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ORIGINAL RESEARCH

Novel LAM Assay Shown Satisfactory Results in the Detection of Tuberculosis

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Background: Diagnosing tuberculosis (TB) infection remains a challenge for clinicians. According to recommendations from the World Health Organization (WHO), lipoarabinomannan (LAM) testing can be used to diagnose TB infection in individuals. A new generation of urinary LAM testing is now available. However, studies on its accuracy are limited and warrant further exploration.

Objective: This study aims to evaluate the accuracy of a new urinary LAM testing using LAM for diagnosing TB infection.

Methods: A cross-sectional study was conducted at the Fourth People's Hospital of Nanning, China. Participants were enrolled from December 2023 to May 2024. Fresh urine samples were collected from the participants and tested using LAM. The diagnostic accuracy of the LAM was compared with other tests for Mycobacterium tuberculosis (sputum culture, sputum smear or molecular biology testing). We compared the positive rates of different TB detection methods to evaluate the effectiveness of LAM. In the comparative analysis, the 95% confidence interval was calculated using the Wilson score method. The kappa value was computed, and the corresponding P-value was reported.

Results: The positive agreement rate of LAM was 64.37%, the negative agreement rate was 94.29%, and the overall agreement rate was 80.73%. The Kappa value was 0.6013, indicating good consistency between the test reagent and the reference method.

Conclusion: LAM can be used for the diagnosis of TB. It provides diagnostic information quickly, easily, and cost-effectively, particularly showing good performance in diagnosing TB.

Keywords: tuberculosis, lipoarabinomannan, diagnostic accuracy

Introduction

Tuberculosis (TB) is a chronic infectious disease caused by Mycobacterium tuberculosis that can affect various organs throughout the body, with pulmonary TB being the most common and posing a serious threat to human health.[1,2] According to the World Health Organization (WHO), approximately one-third of the global population is infected with Mycobacterium tuberculosis, and around 10% of those infected will develop active TB. The WHO's 2023 Global TB report reveals that in 2022, there were 7.5 million newly diagnosed TB cases worldwide.[3,4] Among the 30 high TB burden countries, China ranks third, following India and Indonesia, in terms of TB incidence. There is a significant gap between the estimated number of new TB cases globally and those that are definitively diagnosed, with a marked decline in the number of newly diagnosed patients.[3,5,6] This highlights the limitations in TB diagnosis and underscores the urgent need for more effective diagnostic strategies and more efficient, convenient testing methods.

Currently, traditional methods of TB detection have certain limitations. While bacteriological examination, including smear and culture methods, remains the gold standard for TB diagnosis, these approaches suffer from low detection rates,

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limited sensitivity, and long processing times.[7,8] The tuberculin skin test (TST) is easily influenced by comorbidities and immune status, and it has cross-reactivity with the Bacillus Calmette Guerin vaccine (BCG vaccine), leading to low specificity and certain risks.[9] Given the large population of TB patients, early screening and diagnosis of pulmonary TB are crucial for controlling the spread of the disease.

Among existing diagnostic methods, bacteriological examination, despite being the gold standard, shows variability in detection among individuals and has limited sensitivity.[10] Patients with smear-negative TB are common in clinical practice, and pathogen culture takes time, making rapid diagnosis difficult. Imaging, while nonspecific, is subject to subjective interpretation and may lead to misdiagnosis.[11] The TST can be affected by comorbidities and immune status, and cross-reactivity with the BCG vaccine is a concern. Serological testing has low accuracy and unstable results, offering limited clinical utility. Although nucleic acid amplification tests offer high specificity, they require samples containing the bacteria and demand advanced laboratory techniques, which are challenging for general hospitals to implement.[12]

Additionally, many detection methods rely on sputum samples, which can be difficult to obtain from children or severely ill patients. For patients with extrapulmonary TB, sputum may not contain the bacteria, often necessitating invasive sampling from the affected tissues, causing significant discomfort to the patient.[13]

To address these limitations and achieve rapid, sensitive, and non-invasive diagnosis of TB, many researchers have identified lipoarabinomannan (LAM) as a viable diagnostic method. LAM is a key component of the Mycobacterium tuberculosis cell wall with important and unique immunomodulatory properties. It is metabolized and excreted in the urine, making it a potential biomarker for diagnosing both active TB and latent Mycobacterium tuberculosis infection. The measurement of LAM levels in TB patients can partially reflect bacterial load. LAM detection can improve the identification rate of active TB, predict clinical risk, and assess prognosis.[14,15]

Our study aims to evaluate the accuracy of diagnosing TB infection using a new LAM detection kit (chemiluminescent method) produced by Guangzhou Reador Biotechnology Co., Ltd. This is a new LAM testing reagent developed in China, and the relevant data has not been reported yet. The study utilizes a double-antibody sandwich chemiluminescence immunoassay to measure LAM levels in patients' urine. By conducting a comparative analysis, this research seeks to explore the sensitivity of this assay in diagnosing TB, providing new insights and reference points for clinical testing of TB patients.

Methods

Participant Selection and Sample Collection

All the participants were from the Fourth People's Hospital of Nanning, with the recruitment period spanning from December 2023 to May 2024. Inclusion Criteria: No restrictions on gender or age; suspected TB patients with TB-related signs/symptoms, patients requiring TB-related testing, patients with non-TB respiratory diseases, or patients with other diseases that are easily confused with TB; no other complications, such as hyperglycemia, diabetes, human immunodeficiency virus carrying, liver and kidney function damage; willing to participate in this clinical trial and sign the relevant informed consent form; LAM must be completed, and it is necessary to complete any one of the three tests: sputum culture, sputum smear, and molecular biology testing (GeneXpert MTB/RIF).

Exclusion Criteria: Participants unable to cooperate with sample collection, or whose samples were not collected, processed, or stored as required; participants/samples with incomplete medical information (including but not limited to participant ID, gender, age, clinical diagnosis background, and sample collection time); participants deemed unsuitable for the trial for other reasons by the researchers.

Sample Collection

Urine: Each sample must have a total urine volume of no less than 10 mL. Clean midstream urine should be collected, avoiding samples with high protein or lipids; if the testing cannot be completed timely, the sample needs to be stored at −15 °C.

Sputum Collection: Samples were collected on the morning of the testing day. Patients were required to fast in the morning, rinse their mouths gently with clean water twice, and then cough sputum directly into a sterile sputum cup, with the volume reaching 5–10 mL. All samples were submitted for testing within 1 hour of collection.

Composite Reference Standard

Our center, in accordance with international guidelines, defines the gold standard for TB diagnosis as meeting any one of the following criteria: positive acid-fast bacilli (AFB) smear; positive Mycobacterium TB culture; positive molecular test (eg, GeneXpert MTB/RIF).[16,17]

The criteria for the Composite Reference Standard (CRS) encompassed the following patient groups: those with positive culture results; those who tested positive for Xpert Ultra (high/medium intensity); those who tested positive for Xpert Ultra (low/very low/trace intensity) and presented clinical features, cytological/radiological/other laboratory findings suggestive of TB, along with a response to anti-TB treatment (ATT); and those who tested negative for Xpert Ultra but exhibited clinical features, cytological/radiological/other laboratory findings suggestive of TB, plus a response to ATT.[18]

Test Principle

Sputum culture was performed using an automated liquid culture medium (BACTEC MGIT 960 System). Sputum smears were prepared and examined in accordance with WHO guidelines.[16] A 1–2 mL aliquot of the digested sample was frozen at −80 °C while culture processing was underway. Once thawed, the specimen was resuspended using a vortex mixer, and 1 mL of this resuspended specimen was utilized following the manufacturer's guidelines. In brief, the diluted sample was combined with 2 mL of GeneXpert sample reagent, inverted 10 times, and incubated for 15 minutes at room temperature—with an additional inversion performed after the initial 8 minutes. The mixture was subsequently transferred to the cartridge, loaded into the GeneXpert instrument (Cepheid, Sunnyvale, CA), and the instrument then generated and reported the relevant results. All conventional procedures for smear, sputum culture and GeneXpert MTB/RIF were performed following standards.[19]

The chemiluminescence immunoassay method is used to detect the LAM content in human urine (Fully automatic chemiluminescence immunoassay analyzer; equipment model/specification: SMART 500S; Chongqing Kosmai Biotechnology Co., Ltd). Magnetic beads coated with LAM capture antibodies bind to the LAM in the sample, forming a magnetic bead-antibody-antigen complex. This complex then binds to a luminescent marker, forming a magnetic bead-antibody-antigen-acridinium ester-labeled LAM detection antibody immunocomplex. After magnetic separation and washing, pre-trigger and trigger solutions are added to the reaction mixture. The LAM content in the sample is proportional to the Relative Light Units value. Our kit consists of magnetic bead coating (LAM capture antibody coated magnetic beads), luminescent reagent (acridine ester labeled LAM detection antibody), auxiliary reagent (buffer containing surfactant), and LAM antigen freeze-dried powder.

Ethical Approval

This study complied with the Declaration of Helsinki and was approved by the medical ethics committee of the Fourth People's Hospital of Nanning and GuangXi Health Science College. All methods were carried out in accordance with relevant guidelines and regulations. All the enrolled subjects signed informed consent forms. For minors, we have also obtained permission from their guardians and signed informed consent forms. Clinical research registration information can be queried on the following platforms: China National Health Security Information Platform (https://www.medicalresearch.org.cn) (Record number: MR-41-23-044995).

Statistical Analysis

Statistical analysis was performed using SPSS 22.0. All data were statistically described. For categorical data, frequency and the corresponding percentages were reported. The consistency between the results of the test reagent and the reference method were evaluated using the following indicators: positive agreement rate, negative agreement rate, total agreement rate, and Kappa coefficient. The 95% confidence interval was calculated using the Wilson score method.

A kappa value of ≥0.75 was defined as indicating high agreement between results; a value of 0.75 > kappa ≥ 0.40 was defined as moderate agreement; and a value of <0.40 was defined as poor agreement. The kappa value was computed, and the corresponding P-value was reported, with $P < 0.05$ considered statistically significant.

Results

Basic Information of Participants

A total of 193 participants were enrolled in this clinical trial, of which 192 completed the trial, and 1 withdrew. LAM testing was completed for 192 participants, and all results were valid. Other TB test results for all 192 participants were complete. Among the 192 participants, 134 were male (69.79%) and 58 were female (30.21%), with an average age of 53.69±17.62 years, ranging from 8 to 87 years. The age distribution (<20, 20–29, 30–39, 40–49, 50–59, ≥60) was as follows: 12 (6.25%), 14 (7.29%), 14 (7.29%), 24 (12.50%), 44 (22.92%), and 84 (43.75%). On the basis of meeting the gold standard plus the CRS, 87 cases were diagnosed with TB, including: 80 cases of pulmonary TB (41.67%, 80/192), 7 cases of extrapulmonary TB (EPTB) (3.65%, 7/192), and 105 cases of non-TB (54.69%, 105/192), as shown in Table 1.

Analysis of Evaluation Indicators

Qualitative Analysis Results

Among the total 192 samples, the LAM test results showed 62 positive cases (62/192) and 130 negative cases (130/192). Among the 87 enrolled subjects clinically diagnosed with TB who met the CRS, 56 tested positive for LAM. Among the 105 enrolled subjects excluded from clinical TB diagnosis under the CRS, 99 tested negative for LAM. Using the CRS as the standard, the positive agreement rate of LAM was 64.37% (56/87), the negative agreement rate was 94.29% (99/105), the total agreement rate was 80.73% ((56+99)/192), and the Kappa value was 0.6013. The chi-square test showed a P-value of 0.009, as shown in Table 2.

Performance Analysis for Different Types of TB

For the 80 cases of pulmonary TB, the positive agreement rate of the LAM test was 62.50% (50/80). For the 7 cases of extrapulmonary TB, the positive agreement rate of the LAM test was 85.71% (6/7).

Table 1 Baseline Demographic and Clinical Characteristics of the Study Participants

Characteristic	All (n=192)	Characteristic	All (n=192)
Gender, male (%)	134 (69.79%)	Non TB, N(%)	105(54.69)
Age, year, Mean ± SD	53.69 ± 17.62	AIDS, N(%)	39(37.14%)
TB, N(%)	80 (41.67)	Pneumonia, N(%)	33(31.43%)
EPTB, N(%)	7 (3.65)	Lung cancer, N(%)	11(10.48%)

Abbreviations: AIDS, Acquired Immune Deficiency Syndrome; EPTB, extrapulmonary tuberculosis; TB, Tuberculosis.

Table 2 Results of LAM Detection in Participants Clinically Diagnosed with TB

		Diagnosed with TB		Total	*Kappa*	95% CI	P
		Positive	Negative				
LAM	Positive	56	6	62	0.6013	0.4904–0.7123	<0.001
	Negative	31	99	130			
Total		87	105	192			

Notes: Kappa=(PA-Pe)/(1-Pe), PA=(56+99)/192,Pe=[62*87+130*105]/192^2. TB=Tuberculosis.

Bacteriological Examination Results

Among the 87 clinically diagnosed TB patients, 85 underwent sputum smear examination, and 73 underwent sputum culture examination.

Sputum Smear: Of the 85 TB patients with sputum smear results, 20 were smear-positive (smear-positive detection rate: 23.53% (20/85)), and 54 were LAM-positive while 31 were LAM-negative, with a LAM positive detection rate of 63.53% (54/85) (P<0.001), as shown in Table 3.

Among the 20 smear-positive participants, 12 were LAM-positive and 8 were LAM-negative, with a positive detection rate of 60.00% (12/20). Of the 65 smear-negative TB patients, 42 were LAM-positive, and 23 were LAM-negative, with a positive detection rate of 64.62% (42/65).

Sputum Culture: Among the 73 TB patients with sputum culture results, 24 were culture-positive (culture-positive detection rate: 32.88% (24/73)), and 48 were LAM-positive while 25 were LAM-negative, with a LAM positive detection rate of 65.75% (48/73) (P<0.001), as shown in Table 4.

Among the 24 culture-positive participants, 18 were LAM-positive and 6 were LAM-negative, with a positive detection rate of 75.00% (18/24). Of the 49 culture-negative TB patients, 30 were LAM-positive, and 19 were LAM-negative, with a positive detection rate of 61.22% (30/49).

Molecular Biology Examination Results

Among the 87 clinically diagnosed TB patients, 82 underwent molecular biology testing. Of these, 43 were molecular biology-positive (molecular biology-positive detection rate: 52.44% (43/82)), while 51 were LAM-positive and 31 were LAM-negative, with a LAM positive detection rate of 62.20% (51/82) (P=0.207), as shown in Table 5. Among the 43 molecular biology-positive patients, 31 were LAM-positive and 12 were LAM-negative, with a positive detection rate of 72.09% (31/43). Of the 39 molecular biology-negative patients, 20 were LAM-positive and 19 were LAM-negative, with a positive detection rate of 51.28% (20/39).

Table 3 Comparison of Sputum Smear Results and LAM Test Results in TB Patients

		LAM				Total	Proportion of LAM Positivity	95% CI
		Positive		Negative				
		TB	EPTB	TB	EPTB			
Diagnosed with TB	Sputum smear positive	12	0	8	0	20	60.00%	38.66%-78.12%
	Sputum smear negative	36	6	22	1	65	64.62%	52.48%-75.12%
Total		48	6	30	1	85	63.53%	52.92%-72.97%

Abbreviations: TB, Tuberculosis; EPTB, extrapulmonary tuberculosis.

Table 4 Comparison of Sputum Culture Results and LAM Test Results in TB Patients

		LAM				Total	Proportion of LAM Positivity	95% CI
		Positive		Negative				
		TB	EPTB	TB	EPTB			
Diagnosed with TB	Sputum culture positive	18	0	6	0	24	75.00%	55.10%-88.00%
	Sputum culture negative	26	4	18	1	49	61.22%	47.25%-73.57%
Total		44	4	24	1	73	65.75%	54.33%-75.61%

Abbreviations: TB, Tuberculosis; EPTB, extrapulmonary tuberculosis.

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Table 5 Comparison of Molecular Biology Test Results and LAM Test Results in TB Patients

		LAM				Total	Proportion of LAM Positivity	95% CI
		Positive		Negative				
		TB	EPTB	TB	EPTB			
Diagnosed with TB	Molecular biology testing positive	30	1	12	0	43	72.09%	57.31%-83.25%
	Molecular biology testing negative	16	4	18	1	39	51.28%	36.20%-66.13%
Total		46	5	30	1	82	62.20%	51.38%-71.92%

Abbreviations: TB, Tuberculosis; EPTB, extrapulmonary tuberculosis.

Discussion

We compared the detection rates of the LAM produced by Guangzhou Reador Biotechnology Co., Ltd with other TB diagnostic methods, and the results show that the LAM developed by Guangzhou Red Biotechnology Co., Ltd. performs well for in vitro qualitative detection of LAM levels in human urine samples to aid in the diagnosis of TB.

TB is a chronic disease caused by infection with Mycobacterium tuberculosis when the immune system is weakened.[20,21] It can involve almost any organ of the body such as the lungs, kidneys, and pleura.[22] TB has a high infection rate and strong drug resistance, severely impacting the physical and mental health of patients and placing a heavy burden on their families. China, ranked as the third highest TB-burden country, sees healthcare institutions, especially primary care facilities, seeking simple, rapid, and easy-to-use diagnostic methods to promptly identify and diagnose TB patients as a key measure in controlling the spread of TB.[3,23] LAM, a key glycolipid component of the Mycobacterium tuberculosis cell wall, can make up to 15 mg/g of the total bacterial weight and serves as a specific antigen for Mycobacterium tuberculosis.[24] Urinary LAM testing is an important diagnostic tool for TB, with potential advantages in reflecting bacterial load. Currently, the WHO recommends the use of LAM.[25,26] To address LAM's limitation of only moderate sensitivity, Japan has developed the next-generation Fujifilm SILVAMP TB LAM (FujiLAM) test.[27] This study applied the LAM test kit (chemiluminescence method) developed by Guangzhou Red Biotechnology Co., Ltd. for the in vitro qualitative detection of LAM levels in human urine samples. The results indicate that urine-based LAM testing offers high specificity and, when combined with traditional pathogen detection methods, can significantly improve detection rates. Additionally, it demonstrated a high positive agreement rate in diagnosing TB. In TB-negative cases, LAM urine testing showed high specificity (with a negative agreement rate of 94.29%), effectively reducing false positives and helping rule out non-TB cases. Compared to traditional diagnostic methods such as sputum smear, sputum culture, and molecular biology testing, urine-based LAM testing exhibited a significantly higher detection rate ($P < 0.05$). Combining urinary LAM antigen testing with traditional pathogen diagnostics may offer a novel approach for diagnosing pulmonary TB.

This study compared LAM urine testing with other standard TB diagnostic methods and found that LAM has clear feasibility and advantages in assisting TB diagnosis. The results showed that LAM had an overall agreement rate of 80.73%, a positive agreement rate of 64.37%, and a negative agreement rate of 94.29%. This suggests that LAM has specificity in detecting TB, particularly in ruling out non-TB cases, especially for pulmonary TB. Compared to traditional sputum smear and sputum culture methods, LAM displayed varying strengths across different types of TB patients. Among patients with positive sputum smears, LAM's positive detection rate was 60.00%, while among patients with positive sputum cultures, the positive detection rate was 75.00%. This indicates that when combined with other diagnostic methods, LAM can serve as a powerful adjunct tool to improve the overall diagnostic accuracy for TB.

Among the 87 patients clinically diagnosed with TB, 85 underwent sputum smear testing alongside urinary LAM testing. The positive detection rate for sputum smear was 52.44%, while for urinary LAM testing, it was 62.20%. Out of the 73 patients who underwent sputum culture along with urinary LAM testing, the positive detection rate for sputum culture was 32.88%, compared to 65.75% for urinary LAM testing. Furthermore, among the 82 patients who underwent molecular biology testing along with urinary LAM testing, the positive detection rate for molecular biology testing was

32.88%, while it was 62.70% for urinary LAM testing. Additionally, molecular biology testing showed that LAM had a positive detection rate of 72.09% among molecular biology-positive patients, further validating its effectiveness as an auxiliary diagnostic tool. This confirms that LAM is a feasible method for diagnosing TB patients. In addition, we observed that in the comparison of these three detection methods with LAM, LAM exhibited an overall higher positive agreement rate, which may be attributed to two main factors. First, the collection site and concentration of sputum specimens are associated with the test results. We only collected sputum expectorated by patients, which is likely to have influenced the outcomes. This suggests that LAM is a relatively ideal detection method for patients who refuse bronchoscopy sampling. Second, for the 7 cases of EPTB, the positive agreement rate of the LAM test was 85.71%, and the data from these patients also affected the positive detection rates of different methods. For instance, we noted that among patients with negative GeneXpert results, the positive rate of LAM testing was as high as 20/39; however, after excluding data from EPTB patients, this ratio decreased to 16/39. Based on these findings, we confirm the effectiveness of LAM for EPTB detection and recognize its "non-invasive advantage" and high sensitivity in patients "unable to expectorate sputum (eg, children, critically ill patients)" or those with inadequately obtained sputum specimens.For patients who have difficulty producing sputum, such as children and critically ill patients, LAM testing offers a non-invasive alternative diagnostic method, reducing patient discomfort and pain.[28–30] Based on the results of this study, LAM testing has potential for the diagnosis of TB.

In fact, the diagnostic value of the LAM urine testing method obtained in this study aligns with previous international studies evaluating its diagnostic potential.[31] Urinary LAM antigen testing has significant potential for preliminary TB screening, as well as for diagnosis and prognosis monitoring in pediatric TB patients. A study by Broger T et al which included 372 HIV-negative outpatients, showed that, compared to microbiological reference standards (MRS), the sensitivities of AlereLAM, FujiLAM, and EclLAM were 10.8%, 53.2%, and 66.7%, respectively. The specificities of AlereLAM, FujiLAM, and EclLAM were 92.3%, 98.9%, and 98.1%, respectively.[32] This is consistent with our study's findings, which, although not limited to outpatient populations, yielded similar diagnostic results, indicating that the LAM test kit (chemiluminescence method) developed by Guangzhou Red Biotechnology Co., Ltd. for FujiLAM urine testing could be used for population-wide screening in high-TB-burden cities in China.

The clinical significance of LAM testing lies in its ability to quickly and easily provide diagnostic information. Traditional TB diagnostic methods, such as sputum culture, require a long time, while new technologies such as Xpert MTB/RIF Ultra and Xpert MTB/RIF offer higher sensitivity but rely on specialized testing equipment and come with high costs. In comparison, urinary LAM test kits are much more affordable.[33–35] The implementation of systematic LAM urine testing is straightforward and requires only minimal training, making it suitable for primary healthcare institutions. Its simplicity and speed make it suitable for use in primary healthcare settings and resource-limited areas, may help to improve the early diagnosis and timely treatment of TB. In the future, LAM testing could be considered for inclusion in standard TB screening programs to complement existing diagnostic methods and enhance overall diagnostic accuracy for TB. In cases where traditional methods struggle, LAM could provide an complementary tool. With further large-scale clinical studies and multi-center validation, LAM testing is expected to play a greater role in TB diagnosis and contribute to the progress of TB prevention and control efforts.

Limitations

Despite the potential of LAM testing for diagnosing TB, this study also has some limitations. This study involved a relatively small sample size, mainly concentrated in a single region. The sample size of EPTB is only 7 cases, and the 85.71% detection rate of LAM for EPTB still requires validation through large-sample experiments. Future clinical trials with larger sample sizes and broader study areas are needed to validate the stability and reliability of these preliminary findings and to assess the testing's effectiveness in different regions and populations. In addition, the results of each detection method only involve qualitative evaluation. We did not record specific test values or conduct detailed comparative analyses. In future studies, we will further verify the differences in quantitative analysis and conduct additional validation of the results.

Conclusion

In summary, the LAM test kit developed by Guangzhou Reador Biotechnology Co., Ltd. can be used for in vitro qualitative detection of LAM in human urine samples, aiding in the diagnosis of TB. It provides diagnostic information quickly, easily, and cost-effectively, particularly showing good performance in diagnosing TB. Therefore, urinary LAM antigen testing holds great promise for application in high TB burden areas. This study provides a theoretical basis for the promotion of urinary LAM assay in healthcare institutions in China.

Abbreviations

TB, Tuberculosis; WHO, World Health Organization; LAM, lipoarabinomannan; TST, tuberculin skin test; BCG, Bacillus Calmette Guerin; EPTB, extrapulmonary tuberculosis; ATT, anti-tuberculosis treatment.

Data Sharing Statement

The datasets generated during and/or analyzed during the current study are available from corresponding author Huaying Liu on reasonable request.

Ethical Statement

This study was approved by the medical ethics committee of the Fourth People's Hospital of Nanning and GuangXi Health Science College. All methods were carried out in accordance with relevant guidelines and regulations. All the enrolled subjects signed informed consent forms. Clinical research registration information can be queried on the following platforms: China National Health Security Information Platform (https://www.medicalresearch.org.cn) (Record number: MR-41-23-044995).

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Disclosure

Xiaolu Luo, Keke Xin, Feie Lai, and Zhouhua Xie are co-first authors for this study. The authors declare that they have no conflicts of interest in this work.

References

1. Suárez I, Fünger SM, Kröger S, Rademacher J, Fätkenheuer G, Rybniker J. The diagnosis and treatment of tuberculosis. *Dtsch Arztebl Int*. 2019;116(43):729–735. doi:10.3238/arztebl.2019.0729
2. Natarajan A, Beena PM, Devnikar AV, Mali S. A systemic review on tuberculosis. *Indian J Tuberc*. 2020;67(3):295–311. doi:10.1016/j.ijtb.2020.02.005
3. World Health Organization. Global tuberculosis report 2023[M/OL]. Geneva: World Health Organization, 2023. https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2023. Accessed November 06, 2025.
4. Koegelenberg CFN, Schoch OD, Lange C. Tuberculosis: the past, the present and the future. *Respiration*. 2021;100(7):553–556. doi:10.1159/000516509
5. Li T, Yan X, Du X, et al. Extrapulmonary tuberculosis in China: a national survey. *Int J Infect Dis*. 2023;128:69–77. doi:10.1016/j.ijid.2022.12.005
6. Reid M, Agbassi YJP, Arinaminpathy N, et al. Scientific advances and the end of tuberculosis: a report from the lancet commission on tuberculosis. *Lance*. 2023;402(10411):1473–1498. doi:10.1016/S0140-6736(23)01379-X
7. Domínguez J, Boeree MJ, Cambau E, et al. Clinical implications of molecular drug resistance testing for mycobacterium tuberculosis: a 2023 TBnet/RESIST-TB consensus statement. *Lancet Infect Dis*. 2023;23(4):e122–e137. doi:10.1016/S1473-3099(22)00875-1
8. Kontsevaya I, Cabibbe AM, Cirillo DM, et al. Update on the diagnosis of tuberculosis. *Clin Microbiol Infect*. 2024;30(9):1115–1122. doi:10.1016/j.cmi.2023.07.014
9. Santos JA, Duarte R, Nunes C. Tuberculin skin test and interferon-γ release assays: can they agree? *Clin Respir J*. 2023;17(2):109–114. doi:10.1111/crj.13569
10. Morel F, Jaffré J, Sougakoff W, Aubry A, Véziris N. Place de la biologie moléculaire dans le diagnostic de la tuberculose [Molecular diagnosis of tuberculosis]. *Rev Mal Respir*. 2020;37(5):412–416. doi:10.1016/j.rmr.2019.09.004
11. Chen X, Zhao J, Chen L, Chen Y, Liu J. Pulmonary Talaromyces marneffei misdiagnosed as smear-negative pulmonary tuberculosis. *Clin Respir J*. 2023;17(8):816–818. doi:10.1111/crj.13661
12. Mor P, Dahiya B, Parshad S, Gulati P, Mehta PK. Recent updates in diagnosis of abdominal tuberculosis with emphasis on nucleic acid amplification tests. *Expert Rev Gastroenterol Hepatol*. 2022;16(1):33–49. doi:10.1080/17474124.2022.2021068

13. Baykan AH, Sayiner HS, Aydin E, Koc M, Inan I, Erturk SM. Extrapulmonary tuberculosıs: an old but resurgent problem. *Insights Imaging*. 2022;13(1):39. doi:10.1186/s13244-022-01172-0
14. Flores J, Cancino JC, Chavez-Galan L. Lipoarabinomannan as a point-of-care assay for diagnosis of tuberculosis: how far are we to use it? *Front Microbiol*. 2021;12:638047. doi:10.3389/fmicb.2021.638047
15. Kraef C, Lindquist E, Svensson E, Cambau E. Diagnostic toolkit for tuberculosis: should we include urine lipoarabinomannan (LAM) detection in the WHO European region? *Clin Microbiol Infect*. 2022;28(11):1406–1408. doi:10.1016/j.cmi.2022.06.022
16. *WHO Consolidated Guidelines on Tuberculosis: Module 3: Diagnosis*. Geneva: World Health Organization; 2025.
17. Gopalaswamy R, Dusthackeer VNA, Kannayan S, Subbian S. Extrapulmonary tuberculosis –An update on the diagnosis, treatment and drug resistance. *J Respir*. 2021;1:141–164.
18. Kaswala C, Schmiedel Y, Kundu D, et al. Accuracy of Xpert MTB/RIF ultra for the diagnosis of tuberculosis in adult patients: a retrospective cohort study. *Int J Infect Dis*. 2022;122:566–568. doi:10.1016/j.ijid.2022.07.016
19. World Health Organization.Global Laboratory Initiative. Mycobacteriology laboratory manual. Available from: https://www.who.int/tb/laboratory/mycobacteriology-laboratory-manual.pdf. Accessed February 6, 2024.
20. Bo H, Moure UAE, Yang Y, et al. Mycobacterium tuberculosis-macrophage interaction: molecular updates. *Front Cell Infect Microbiol*. 2023;13:1062963. doi:10.3389/fcimb.2023.1062963
21. Mir MA, Mir B, Kumawat M, Alkhanani M, Jan U. Manipulation and exploitation of host immune system by pathogenic mycobacterium tuberculosis for its advantage. *Future Microbiol*. 2022;17:1171–1198. doi:10.2217/fmb-2022-0026
22. Ahmed S, Mustahsan SM, Jamil B, Ilyas F. Nasopharyngeal tuberculosis. *J Coll Physicians Surg Pak*. 2022;32(4):S39–S40. doi:10.29271/jcpsp.2022.Supp1.S39
23. Xu C, Xia Y, Hu D, Zhang X, Zhao Y. Financial burden of tuberculosis patients - China, 2020. *China CDC Wkly*. 2023;5(12):266–270. doi:10.46234/ccdcw2023.048
24. Cantera JL, Lillis LM, Peck RB, et al. Performance of novel antibodies for lipoarabinomannan to develop diagnostic tests for mycobacterium tuberculosis. *PLoS One*. 2022;17(9):e0274415. doi:10.1371/journal.pone.0274415
25. Dhana A, Hamada Y, Kengne AP, et al. Diagnostic accuracy of WHO screening criteria to guide lateral-flow lipoarabinomannan testing among HIV-positive inpatients: a systematic review and individual participant data meta-analysis. *J Infect*. 2022;85(1):40–48. doi:10.1016/j.jinf.2022.05.010
26. *WHO Consolidated Guidelines on Tuberculosis: Module 6: Tuberculosis and comorbidities*. Internet. Geneva: World Health Organization; 2024. PMID: 38713785.
27. Herrmann Y, Lainati F, Castro MDM, et al. User perspectives and preferences on a novel TB LAM diagnostic (Fujifilm SILVAMP TB LAM)-a qualitative study in Malawi and Zambia. *PLOS Glob Public Health*. 2022;2(7):e0000672. doi:10.1371/journal.pgph.0000672
28. Comella-Del-Barrio P, Molina-Moya B, Gautier J, et al. Diagnostic performance of the Fujifilm SILVAMP TB-LAM in children with presumptive tuberculosis. *J Clin Med*. 2021;10(9):1914. doi:10.3390/jcm10091914
29. Osório DV, Munyangaju I, Muhiwa A, Nacarapa E, Nhangave AV, Ramos JM. Lipoarabinomannan antigen assay (TB-LAM) for diagnosing pulmonary tuberculosis in children with severe acute malnutrition in mozambique. *J Trop Pediatr*. 2021;67(3):fmaa072. doi:10.1093/tropej/fmaa072
30. Huerga H, Cossa L, Manhiça I, et al. Systematic, point-of-care urine lipoarabinomannan (Alere TB-LAM) assay for diagnosing tuberculosis in severely immunocompromised HIV-positive ambulatory patients. *Am J Trop Med Hyg*. 2020;102(3):562–566. doi:10.4269/ajtmh.19-0493
31. Mathabire Rucker SC, Cossa L, Harrison RE, et al. Feasibility of using determine TB-LAM to diagnose tuberculosis in HIV-positive patients in programmatic conditions: a multisite study. *Glob Health Action*. 2019;12(1):1672366. doi:10.1080/16549716.2019.1672366
32. Broger T, Nicol MP, Sigal GB, et al. Diagnostic accuracy of 3 urine lipoarabinomannan tuberculosis assays in HIV-negative outpatients. *J Clin Invest*. 2020;130(11):5756–5764. doi:10.1172/JCI140461
33. Broger T, Koeppel L, Huerga H, et al. Diagnostic yield of urine lipoarabinomannan and sputum tuberculosis tests in people living with HIV: a systematic review and meta-analysis of individual participant data. *Lancet Glob Health*. 2023;11(6):e903–e916. doi:10.1016/S2214-109X(23)00135-3
34. Kohli M, Schiller I, Dendukuri N, et al. Xpert MTB/RIF Ultra and Xpert MTB/RIF assays for extrapulmonary tuberculosis and rifampicin resistance in adults. *Cochrane Database Syst Rev*. 2021;1(1):CD012768. doi:10.1002/14651858.CD012768.pub3
35. Park M, Kon OM. Use of xpert MTB/RIF and xpert ultra in extrapulmonary tuberculosis. *Expert Rev Anti Infect Ther*. 2021;19(1):65–77. doi:10.1080/14787210.2020.1810565