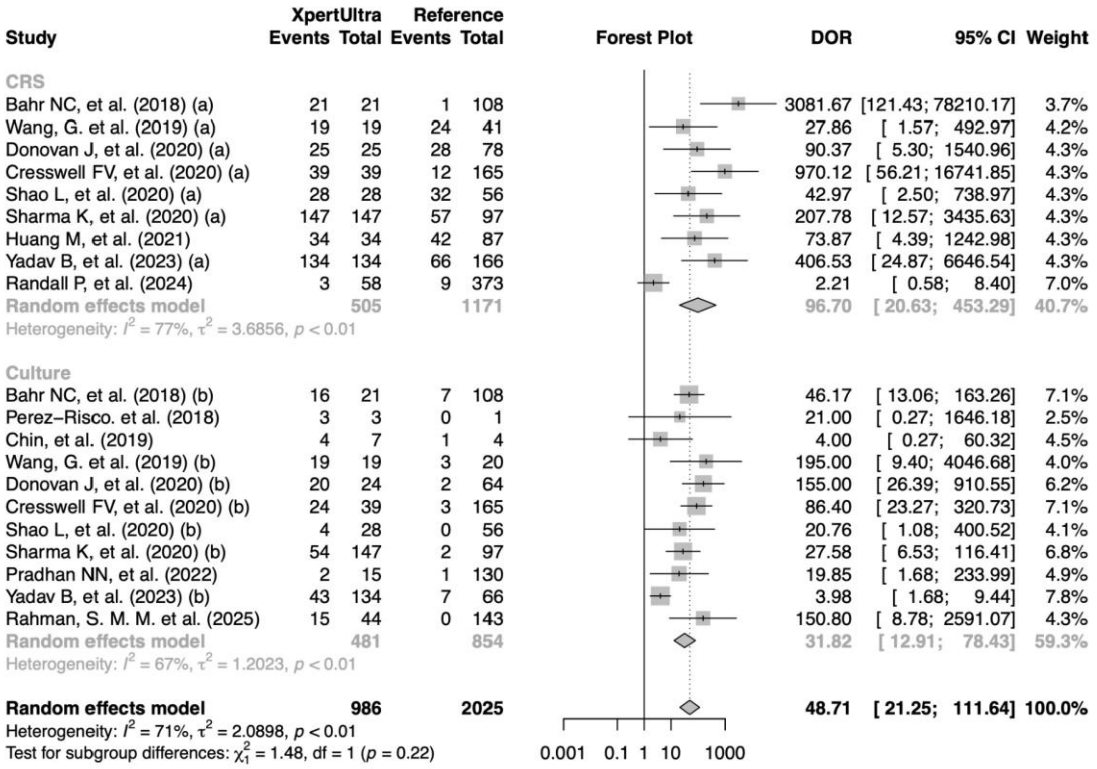

Figure 5. Pooled Diagnostic Odds Ratio (DOR)

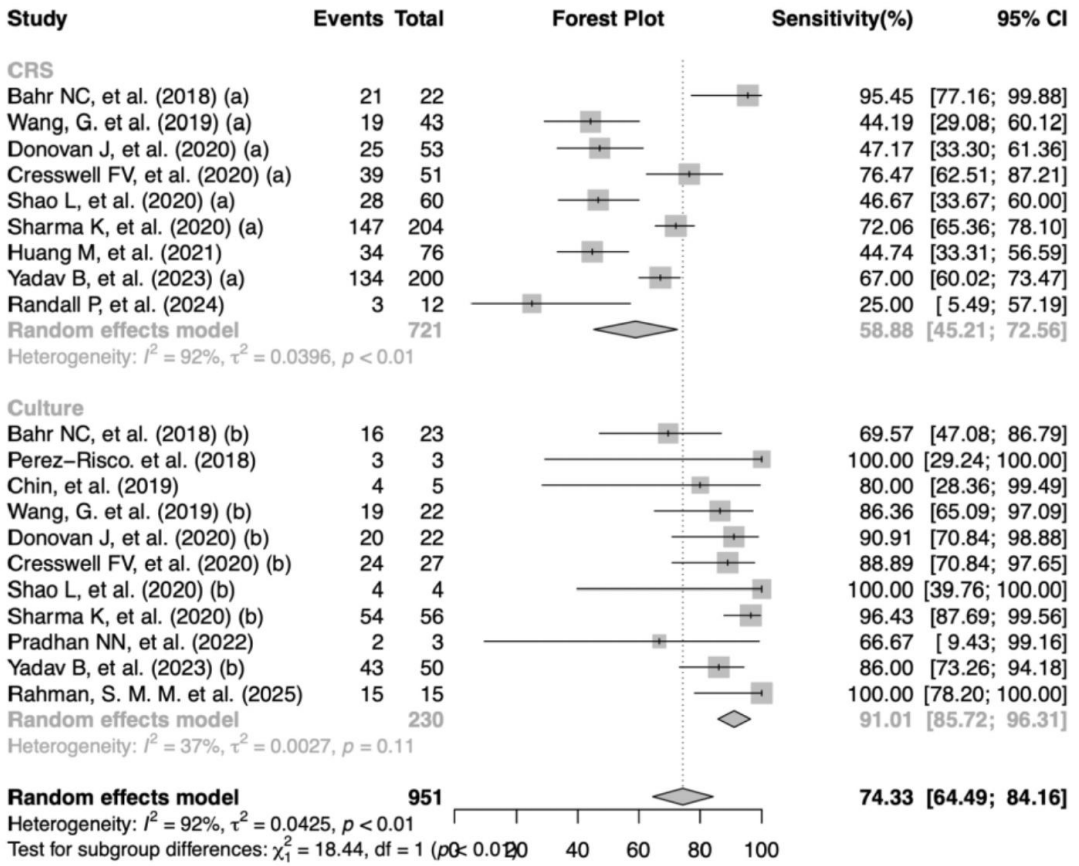

Figure 6. Pooled Sensitivity of Xpert Ultra

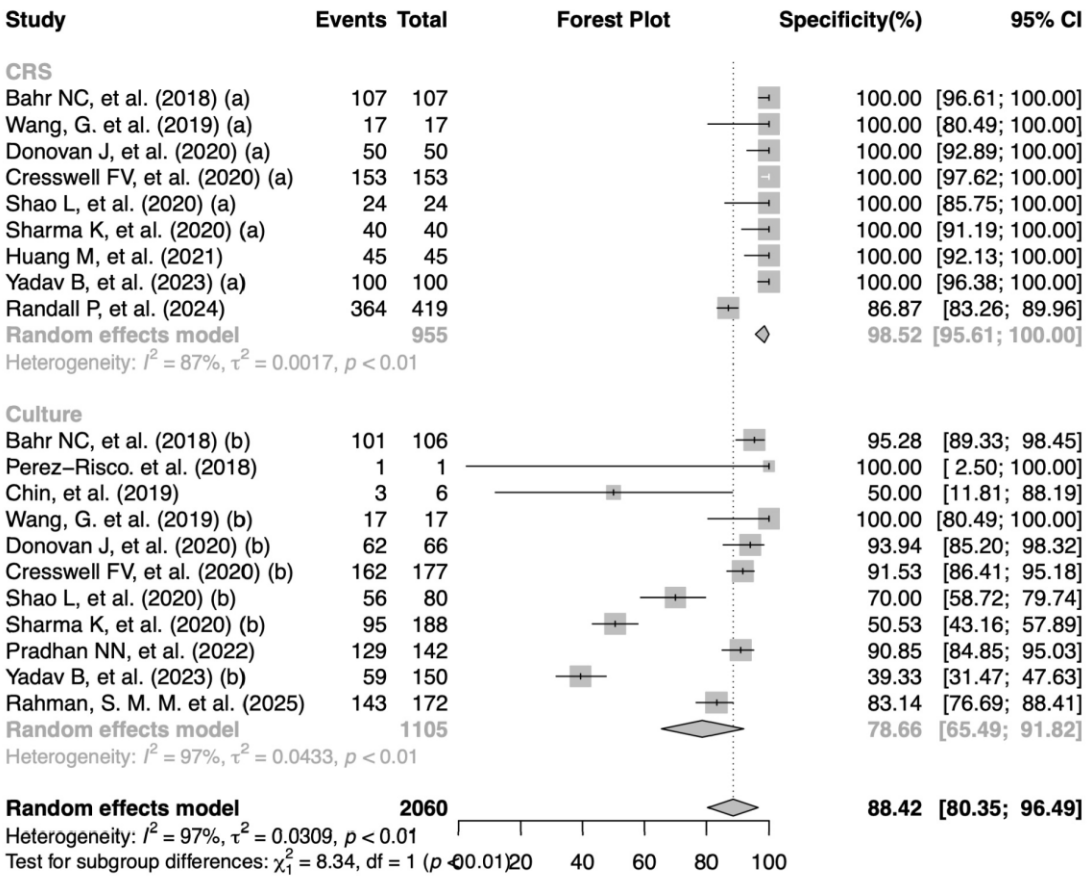

Figure 7. Pooled Specificity of Xpert Ultra

3.4.2 Culture Subgroup Analysis

The culture-based subgroup analysis showed that pooled sensitivity remained generally high across most categories, while specificity and overall discriminatory performance varied more substantially. Studies with a low risk of bias demonstrated similar sensitivity to high-risk studies but higher specificity and DOR, suggesting more reliable diagnostic performance in methodologically stronger studies. Frozen CSF samples showed slightly lower sensitivity than fresh samples but higher specificity, whereas mixed samples produced the highest sensitivity but substantially lower specificity. Centrifugation was associated with higher specificity, LR+, and DOR than studies without centrifugation or with unreported processing methods, indicating that specimen concentration may improve diagnostic yield. Diagnostic performance also varied by HIV status: HIV-positive populations showed lower sensitivity but very high specificity and LR+, while mixed and HIV-negative populations demonstrated more balanced estimates. These subgroup findings suggest that study quality, CSF condition, specimen processing, and HIV status may contribute to heterogeneity; however, categories based on few studies or with unavailable heterogeneity estimates should be interpreted cautiously.

Subgroup	Category	Sensitivity (%)	I^2 Sens (%)	Specificity (%)	I^2 Spec (%)	LR^+	LR^-	DOR
Risk of Bias	High	91.48	26	62.67	98	2.450	0.136	18.01
	Low	90.21	50	89.43	86	8.535	0.109	77.96
Sample	Fresh	91.14	23	76.92	97	3.948	0.115	34.29
	Frozen	85.91	36	89.52	88	8.197	0.157	52.09
	Mixed	96.43	-	50.53	-	1.949	0.071	27.57
Centrifugation	No	93.05	0	77.87	96	4.205	0.089	47.10
	Not reported	86.00	-	39.33	-	1.418	0.356	3.984
	Yes	90.68	57	87.46	87	7.233	0.107	67.87
HIV Status	Mixed	88.82	0	91.65	39	10.636	0.122	87.16
	Negative	89.49	0	85.19	95	6.043	0.123	48.99
	Not reported	94.95	40	62.35	97	2.522	0.081	31.15
	Positive	69.57	-	95.28	-	14.735	0.319	46.16

Table 2. Culture Subgroup Analysis Summary

3.4.3 CRS Subgroup Analysis

The CRS-based subgroup analysis showed consistently high specificity across nearly all categories, while sensitivity varied considerably between subgroups. Studies classified as high risk of bias demonstrated higher sensitivity than low-risk studies (69.65% vs. 55.30%), although specificity remained excellent in both groups. Fresh CSF samples produced higher sensitivity than frozen samples (63.98% vs. 53.95%), while both fresh and mixed specimens achieved 100% specificity. Centrifugation was associated with the highest sensitivity among specimen-processing categories (66.79%) and maintained 100% specificity, whereas studies that did not report centrifugation showed the lowest sensitivity (47.73%) and lower specificity (93.52%). Diagnostic performance also varied according to HIV status. The HIV-positive subgroup showed the highest sensitivity (95.45%) with 100% specificity, whereas sensitivity was lower in HIV-negative and mixed populations. Several subgroups produced infinite LR+ and DOR values because no false-positive results were observed, indicating very strong rule-in performance; however, these estimates should be interpreted cautiously, particularly when based on few studies or small samples. Overall, the CRS subgroup findings suggest that CSF processing, HIV status, and methodological characteristics may influence sensitivity, while specificity remains consistently high across most subgroups.

Subgroup	Category	Sensitivity (%)	I^2 Sens (%)	Specificity (%)	I^2 Spec (%)	LR^+	LR^-	DOR
Risk of Bias	High	69.65	18	100.00	0	∞	0.30	∞
	Low	55.30	94	98.06	90	28.50	0.46	61.96
Sample	Fresh	63.98	81	100.00	0	∞	0.36	∞
	Frozen	53.95	96	96.48	95	15.33	0.48	31.94
	Mixed	58.81	94	100.00	0	∞	0.41	∞
Centrifugation	No	54.47	92	100.00	0	∞	0.46	∞
	Not reported	47.73	91	93.52	98	7.37	0.56	13.16
	Yes	66.79	95	100.00	0	∞	0.33	∞
HIV Status	Mixed	51.02	89	95.71	97	11.89	0.51	23.31
	Negative	45.25	0	100.00	0	∞	0.55	∞
	Not reported	69.65	18	100.00	0	∞	0.30	∞
	Positive	95.45	–	100.00	–	∞	0.05	∞

Table 3. CRS Subgroup Analysis Summary

3.5 Publication Bias

Publication bias was assessed for the culture-based analysis using Begg's funnel plot and Egger's regression test. Visual inspection of the funnel plot did not demonstrate marked asymmetry, and Egger's regression test was not statistically significant (p = 0.1984). These findings suggest no strong evidence of publication bias in the culture-based diagnostic accuracy analysis. Publication bias assessment was not performed for the CRS-based analysis because the number of eligible studies was limited, which may reduce the reliability of funnel plot interpretation and regression-based asymmetry testing.

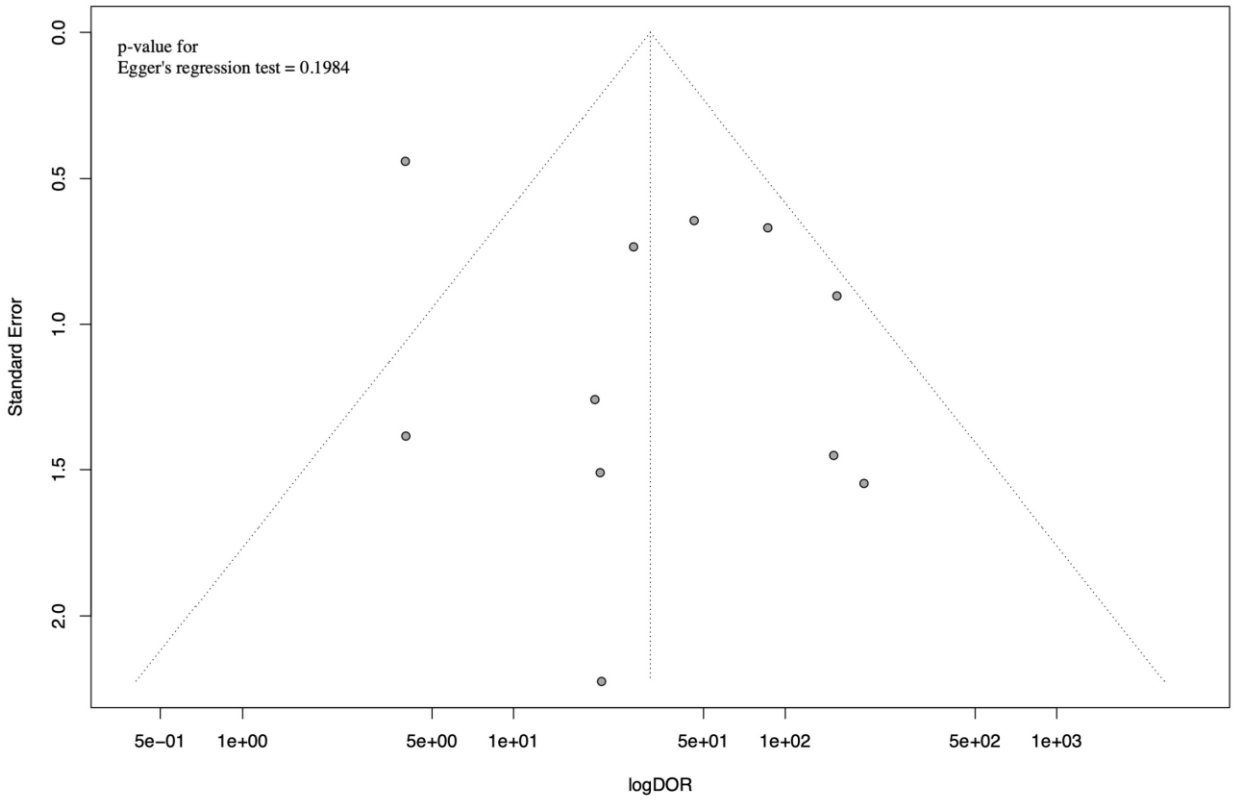

Figure 8. Begg's Funnel Plot and Egger's Test for Publication Bias (Culture)

4. Conclusion

This systematic review and meta-analysis demonstrated that GeneXpert MTB/RIF Ultra is a valuable diagnostic tool for tuberculous meningitis, showing strong overall diagnostic performance against both microbiological culture and Composite Reference Standard (CRS). When evaluated using culture, the assay achieved high sensitivity, whereas comparison with CRS demonstrated excellent specificity despite lower sensitivity, supporting its role as a reliable rule-in test rather than a standalone rule-out test. These findings highlight the importance of interpreting GeneXpert MTB/RIF Ultra results alongside clinical assessment, cerebrospinal fluid findings, neuroimaging, and conventional microbiological methods. Although heterogeneity among studies and differences in specimen processing may have influenced diagnostic performance, the assay remains clinically useful because of its rapid turnaround time and ability to detect rifampicin resistance. Future well-designed diagnostic accuracy studies with standardized cerebrospinal fluid processing protocols and consistent reporting of patient characteristics are needed to further optimize the clinical application of GeneXpert MTB/RIF Ultra for tuberculous meningitis.

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Conflicts of Interest: The authors declare no conflict of interest.

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