A Quick Glance of Innovative Tuberculosis Diagnostic Technologies from China 2025

IATB website:https://chinaiatb.org/site-en/

INNOVATION ALLIANCE ON TUBERCULOSIS DIAGNOSIS AND TREATMENT （BEIJING）

October 2025

Forewords

Tuberculosis (TB) is a major public health challenge faced by all humanity. According to the World Health Organization's (WHO) latest estimates, there were nearly 10.8 million new incident TB cases and over 1.2 million TB-related deaths globally in 2023. As a high TB burden country, China has made remarkable achievements in TB control and prevention, however, it continues to face challenges that are common worldwide.

Inability to achieve early TB case detection as well as the large number of incident cases left out of the existing diagnostic cascade have been identified as the greatest challenges facing the End-TB roadmap today. These challenges have been largely due to the inherent limitations of traditional radiological and bacteriological means of detection, which render these technologies unable to meet the demands of proactive case detection among general and at risk populations. Therefore, development, clinical and real-world validation as well as frontline uptake of novel TB screening and diagnosing tools that are suitable for different use cases is urgently needed.

In recent years, China has made rapid advancement in biomedical technology R&D. Many of these innovations have revolutionized TB in-vitro diagnostics (IVD). A number of innovative TB diagnostic and screening products that are novel in mechanism and accurate in performance have been successfully developed by Chinese IVD manufacturers. Evidence from domestic clinical evaluation and operational studies carried out under programmatic conditions have demonstrated that these novel TB IVDs are either on par or close to the thresholds outlined by the latest WHO Target Product Profiles (WHO TPPs).

In order to systematically introduce Chinese developed TB IVD technologies and products to the world. In October 2024, IATB had edited and published the first handbook under the title of 'A Quick Glance of Innovative Tuberculosis Diagnostic Technologies from China.' The handbook made in-depth introduction of 12 Chinese developed TB IVD and CAD products in a format borrowed from the WHO TPPs. Since its publication, the handbook has been well received by TB research communities in and out of China with many positive feedbacks. Built on this momentum, IATB has compiled the second edition of the handbook in which another 12 Chinese indigenously developed novel

TB IVD products (some of the products appeared in the first edition but have been updated in the second edition with new evidence generated in the intervening months) are systematically introduced against the framework as well as performance thresholds given out by the WHO TPPs with an emphasis on the evidences showcasing their accuracy, operational characteristics as well as health-economics generated in real-world and clinical studies so far.

Founded by the initiative of the Beijing Chest Hospital, the Innovation Alliance on Tuberculosis Diagnosis and Treatment (IATB) is a Beijing based not-for-profit and non-government organization with a membership that spans over 85 TB designated hospitals and 45 industrial partners across China. IATB is committed to the fostering of promising indigenously developed novel TB therapeutics, diagnostics and prophylactics through a mechanism known as RITA, or Research, Innovation, Translation and Application. Since founding, IATB has carried out large number of works in the following five domains, namely TB clinical research, R&D and validation of novel TB IVDs, international cooperation, digital medical platform and services, academic promotion as well as capacity building. And IATB stands ready to be a bridging force introducing the most promising of China's innovative TB solutions that are safe, effective and affordable to the world, especially those resource constraint high burden countries.

Dr. Li Liang Dr. Li Liang

Chairman of the Innovation Alliance on Tuberculosis Diagnosis and Treatment (Beijing)
Deputy director of Beijing Chest Hospital, Capital Medical University
Former chair to the Chinese Tuberculosis Society, Chinese Medical Association

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Introduction of IATB

Innovation Alliance on Tuberculosis Diagnosis and Treatment (IATB) is a Beijing based not-for-profit non-gov civil organization. In 2016, it was established by several major tertiary level TB designated hospitals (founding members are Beijing Chest Hospital, Tianjin Haihe Hospital, Wuhan Pulmonary Hospital and Shannxi Provincial TB Hospital) with the initiative of Beijing Chest Hospital. Now IATB has grown to include 130 members including 85 TB hospitals and 45 industrial members. Founding mission of the IATB is in short known as RITA, which stands for Research, Innovation, Translation and Application of promising technologies and tools on the road to END TB in China and beyond.

Under the leadership of a board and a secretariat, IATB operates in the following domains, namely a clinical research consortium, education and training, laboratory quality assurance, remote and online medical services as well as international cooperation. Since its founding, IATB has been operating the China Tuberculosis Clinical Trials Consortium (CTCTC) which was founded in collaboration with the US National Institute of Health (NIH) in September 2013. The research network now covers 34 TB hospitals (all CFDA certified site compliant with GCP standards) and has conducted a number of important clinical researches on novel anti-TB drugs and regimens among Chinese patients. In terms of training and education, IATB organizes a series of important academic events in China, namely the annual China TB R&D Collaboration International Forum, the annual China Tuberculosis International Forum, a co-organizer to the annual National Tuberculosis Academic Forum and the annual Tuberculosis International Training Workshop under the Belt & Road initiative. IATB also conducts cross laboratory quality assurance works, including DST QA, among membership hospitals, and validation studies for innovative TB diagnostics developed by our industrial partners. Since 2017, IATB has been working on a number of online and remote medical platforms, some for clinical data harmonization, the others for remote clinical services for under-developed high-burden regions. IATB recognizes the importance of international cooperation in advancing technological R&D innovation in the field of TB prevention and control. The alliance also recognizes that China has much to offer to the END-TB course through its indigenous innovations and technologies. In this course, IATB has been a driving force for promoting and showcasing Chinese innovative TB solutions on the world stage.

Hugobiotech Co., Ltd.

Company Introduction

1. Company Profile

Hugobiotech, founded in 2017, is a life science enterprise specializing in microbial testing, with a core focus on pathogen identification and antimicrobial resistance (AMR) prediction. Leveraging its proprietary AI-driven microbial multi-omics platform, the company develops advanced technologies for ultra-sensitive pathogen detection and clinical applications, encompassing pathogen identification, drug resistance profiling, adventitious virus screening, and food safety analysis. Our mission is to deliver integrated solutions that strengthen global health systems.

Hugobiotech has long specialized in developing diagnostic solutions for TB. Based on our proprietary primer design platform - MultiPrime, we have developed multiple first-in-class products to meet personalized requirements. For high-burden regions, our high-throughput TB detection system detects 48 tongue-swab samples within 2 hours, offering a simple and efficient solution. Concurrently, another solution delivers accurate species-level identification and relative quantification of MTB and NTM, while simultaneously detecting mutations in TB drug-resistant genes. By supporting precise anti-infective therapy, these approaches empower clinicians to optimize treatments, improve patient outcomes, and combat drug-resistant tuberculosis.

The company's industry leadership is demonstrated through its rigorous evidence-based approach, with over 140 publications accumulating a total Impact Factor (IF) of over 900. Additionally, Hugobiotech's tNGS solution for TB drug resistance prediction was highlighted in a 2024 Lancet Infectious Diseases global analysis as the only solution with evidence-based 24-hour turnaround time (TAT). We collaborate with over 2,000 tertiary hospitals in China and numerous medical institutions worldwide, including those in Indonesia, Singapore, South Africa, Pakistan, and Italy.

2.Basic Information

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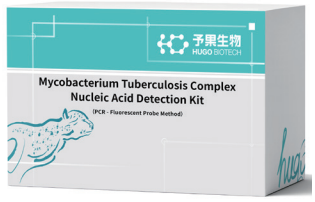
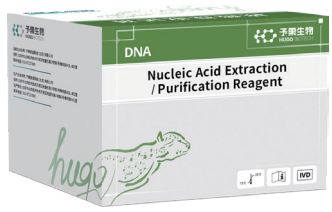
TB-EASY KIT 1.0

1.Product appearance





2. Detailed information

Characteristics	Performance and descriptions	Notes
Intended purpose	The TB-EASY Kit is primarily designed for the detection of tuberculosis (TB) in tongue swabs specimens, enabling rapid and accurate tuberculosis diagnosis. The product is open-platform so it can cover all application scenarios especially primary medical institutions. It can detect 48 samples within 2 hours and be adapted to automation. In this case TB-EASY can be used in screening or diagnosis.	-
Target population	Tuberculosis patients or suspected tuberculosis patients, especially high-risk groups such as HIV and TB co-infected population, People without sputum especially those who are children and patients in ICU.	-
Intended users	The medical personnel with basic testing skills (non-precision pipetting and the most basic sample preparation skills).	-
Regulatory approval of the products	CE	-
Regulatory requirements of manufacture	ISO13485	-
Sensitivity	Compared to sputum Xpert MTB/RIF:89.6% Compared to microbiological reference standard:87.4% [1]	-
Specificity	Compared to sputum Xpert MTB/RIF:96.2% Compared to microbiological reference standard:98.0%[1]	-

Characteristics	Performance and descriptions	Notes
Open platform	TB-EASY kit is suitable for multiple brands of PCR instruments	-
Sample types	tongue swab	-
Time to result	The time from sample collection to result is under 3 hours.	-
Throughput per test	Each test can process up to 48 samples.	-
Reagent kits transport	It is recommended to transport it at -15℃~ -25℃ and 2℃~8℃. Cold chain transportation is required.	-
Shelf life	Valid for 10 - 12 months.	-
Storage environment	Disposable Sample Collection Kit: 10℃ ~ 30℃ Nucleic Acid Extraction/Purification Reagent: 2℃~8℃ Mycobacterium Tuberculosis Complex Nucleic Acid Detection Kit: -15℃ ~ -25℃	-

3. Description of characteristics and advantages

(1) Samples: TB-EASY assay is developed for the in vitro qualitative detection of Mycobacterium Tuberculosis Complex (MTBC) nucleic acid in tongue swabs specimens.

(2) Accuracy: It utilizes target-specific forward and reverse primers, designed from highly-conserved regions of the targeted organisms, to selectively amplify the target nucleic acid from the sample. MTBC is identified through two sets of selective primers and probes that target distinct regions (IS6110 and IS1081). Furthermore, the human housekeeping gene GAPDH serves as internal control (IC) to monitor for potential inhibitory effects within the reaction

TB-Pro Assay

1.Product appearance

2. Detailed information

Characteristics	Performance and descriptions	Notes
Intended purpose	The TB Pro Assay addresses these critical gaps by combining multiplex PCR targeted amplification with next-generation sequencing (NGS) technology. Designed for use with a wide range of clinical samples, including sputum, bronchoalveolar lavage fluid (BALF), blood, and cerebrospinal fluid (CSF), etc., TB Pro delivers accurate species-level identification and relative quantification of MTB and NTM, alongside the detection of mutations in TB drug-resistant genes. This comprehensive approach supports precise anti-infection therapy, positioning TB Pro as an indispensable tool for diagnosing TB, particularly drug-resistant TB. By providing rapid, reliable, and actionable insights, TB Pro empowers clinicians to optimize treatment strategies, improve patient outcomes, and combat the growing threat of drug-resistant tuberculosis.	-
Target population	It is suitable for people who need to undergo TB and related drug resistance testing, especially people with presumed TB or confirmed TB patients, and patients who need drug resistance analysis.	-
Regulatory approval of the products	NMPA Class I	-
Regulatory requirements of manufacture	ISO13485	-

Characteristics	Performance and descriptions	Notes
Sensitivity	TB-Pro showed nearly identical sensitivity compared to TB Pro and Xpert MTB/RIF: 75.5% vs. 74.5%	-
Specificity	Compared to microbiological reference standard:100.0%[2]	Reference(2)
Sample types	including sputum, bronchoalveolar lavage fluid (BALF), blood, and cerebrospinal fluid (CSF), etc.	-
Time to result	The time from sample collection to result is under 24 hours.	-
Reagent kits transport	-15℃~ -25℃	-
Shelf life	Valid for 12 months.	-
Storage environment	-15℃~ -25℃	-

3. Description of characteristics and advantages

(1) The TB Pro assay is designed to identify 49 clinically relevant mycobacterial species, encompassing 10 MTBC and 39 NTM species.

(2) The TB Pro Assay is capable of detecting 26 mycobacterial drug-resistant genes, enabling the prediction of MTBC resistance to 4 first-line and 14 second-line anti-tuberculosis drugs.

(3) The TB Pro assay delivers exceptional sensitivity, with a remarkably low limit of detection (LOD) of 3.0 CFU/mL for M. tuberculosis. The sensitivity and specificity values for the detection of resistance versus WGS were >98%, except for pyrazinamide.

(4) The TB Pro Assay delivers rapid and reliable results with a turnaround time of less than 24 hours, eliminating the need for time-consuming culture-based methods.

4. References

[1] Rapid quantitative PCR on tongue swabs for pulmonary tuberculosis in adults: a prospective multicenter study. Eur Respir J 2025 Jan 2;65(1):2401493.

[2] Application of Targeted Next Generation Sequencing Technology in the Diagnosis of Mycobacterium Tuberculosis and First Line Drugs Resistance Directly from Cell-free DNA of Bronchoalveolar Lavage Fluid. J Infect. 2023 Jan 24:S0163-4453(23)00036-1.

Coyote Bioscience Co., Ltd.

Company Introduction

1.Company Profile

Established in 2009, Coyote Bioscience Co., Ltd. is a national high-tech enterprise focused on molecular diagnostic Point-of-Care Testing (POCT). The company excels in developing innovative products in areas such as instruments, reagents, system platforms, artificial intelligence, and big data. With its headquarters in Beijing, Coyote operates R&D centers in Zhongguancun, Beijing, and Silicon Valley, USA, as well as production facilities in Beijing, Tianjin, and Jiangsu. Additionally, Coyote runs third-party medical testing centers in Tianjin, delivering cutting-edge molecular POCT solutions globally.

Coyote has achieved significant milestones with three generations of advanced molecular diagnostic products. The company possesses independent intellectual property rights and fully domestically manufactured core components that meet international standards. Focusing on infectious diseases, women and children's health, and precision medicine, Coyote provides intelligent and decentralized molecular POCT solutions to enhance user access to diagnostics.

Honors and Achievements

- Designated a national-level high-tech enterprise
- Recognized as a specialized and new "little giant" enterprise
- Demonstration enterprise of the Ministry of Science and Technology's "Torch Program"
- Hosts an academician workstation
- Participated in major national scientific and technological projects
- Winner of the second prize for scientific and technological progress

Coyote's products are available in over 65 countries and regions, certified under ISO13485 quality management standards, and protected by 95 domestic and international patents. The company's products also hold certifications from several countries, including CE (EU), NMPA (China), and ANVISA (Brazil).

Research and Development Status of Existing MTB and MTB&RIF&IHN Products

(1) Automated POCT System

Equipped with a fully automatic nucleic acid detection analyzer and integrated microfluidic consumables, the system integrates sample processing, nucleic acid extraction, and PCR amplification detection steps into the detection cartridge. The operation steps are simple, and the entire process is closed without opening the lid, realizing "sample in, result out".

The detection cartridge is pre-loaded with magnetic beads, lysis buffer, washing buffer, reconstitution buffer, and lyophilized reagents. For sample processing, the sidewall ultrasonic method is adopted to perform 2-minute rapid non-contact processing on the sample in the closed cartridge, which can fully lyse Mycobacterium tuberculosis in the sample. After the sample added, the device automatically performs ultrasonic processing, nucleic acid extraction, reaction system preparation, amplification detection, and result output, thus completing the entire nucleic acid detection process in a closed consumable.

(2) MTB Nucleic Acid Detection and RIF&IHN resistance detection Cartridge

The company has also developed the integrated nucleic acid detection cartridge specifically designed for detecting Mycobacterium tuberculosis in both tongue swab and sputum samples, and simultaneous detection of Mycobacterium tuberculosis, RIF and IHN resistance in sputum samples.

For rifampicin (RIF) resistance testing, the cartridge targets the rpoB gene of Mycobacterium tuberculosis, utilizing four probes that cover the 81-bp rifampin resistance-determining region (RRDR) within the bacterial RNA polymerase beta subunit (rpoB). In terms of isoniazid (IHN) resistance detection, the cartridge incorporates assays for the katG Ser315Thr mutation, mutations at positions -15 and -8 in the inhA promoter region, and the -12T and -6A variations in the aphC promoter region.

To ensure quality assurance, human reference material serves as an internal control, while Bacillus subtilis functions as an external control.

(3) Result interpretation

The detection of MTB, internal quality control, and external quality control showed Ct values and positivity. For the detection of RIF and INH, the melting curve method was used. The Tm values of drug-resistant samples differed from those of wild type samples. Ultimately, the cartridge will determine whether the sample is positive for MTB, as well as whether it shows resistance to rifampicin (RIF) or isoniazid (INH), and specify the resistance or sensitivity status for each of these two drugs.

2.Contact Information

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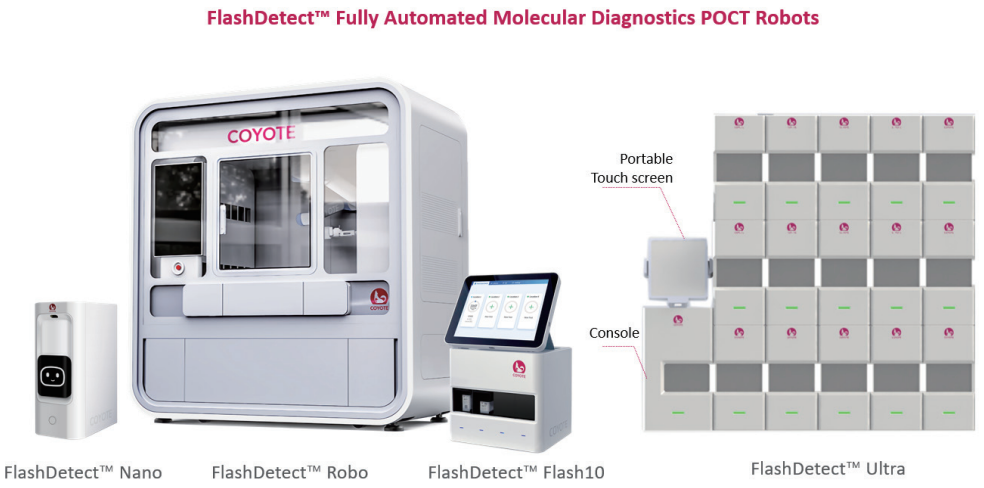
Coyote FlashDetect™ Fully Automated Molecular Diagnostics POCT Robots



1. Product appearance and operation flow chart

MTB&RIF&IHN Assay

FlashDetect™ Ultra

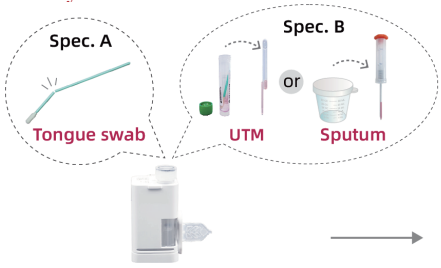
1 Transfer sample to cartridge

2 Insert the cartridge and start test

All-in-One Cartridge, Sample to Result in 60 mins

Fully enclosed and No lid opening during the whole test process

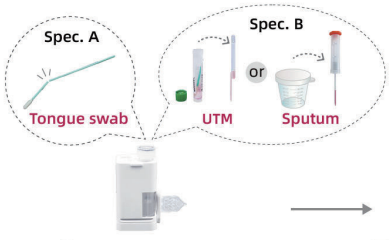
MTB Assay



FlashDetect™ Ultra

1 Transfer sample to cartridge

2 Insert the cartridge and start test



FlashDetect™ Flash10

FlashDetect™ Nano

1 Transfer sample to cartridge

2 Ultra-sonication

3 Insert the cartridge and start test

All-in-One Cartridge, Sample to Result in 30 mins

Fully enclosed and No lid opening during the whole test process after sampling

2. Detailed information

Characteristics	Performance and description		Notes
	MTB&RIF&IHN Assay	**MTB Assay**	
Intended purpose	This product is user-friendly and enables rapid detection, making it ideal for primary healthcare settings. It specifically detects tuberculosis (TB) and identifies resistance to rifampicin (RIF) and isoniazid (INH), providing test results within one hour of the patient's arrival at a medical facility.	This product is user-friendly and enables rapid detection, making it ideal for primary healthcare settings. It specifically targets tuberculosis (TB), with test results available within one hour of the patient's visit to a medical facility.	-
Target population	Testing is available for individuals with suspected or confirmed tuberculosis (TB), including those presenting with symptoms or signs of the disease and their close contacts. The clinical research phase will also encompass children under 14 years of age.	Testing is available for individuals with presumed or confirmed tuberculosis (TB), including those showing symptoms or signs of the disease, as well as their close contacts. The clinical research phase will also include children under 14 years old.	-
Intended users	The product can be operated by medical staff with basic laboratory skills, community health workers, and nursing personnel without specialized training, following a short training session.	Medical staff with basic testing skills, as well as community health workers and nursing staff without specialized training, can operate the product after receiving brief training.	-
Regulatory approval of the products	Currently at the stage of clinical trial of NMPA	CE certification. Currently has completed the clinical trial of NMPA and submission And at the stage of clinical trial of WHO PQ.	-
Regulatory requirements of manufacture	ISO13485	ISO13485	-
Limit of detection	10 CFU/mLfor MTB, 300 CFU/mL for resistance	10 CFU/mL	-

Characteristics	Performance and description		Notes
	MTB&RIF&IHN Assay	**MTB Assay**	
Sensitivity	Clinical trials are about to commence, with data expected to be available by the end of February, 2026.	Sputum-98.95%; Tongue swab-87.40%	-
Specificity	Clinical trials are about to commence, with data expected to be available by the end of February, 2026.	Sputum-98.69%; Tongue swab-99.67%	-
Multiplexing, Mult disease platform	FlashDetect™ Ultra features multiple independent modules capable of detecting distinct pathogens or processing different sample types simultaneously.	FlashDetect™ Flash 10 have four independent modules that can respectively detect different pathogens or different samples; FlashDetect™ Ultra features multiple independent modules capable of detecting distinct pathogens or processing different sample types simultaneously.	-
Sample types	Sputum	Sputum/Tongue swab	-
Manual prep of samples	Low workload	Low workload	-
Time to result	It only takes **60 minutes** from sample collection to results	It only takes 30 minutes from sample collection to results	-

Characteristics	Performance and description		Notes
	MTB&RIF&IHN Assay	**MTB Assay**	
Throughput per test	**Ultra Model:** Equipped with four independent detection modules, this model enables simultaneous analysis of **different pathogens or samples**. Additionally, it supports daisy-chaining up to 10 devices, facilitating high-throughput screening of **40 samples in parallel**. **FlashDetect™ Nano Ultra Model:** This model is equipped with a single detection module, providing efficient testing for individual samples.	**Ultra Model:** Equipped with four independent detection modules, this model enables simultaneous analysis of different pathogens or samples. Additionally, it supports daisy-chaining up to 10 devices, facilitating high-throughput screening of 40 samples in parallel. **FlashDetect™ Nano Ultra Model:** This model is equipped with a single detection module, providing efficient testing for individual samples. **Flash10 Model:** This model consists of four independent detection modules that can simultaneously analyze different pathogen samples. It also supports the connection of up to 10 devices, allowing for the detection of 40 samples at once. **FlashDetect™ Nano Model:** This model features a single detection module, offering efficient testing for individual samples. **FlashDetect™ Robo Model:** With 16 or 32 independent detection modules, this model can simultaneously detect multiple pathogen samples, significantly increasing testing capacity and efficiency.	-
POC or near POC	Yes	Yes	-

Characteristics	Performance and description		Notes
	MTB&RIF&IHN Assay	**MTB Assay**	
Power requirement	**Flash10 Ultra:** Power supply required **FlashDetect ™ Nano Ultra:** Compatible with both power banks.	FlashDetect ™ Nano and Nano Ultra: Compatible with rechargeable batteries (power bank); FlashDetect ™ Robo, Flash10, Flash10 Ultra: Power supply required	-
Operation environment	**Operating Conditions:** •**Temperature:** 10°C to 40°C •**Relative Humidity:** Maximum 80% at temperatures below 31°C; 50% relative humidity at 40°C. **Dust Prevention Measures:** A dust cover is available as an optional accessory.	Operating Conditions: • Temperature: 10°C to 40°C ·Relative Humidity: Maximum 80% at temperatures below 31°C; 50% relative humidity at 40°C. Dust Prevention Measures: A dust cover is available as an optional accessory.	-
Reagent kits transport	Test kits and quality control products should be transported at room temperature (2–28°C) and must not be in transit for more than 5 days.	Test kits and quality control products should be transported at room temperature (2-28°C) and must not exceed a transportation time of 5 days.	-
Shelf life	Valid for 12 months.	Valid for 12 months.	-
Storage environment	Test kits and sample processing quality control products should be stored at 2–28°C and protected from light.	The test kits and sample processing quality control products should be stored at 2-28°C, protected from light. Reference quality control products should be stored at 2-8°C, also away from light.	-

3.Description of Characteristics and Advantages

Unique Highlights

(1) Innovative Sample Types (MTB Assay)

This FlashDetect™ LyocartE MTB Assay is designed for both tongue swabs and sputum samples. Unlike other sample types (such as alveolar lavage fluid, gastric fluid, blood, and feces), tongue swabs are non-invasive, easy to collect,

and pose lower infection risks. This makes them ideal for self-sampling and large-scale screenings, while also reducing sample contamination. This feature is particularly advantageous for a broader demographic, especially children under 14, and has promising applications in clinical diagnostics.

(2) Rapid and Efficient Testing

The FlashDetect™ LyocartE MTB Assay can deliver the results in under 30 minutes from sample input to output.

And the FlashDetect™ Lyocart MTB&RIF&IHN Assay delivers results in under 60 minutes from sample input to output, including both Mycobacterium tuberculosis (MTB) detection and drug resistance profiling (for rifampicin and isoniazid).

This rapid turnaround makes it ideal for immediate testing and point-of-care diagnostics, enabling timely result delivery to patients and reducing the risk of healthcare-associated infections. Notably, it is the first QPCR-based system to achieve such speed while maintaining reliable performance with sputum samples.

(3) Fully Enclosed Design

The all-in-one test kit features a fully enclosed design that integrates ultrasonic treatment, nucleic acid extraction, and PCR amplification—with no need to open the lid at any stage of the testing process. This hermetically sealed design significantly minimizes the risk of cross-contamination, thereby ensuring both operator safety and result accuracy.

(4) High Accuracy

The system employs high-efficiency ultrasonic treatment to liquefy sputum samples and lyse Mycobacterium tuberculosis (MTB) in just 2 minutes. With sensitivity and specificity exceeding those of comparable products, it significantly enhances diagnostic reliability.

(5) Integrated Sampling and Testing

The system is engineered for user-friendliness, requiring only minimal training for operators—no extensive professional expertise is needed. This design makes it well-suited for deployment in primary healthcare facilities, community clinics, and resource-limited regions, thereby expanding access to essential diagnostic services.

Guangzhou Pluslife Biotech Co., Ltd.

Company Introduction

1.Company Profile

Founded in 2017, Pluslife is a biotechnology company engaged in the research, development, production, and commercialization of molecular diagnostic products. Dedicated to improving access to timely and practical molecular testing in real-world healthcare environments, the company delivers solutions that are reliable, affordable, fast, and simple, supporting use across different levels of care. Pluslife prioritizes products that address diagnostic challenges in decentralized and under-resourced settings.

At the core of Pluslife's platform is RHAM (RNase Hybridization-assisted Amplification), a proprietary isothermal amplification technology that supports simplified molecular testing with high usability and broad applicability.[1] The MiniDock system and multiplex test cards offer compact size, minimal hands-on time, and robust performance. These features make them well-suited for primary healthcare, mobile outreach, and other decentralized settings where conventional molecular diagnostics are impractical.

Pluslife holds over 190 patents and certifications globally, including more than 60 granted patents and over 130 international approvals. In July 2025, its MiniDock MTB Test was listed under the Expert Review Panel for Diagnostics (ERPD), further validating the platform's potential. To date, the company's molecular POCT products have been deployed in over 40 countries. To support broader adoption, Pluslife is conducting a multi-center clinical study across more than 10 low- and middle-income countries, covering over 10,000 samples. These efforts are strengthened by ongoing collaborations with leading global health partners, including the Gates Foundation, FIND, R2D2, and Global Health Labs (GHL), among others, which accelerate commercialization across TB, respiratory, STI, and veterinary pipelines.

1 Xiao Z, Liu X, Kang X, Feng Y, Zheng L, Chen C. Rapid and accurate detection of SARS-CoV-2 using the RHAM technology. Sci Rep. 2023;13:22798. doi:10.1038/s41598-023-49733-7.

2. Basic Information

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MiniDock MTB Test

1. Product Appearance and Operation Flow

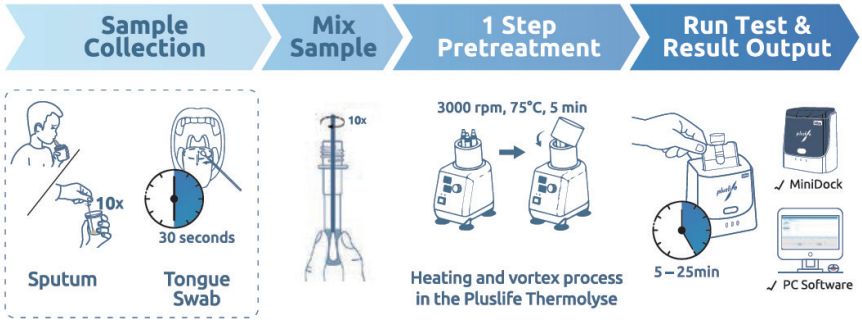
(1) MiniDock MTB Test

(10 Tests/kit, suitable for sputum and tongue swab samples)

(2) Pluslife Thermolyse

(3) MiniDock Ultra

(4) Operation Flow



2. Detailed Information

Characteristics	Performance and descriptions	Notes
Intended purpose	The MTB Nucleic Acid Test Card is a qualitative in vitro diagnostic test for detecting Mycobacterium tuberculosis (MTB) complex DNA in raw sputum and tongue swab samples. This test is intended for the aid of pulmonary tuberculosis diagnosis, and in conjunction with culture and other laboratory findings, as well as clinical signs and symptoms.	-
Target population	Individuals aged 12 years and older, who have not received treatment for TB infection or disease within the previous 12 months or taken medications with antimycobacterial activity within the past 2 weeks, and who are either clinically suspected of having pulmonary tuberculosis (e.g., presenting with a new or persistent cough lasting more than 2 weeks) or at increased risk of TB (including those with HIV infection, self-reported close contact with a TB patient, a history of mining work, and etc).	-
Intended users	Trained users working in laboratory or near point-of-care settings.	-
Regulatory approval of the products	CE-IVD, ERPD listing	In progress: WHO PQ, NMPA
Regulatory requirements of manufacture	ISO13485	-
Sensitivity	Steadman et al.[2] reported MiniDock MTB sensitivity of 85.7% on tongue swabs (60/70; 95% CI: 75.3–92.9%) and 89.9% on sputum swabs (62/69; 95% CI: 80.2–95.8%) vs. MGIT culture.	-
Specificity	Specificity was 100.0% for tongue swabs (226/226; 95% CI: 98.4–100.0%) and 98.2% for sputum swabs (219/223; 95% CI: 95.5–99.3%) vs. MGIT culture.	-

2 Steadman A, Kumar KM, Asege L, Kato-Maeda M, Mukwatamundu J, Shah K, et al. Diagnostic accuracy of swab-based molecular tests for tuberculosis using novel near point-of-care platforms: A multi-country evaluation. medRxiv [Preprint]. 2025. doi:10.1101/2025.04.12.25325603.

Characteristics	Performance and descriptions	Notes
Multiplexing, multi-disease platform	MiniDock Ultra (PM001 Ultra) supports a broad, multiplex assay menu across high-burden infectious diseases—respiratory and STIs—including SARS-CoV-2, monkeypox (mpox), SARS-CoV-2/Flu A/Flu B, Flu A/Flu B/RSV, RSV, Strep A, CT/NG/UU, TV/MG, HPV 16/18/45, GBS, etc., with additional assays in development.	-
Sample types	Sputum, Tongue swab	-
Manual prep of samples	Low workload. The manual preparation before the automated operation of the instrument takes 5 min.	-
Time to result	Result in 5-25 min. Overall TAT ~30 min.	-
Throughput per test	1 sample per run	-
POC or near POC	**Near-POC compatible:** compact, low-complexity workflow for primary clinics, TB centers, and mobile/outreach settings. Requires only MiniDock Ultra and Pluslife Thermolyse—no separate extraction system. Optional: PC software/mobile app available. Connectivity: Type-C/Wi-Fi available.	-
Power requirement	**MiniDock Ultra (PM001 Ultra):** DC 5 V, ≥3 A via USB-C (use supplied DC cable); operates from AC 100–240 V, 50/60 Hz through a standard USB power adapter; UPS-/power-bank–compatible (ensure output meets device rating). **Pluslife Thermolyse (WD002):** AC 100–240 V, 50/60 Hz input via adapter; device runs at DC 12 V; rated power 75 W (heating 60 W; motor 15 W); UPS-compatible. This means MiniDock Ultra and Pluslife Thermolyse work with worldwide AC standards (100–240 V, 50/60 Hz) for reliable use across regions.	-
Operation environment	Room temperature 5–40°C.	-
Reagent kits transport	Transport Reagents at 0–40°C; ship/transport under ambient conditions consistent with this range—cold chain not required.	-
Shelf life	Valid for 13 months.	-

Characteristics	Performance and descriptions	Notes
Storage environment	Store kits at 0–40 °C; keep dry and away from sunlight.	-

3. Description of Characteristics & Advantages

(1) Integrated and User-Friendly Design

The system features a compact, all-in-one design, integrating sample preparation, nucleic acid amplification, and result interpretation in a single platform. This streamlined workflow reduces complexity and makes high-quality molecular diagnosis accessible beyond traditional laboratory environments.

(2) Rapid Results and High Accuracy

With a turnaround time (TAT) of approximately 30 minutes from sample to result, the system enables rapid diagnosis and supports timely clinical decision-making.

In a multi-country preprint analysis versus sputum liquid culture–based MRS, MiniDock MTB showed sputum sensitivity 89.9% and specificity 98.2%; tongue swab sensitivity 85.7% and specificity 100%. These results meet the WHO TPP (non-sputum POC) minimums (≥75% sensitivity; >98% specificity).[2]

Additionally, a large multi-country clinical study is ongoing in collaboration with the R2D2 TB Network, preliminary phase data (n > 1,600) also meet the WHO TPP minimums for non-sputum POC TB diagnostics.

(3) Minimal Hands-On Time and Ease of Use

Less than five minutes of manual handling per test is required, with all critical steps fully automated. This minimizes the risk of user error and allows operation by healthcare providers with only basic training, supporting broader access to reliable diagnostics in decentralized settings.

(4) Flexible Sample Collection Options

Supports sputum or tongue swab samples, expanding access for individuals who struggle to produce sputum—such as children, older adults, and people with conditions that hinder sputum collection. This flexibility broadens inclusion and enables high-quality TB testing across primary care, outreach, and other decentralized settings, helping close the diagnostic gap.

(5) Consistent Performance in Diverse Environments

Both device and reagents are engineered for stability during storage and transport, without the need for cold chain. This ensures dependable performance in a wide range of healthcare environments, including primary care and remote facilities.

(6) Suitable for Decentralized Use

Requiring only a basic power supply and minimal infrastructure—compatible with UPS (uninterruptible power supply) and power banks—the system is well suited for primary care clinics, outpatient departments, and other decentralized healthcare settings. Digital connectivity options, such as USB Type-C and Wi-Fi, facilitate efficient results management and secure data exchange.

(7) Supports People-Centered Diagnostic Pathways

Rapid and accessible testing facilitates early diagnosis and timely linkage to appropriate care, helping to reduce delays and improve health outcomes for individuals being evaluated for tuberculosis.

4. References

[1] Xiao Z, Liu X, Kang X, Feng Y, Zheng L, Chen C. Rapid and accurate detection of SARS-CoV-2 using the RHAM technology. Sci Rep. 2023,13:22798.

[2] Steadman A, Kumar KM, Asege L, Kato-Maeda M, Mukwatamundu J, Shah K, et al. Diagnostic accuracy of swab-based molecular tests for tuberculosis using novel near point-of-care platforms: A multi-country evaluation. medRxiv [Preprint]. 2025.

Leide Biosciences Co., Ltd.

Company Introduction

1. Company Profile

Leide Biosciences Co., Ltd. (LDEBIO), headquartered in Guangzhou, China, is dedicated to delivering innovative in-vitro diagnostic (IVD) solutions for immune-mediated diseases. Our product portfolio includes IVD reagents, diagnostic instruments, and clinical testing services.

LDEBIO operates a modern and integrated R&D, manufacturing, and sales network, highlighted by the **AIMDX Research Center** in Maryland, USA, and the **Leide Clinical Service Laboratory** in Guangzhou. The company is certified with **ISO 13485, ISO 15189, NMPA Class III, CE**, and other key industry qualifications.

Our diagnostics focus on infectious diseases, oncology, organ transplantation, and immunotherapy, with a strong commitment to advancing global health through efficient and accurate diagnostics.

Tuberculosis Diagnostic Pipeline
LDEBIO is actively developing and commercializing tuberculosis diagnostics across multiple platforms:

- AIMTB: Interferon-gamma release assays (IGRAs) for latent TB infection (LTBI) detection, available in chemiluminescence (CLIA), enzyme-linked immunosorbent assay (ELISA), and fluorescence lateral flow (FLF) formats.
  - All AIMTB formats have received NMPA Class III certification.
  - AIMTB supports LTBI screening and TB outbreak control across hospitals, primary care, and public health settings.
  - Performance: FLF-AIMTB shows a sensitivity of 95.56%, specificity of 96.34%, and an overall concordance of 95% compared to the WHO-recommended reference standard.
- AIMLAM: Urine-based lipoarabinomannan (LAM) tests for the diagnosis of active TB.
  - Designed for use in resource-limited settings and among populations where sputum collection is difficult.

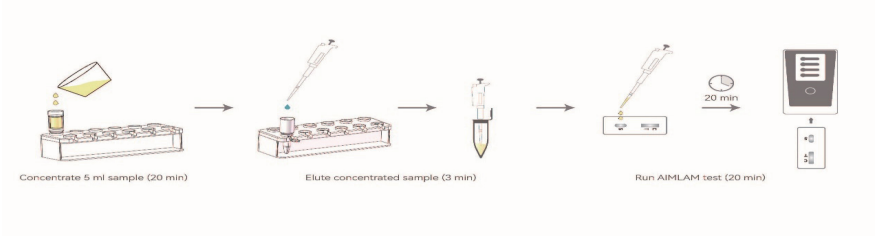
- Demonstrates approximately 70% sensitivity in HIV-negative patients (based on microbiological reference standards, MRS).

2. Basic Information

Company name: Leide Biosciences Co., Ltd.
Address: 7D, Science & Technology Innovation Base, #80 Lanyue Road, Huangpu District, Guangzhou, P.R.China
Official website: www. leidebio.com
Email: overseas@leidebio.com
Telephone: +86 20 32029495

LDEBIO AIMLAM TB Lipoarabinomannan Detection Kit Fluorescence Lateral Flow (FLF)

1. Product appearance and operation flow chart



2. Detailed information

Characteristics	Performance and descriptions	Notes
Intended purpose	Used for auxiliary diagnosis of pulmonary TB and extrapulmonary TB	Results can be obtained on the same day.
Target population	General population (regardless of HIV status) including adults, adolescence, children	-
Intended users	Operators with basic laboratory training	Only one step needs accurate pipetting; the rest can be done with basic sample prep skills and non-precise pipetting

Characteristics	Performance and descriptions	Notes
Regulatory approval of the products	CE	-
Regulatory requirements of manufacture	ISO13485	-
Sensitivity	76.00% (HIV+)	Reference to the instruction manual
Specificity	97.14%	Reference to instruction manual
Sample types	Urine	-
Manual prep of samples	Low workload	-
Time to result	< 1 hour	-
Throughput per test	Single sample, single pathogen	-
POC or near POC	POCT	-
Power requirement	Built-in rechargeable lithium battery	-
Operation environment	Test kit: Temperature 18~28℃, humidity below 80% Chromatography: Temperature -40℃~55℃, humidity not higher than 93%	-
Reagent kits transport	2-30℃, no humidity requirement, no cold chain required	-
Shelf life	24 months	-
Storage environment	Temperature 2-30℃, no humidity requirement	-

3. Description of characteristics and advantages

In addition to advantages listed in the above table, AIMLAM also has the following advantages:

(1) Overcomes the limitations of sputum-based testing by offering non-invasive sampling

AIMLAM overcomes the limitations of traditional TB detection methods that rely on sputum samples by enabling non-invasive detection using urine. It is particularly suited for patients who are unable to produce sputum or have difficulty in sputum collection, such as children, the elderly, critically ill patients, and those with extrapulmonary TB, thereby expanding the test's scope of application.

(2) Near-POC testing: a fast and efficient diagnostic tool

Using its Fluorescence Lateral Flow (FLF) platform, AIMLAM can complete the entire process from sample preparation to result analysis within 1 hour. The detection process is simple, easy to operate, and requires minimal professional skills, enabling rapid diagnosis. This makes it particularly suitable for clinical rapid testing and resource-limited settings.

(3) An ideal alternative testing method for patients with negative etiology results

AIMLAM is an ideal alternative method for patients with negative etiology. It can identify additional TB cases among patients who have tested negative using Gene Xpert, sputum smear, and sputum culture. Therefore, AIMLAM serves as an important supplementary tool in clinical practice, helping to improve the accuracy and comprehensiveness of TB detection.

(4) Innovative detection technology: A urine concentration design that accurately captures samples and improves the detection rate

AIMLAM employs a unique urine concentration device that effectively concentrates lipoarabinomannan (LAM) in urine and combines it with highly specific monoclonal antibodies to accurately capture LAM molecules. This design significantly enhances detection sensitivity and is particularly advantageous for patients with negative etiological results or insufficient sputum.

RIOMAVIX

NOTIFICATION OF REGISTRATION

This is to certify that, according to the European Council Directive 98/79/EC, Riomavix S.L.performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: Leide Biosciences Co., Ltd.

ADDRESS: D-701, 80 LANYUE RD, Guangzhou Science City, Guangdong, CHINA

The manufacturer has provided Riomavix S.L. with all the appropriate declaration according to the European Council Directive 98/79/EC including the Declaration of Conformity confirming that its in vitro diagnostic medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Directive 98/79/EC.

IVD Devices: TB Lipoarabinomannan Determination Kit (Immunochromatography)

Classification: Others

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Directive 98/79/EC are met.

The notification of abovementioned device has been completed by the European Authorized Representative in Spain. The Spain Competent Authority is notifed of the manufacture's device and has allocated registration. The registration number is **RPS/1766/2022**

RIOMAVIX R RIOMAVIX

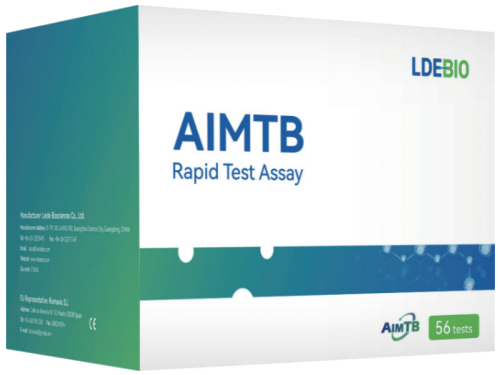
Issue date: 29/Apr/2022
Cert. No.: R20210202-6

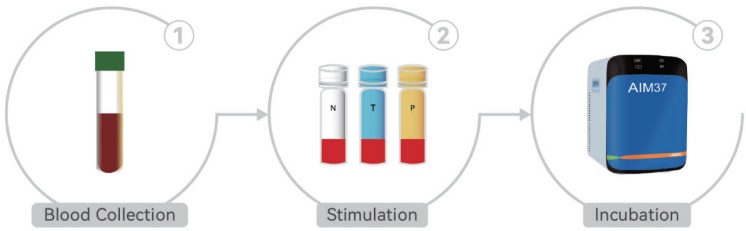
CE

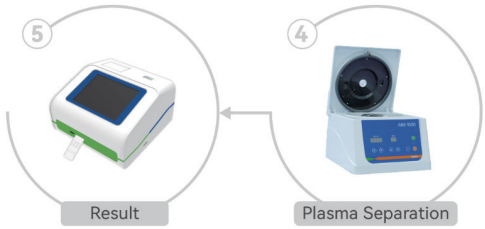
Riomavix S.L. (ES-AR-000001202)
Calle de Almansa 55, 1D, Madrid 28039 Spain

LDEBIO AIMTB - MTB Specific Cellular Immune Response Detection Kit Fluorescence Lateral Flow (FLF)

1. Product appearance and operation flow chart



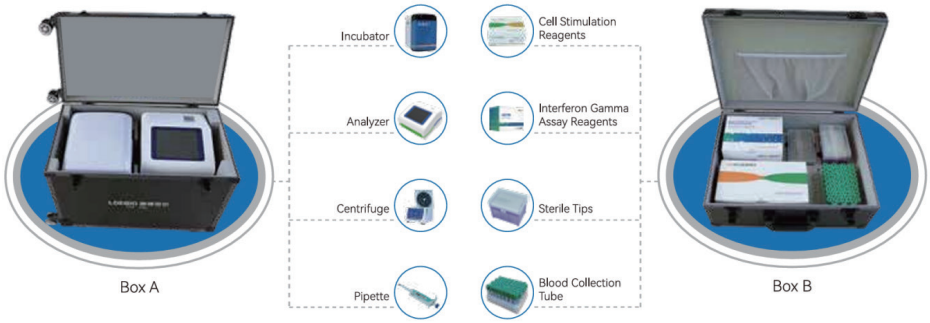




2. Detailed information

Characteristics	Performance and descriptions	Notes
Intended purpose	Used for TB infection testing in primary health-care centers, the results can be obtained the next day	-
Target population	All populations, population under 14 years old was not covered in the validation study	-
Intended users	Medical personnel with basic testing skills	-
Regulatory approval of the products	CE, NMPA Category III certification	-
Regulatory requirements of manufacture	ISO13485	-
Sensitivity	95.56%	Reference to manual
Specificity	96.34%	Reference to manual
Multiplexing, multi-disease platform	Other pathogens can be detected	-
Sample types	Venous whole blood	-
Manual prep of samples	Medium workload	-
Time to result	16.5-24.5 hours	-
Throughput per test	One sample targeting one pathogen can be processed at a time	-
POC or near POC	Near POCT	-
Power requirement	No built-in power supply, can be powered by renewable energy	-
Operation environment	Test kit: 18~28℃, humidity below 80% Chromatography: -10℃~55℃, relative humidity not exceeding 80%.	-
Reagent kits transport	2-30℃, no humidity requirement	-
Shelf life	18 months	-
Storage environment	2-30℃, no humidity requirement	-

3. Description of characteristics and advantages



Based on a sample size of 511, the product shows 94.52% overall agreement with the WHO-recommended IGRA and is broadly applied in both TB auxiliary diagnosis and LTBI screening. This product can be used with mIGRA, a mobile TB detection system. mIGRA is the world's first portable TB detection system, which includes test kits, incubators, chromatographs, centrifuges, pipettes, sterile tips, and blood collection tubes, providing an integrated solution for IGRA TB detection. Its functions encompass sampling, stimulation, incubation, plasma separation and detection. mIGRA enables on-site detection and management of sporadic TB outbreaks, clustered outbreaks, and public health emergencies. It is particularly suitable for scenarios such as emergency close-contact screening and management, as well as screening key populations at the primary level. Additionally, it can be utilized to enhance TB prevention and control capabilities in primary medical and public health institutions.

RIOMAVIX

NOTIFICATION OF REGISTRATION

This is to certify that, according to the European Council Directive 98/79/EC, Riomavix S.L. performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: Leide Biosciences Co., Ltd.

ADDRESS: D-701, 80 LANYUE RD, Guangzhou Science City, Guangdong, CHINA

The manufacturer has provided Riomavix S.L. with all the appropriate declaration according to the European Council Directive 98/79/EC including the Declaration of Conformity confirming that its in vitro diagnostic medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Directive 98/79/EC.

IVD Devices:

AIMTB Rapid Test Assay

Classification: Others

Where the manufacturer affix the CE r
essential requirements of European Cour

The notification of abovementioned de
Representative in Spain. The Spain Con
and has allocated registration. The regist

Executive Director

Calle de Almansa

中华人民共和国
医疗器械注册证（体外诊断试剂）

注册证编号：国械注准20243401650

注册人名称	广州市雷德生物科技有限公司
注册人住所	广州市高新技术产业开发区揽月路80号科技创新基地D区701
生产地址	广州市高新技术产业开发区揽月路80号科技创新基地C区5楼、D区4楼、D区7楼、G区6楼
代理人名称	/
代理人住所	/
产品名称	结核分枝杆菌特异性细胞免疫反应检测试剂盒（荧光免疫层析法）
包装规格	12人份/盒，28人份/盒，56人份/盒，100人份/盒。
主要组成成分	该产品由细胞刺激试剂和γ-干扰素检测试剂组成。细胞刺激试剂由细胞刺激培养管（阳性对照、阴性对照、特异性刺激抗原）组成；γ-干扰素检测试剂由IFN-γ 检测卡和IFN-γ ID卡组成。（具体内容详见说明书）。
预期用途	本产品用于体外定性检测人新鲜外周静脉抗凝血中结核分枝杆菌特异性的T细胞免疫反应。
产品储存条件及有效期	2～30℃保存，有效期18个月。
附　件	产品技术要求、说明书
其他内容	/
备　注	/

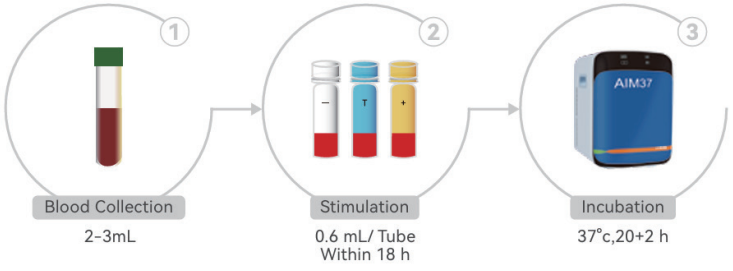
审批部门：国家药品监督管理局

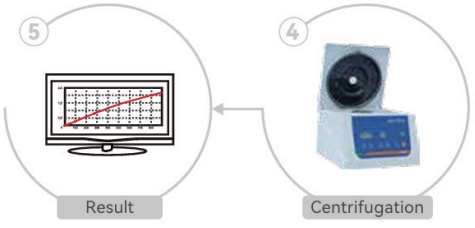
批准日期：二〇二四年九月二日
生效日期：二〇二四年九月二日
有效期至：二〇二九年九月一日

国家药品监督管理局电子证照　https://zwfw.nmpa.gov.cn　2024-09-03 09:49:26:026

LDEBIO AIMTB - MTB Specific Cellular Immune Response Detection Kit Enzyme-linked immunosorbent assay (ELISA)

1. Product appearance and operation flow chart





2. Detailed information

Characteristics	Performance Indicators	Notes
Intended purpose	Used for TB infection testing in laboratories	Results are due the next day
Target population	All populations, population under 14 years old was not covered in the validation study	-
Intended users	Medical personnel with basic testing skills	-
Regulatory approval of the products	CE, NMPA Category III certification	-
Regulatory requirements of manufacture	ISO13485	-
Sensitivity	85.9%	Reference to manual
Specificity	93.6%	Reference to manual
Multiplexing, multi-disease platform	Other pathogens can be detected	-
Sample types	Venous whole blood	-
Manual prep of samples	Highly complex	-
Time to result	23-25 hours	-
Throughput per test	30 samples can be processed at a time, targeting 1 pathogen	-
POC or near POC	No	-
Power requirement	No built-in power supply	-
Operation environment	Cell stimulation kit: Store below 28°C Interferon-γ detection kit: Store at 2~8℃	-
Reagent kits transport	Cell stimulation kit: Store below 28°C Interferon-γ detection kit: Store at 2~8℃	-
Shelf life	12 months	-
Storage environment	Cell stimulation kit: Store below 28°C Interferon-γ detection kit: Store at 2~8℃	-

3. Description of characteristics and advantages

(1) No need for a second visit, results available within 24 hours;
(2) Not affected by BCG and most NTMs;
(3) High sensitivity and specificity;
(4) Highly efficient and cost-effective for screening of LTBI.

RIOMAVIX

NOTIFICATION OF REGISTRATION

This is to certify that, according to the European Council Directive 98/79/EC, Riomavix S.L. performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: Leide Biosciences Co., Ltd.

ADDRESS: D-701, 80 LANYUE RD, Guangzhou Science City, Guangdong, CHINA

The manufacturer has provided Riomavix S.L. with all the appropriate declaration according to the European Council Directive 98/79/EC including the Declaration of Conformity confirming that its in vitro diagnostic medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Directive 98/79/EC.

IVD Devices:

AIMTB Assay

Classification: Others

Where the manufacturer affix the
essential requirements of European

The notification of abovemention
Representative in Spain. The Spai
and has allocated registration. The

Executive Director

Calle de Al

中华人民共和国
医疗器械注册证（体外诊断试剂）

注册证编号：国械注准20193400999

注册人名称	广州市雷德生物科技有限公司
注册人住所	广州市高新技术产业开发区揽月路80号科技创新基地D区701
生产地址	广州市高新技术产业开发区揽月路80号科技创新基地C区5楼、D区4楼、D区7楼、G区6楼
代理人名称	/
代理人住所	/
产品名称	结核分枝杆菌特异性细胞免疫反应检测试剂盒（酶联免疫法）
包装规格	24人份/盒、28人份/盒
主要组成成分	细胞刺激试剂盒、γ干扰素检测试剂盒。（具体内容详见说明书）
预期用途	本产品用于体外定性检测人新鲜外周静脉抗凝血中结核分枝杆菌特异性的T细胞免疫反应。
产品储存条件及有效期	储存条件：细胞刺激试剂盒：28℃以下，γ干扰素检测试剂盒：2~8℃有效期：12个月。
附　件	产品技术要求、说明书
其他内容	/
备　注	/

审批部门：国家药品监督管理局

批准日期：二〇二四年六月十七日
生效日期：二〇二四年十二月十三日
有效期至：二〇二九年十二月十二日

国家药品监督管理局电子证照 https://zwfw.nmpa.gov.cn 2024-06-24 16:06:24:024

Ustar Biotechnologies (Hangzhou) Ltd.

Company Introduction

1. Company Profile

Founded in 2005, Ustar Biotechnologies (Hangzhou) Ltd. Is committed to the research, development, production, and sales of innovative point-of-care molecular diagnostic (POCT) technologies and products. Its products have been exported to over 90 countries and are widely utilized in various scenarios such as primary medical institutions, customs, and airports. The company actively promotes innovative molecular detection products to low- and middle-income countries to enhance local molecular diagnostic capabilities and closely collaborates with international organizations like the Foundation for Innovative New Diagnostics (FIND) to contribute to the prevention and control of major infectious diseases like TB globally.

Ustar's molecular POCT TB diagnostic technology comprehensively encompasses multiple detection items, including rapid TB diagnosis, differential diagnosis of MTB/NTM, detection of MTB and rifampicin resistance mutations, detection of MTB and isoniazid resistance mutations, detection of mycobacterium tuberculosis complex (MTBC) and extensively drug-resistant mutations, and MTB typing, etc. Its MTBC nucleic acid detection kit has obtained NMPA and IVDR certifications. Multiple product features, like "fully automatic POCT detection integration, support for tongue swab detection, and low requirements for the detection environment", help boost the convenience and accessibility of TB detection. Currently, Ustar's molecular POCT TB diagnostic technology has been employed in nearly 500 medical institutions in China and more than ten countries, including India, Indonesia, the Philippines, Pakistan, the United Arab Emirates, South Africa, Uganda, Nigeria, Algeria, and Costa Rica.

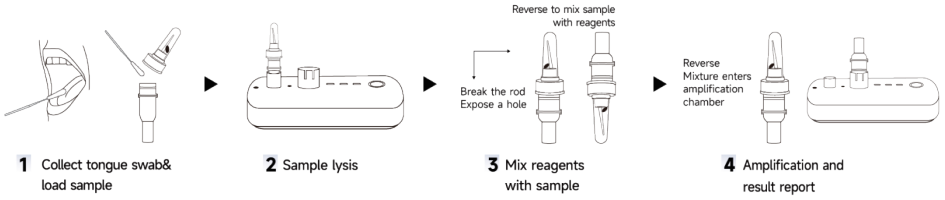
Ustar continuously adheres to its core vision of "Molecular Testing Anywhere" and is dedicated to becoming a unique international biotechnology company, serving the general public with advanced diagnostic technologies.

2. Basic Information

Company Name: Hangzhou Ustar Biotechnologies Co., Ltd.
Address: 6th Floor, Building 2, No. 611, Dongguan Road, Binjiang District, Hangzhou
Official website: www.bioustar.com
Email: sales@bioustar.com
Telephone: 0571-88939388

Ustar PortNAT Nucleic Acid Testing System

1. Product appearance and operation flow chart



2. Detailed information

Characteristics	Performance and description	Notes
Intended purpose	Suitable for deployment at primary institutions, the target diseases for diagnosis is pulmonary TB. It allows patients to get the results on the same day of visiting a medical institution and allows clinicians to make decisions on whether to include anti-TB chemotherapy.	-
Target population	Applicable population for testing: adults, adolescence, children Plan to include children (under 14 years old) in the validation study or clinical research phase	-
Intended users	Suitable for community health workers or caregivers with no skills at all	-
Regulatory approval of the products	CE certification	-

Characteristics	Performance and description	Notes
Regulatory requirements of manufacture	ISO13485, MDSAP	-
Sensitivity	Hunan Chest Hospital and Ustar Biotechnologies (Hangzhou) Ltd. conducted a study on the detection of TB in tongue swabs. The study compared the detection performance of Ustar PortNAT TB Assay and Xpert MTB/RIF Ultra on tongue swabs. The study included 125 tongue swab samples from people with presumed TB. Among all the samples, PortNAT TB Assay detected 56 TB positives and 69 negatives. The control reagent Xpert MTB/RIF Ultra detected 60 TB positives and 65 negatives. The positive coincidence rate of PortNAT TB Assay and Xpert MTB/RIF Ultra was 93.3%, the negative coincidence rate was 100%, and the overall coincidence rate was 96.8%.	-
Specificity		-
Multiplexing, multidisease platform	While testing for TB, other pathogens cannot be tested simultaneously	-
Sample types	In addition to tongue swab samples, sputum samples can also be tested	-
Manual prep of samples	Low workload, self-testing by patient is applicable	Low Medium High
Time to result	About 30 minutes	-
Throughput per test	Each test can process one sample, and one test cannot process samples for multiple different pathogens	-
POCT or near POCT	POCT Device	-
Power requirement	Need to use external rechargeable battery	-
Operation environment	Ambient temperature: 5~40℃ Ambient humidity: 25~90%RH Dust prevention measures: There is a dust cover (and there is no fan inside this product to reduce dust entry).	-
Reagent kits transport	Can be transported at normal temperature (-25~37℃)	-
Shelf life	18 months	-
Storage environment	2~8℃ + 80% RH	-

3. Description of characteristics and advantages

The Ustar PortNAT nucleic acid test system boasts both the convenience of antigen testing and the sensitivity of nucleic acid testing. The device is compact, easy to operate, and can quickly provide test results. It adopts a detachable test tube design to meet a variety of testing needs, including respiratory, reproductive health, food safety and pet pathogen testing, offering a portable and accurate testing method of on-site rapid testing for home users, communities, pharmacies, public places, medical institutions at all levels, airport customs, etc.

The PortNAT nucleic acid test system employs a single-piece design where the incubation base is reusable, and the test tube integrates sample lysis and nucleic acid amplification functions. It is based on the principle of cross primer constant temperature amplification (CPA) and is used for the detection of target nucleic acids (DNA/RNA) in biological samples. It uses fluorescence detection technology and automatically displays the results. When analyzing, users can refer to the corresponding instructions according to the instrument detection data.

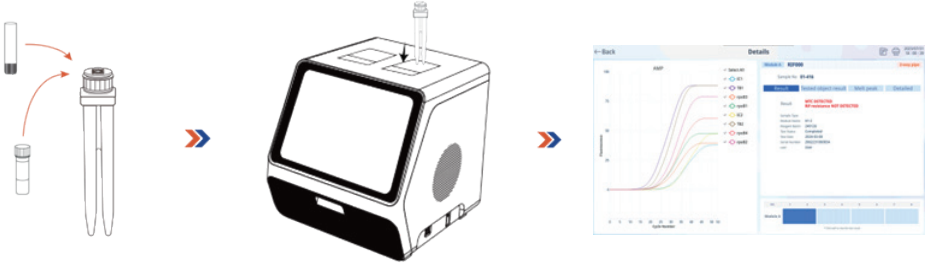
Currently, with the support of the Foundation for Innovative New Diagnostics (FIND) and Stop TB, the Ustar PortNAT nucleic acid testing system is undergoing clinical validation in South Africa, Indonesia, Uganda, Kenya, Nigeria, Cameroon, Vietnam, India and other countries.

4. References

WHO High-priority target product profiles for new TB diagnostics: report of a consensus meeting [C/OL] (28-29 April 2014). https://iris.who.int/bitstream/handle/10665/135617/WHO_HTM_TB_2014.18_eng.pdf?sequence=1

Ustar MultNAT Molecular diagnostic testing system Automatic PCR Analyzer

1. Product appearance and operation flow chart



①Load Sample ②Test ③Report

2. Detailed information

Characteristics	Performance and descriptions	Notes
Intended purpose	Suitable for deployment at primary institutions, the target diseases for diagnosis are pulmonary TB and extrapulmonary TB. It allows patients to get the results on the same day of visiting a medical institution and allows clinicians to make decisions on whether to include anti-TB chemotherapy	-
Target population	Applicable population for testing: adults, adolescence, children Plan to include children (under 14 years old) in validation studies or clinical research	-

Characteristics	Performance and descriptions	Notes
Intended users	Suitable for medical personnel with basic testing skills (non-precision pipetting and minimal sample preparation skills)	-
Regulatory approval of the products	CE, NMPA, FDA	-
Regulatory requirements of manufacture	ISO13485, MDSAP	-
Sensitivity	**MTC/RIF project testing data** Comparision platform:Ustar MultNAT & Cepheid Gene Xpert Ultra **Sample: sputum** Site:Hangzhou Red Cross Hospital (Zhejiang Provincial Hospital of Integrated Traditional Chinese and Western Medicine), Hunan Chest Hospital, Guangzhou Chest Hospital MTC confirmed cases: 585, Positive Concordance rate: 99.32%, 95% CI (98.26%-99.73%) Negative Concordance rate: 99.47%, 95% CI (98.10% -99.86%) Overall concordance rate: 99.38%, 95% CI (98.65%-99.72%) Effective cases: 996, RIF resistance cases: 532 RIF resistance Positive Concordance rate: 100% RIF resistance Negative Concordance rate: 100% RIF resistance Overall concordance rate: 100% **Sample: Tongue Swab** **Suspected MTC/RIF positive samples:108** Positive Concordance rate: 98.46% Negative Concordance rate: 97.67% Overall concordance rate: 98.15% MTB positive samples: 64 RIF resistance Positive Concordance rate: 100% RIF resistance Negative Concordance rate: 100% RIF resistance Overall concordance rate: 100%	-
Specificity		-
Multiplexing, multidisease platform	While testing for TB, other pathogens can be tested simultaneously	-
Sample types	In addition to sputum samples, it can also support tongue swabs, alveolar lavage fluid, pleural effusion, pathological tissue sections, urine, and cerebrospinal fluid samples.	-

Characteristics	Performance and descriptions	Notes
Manual prep of samples	Low workload, self-testing by patient is not applicable	-
Time to result	About 2 hours and 30 minutes	-
Throughput per test	Each test can process up to 16 samples, and one test can process samples for multiple different pathogens	-
POCT or near POCT	No auxiliary equipment required POCT Device	-
Power requirement	External power supply; Or connect to an external UPS that can be charged multiple times.	-
Operation environment	Ambient temperature: 5~40℃ Ambient humidity: 25~90%RH Dust prevention measures: with dust net	-
Reagent kits transport	Can be transported at normal temperature (2~28℃)	-
Shelf life	12 months	-
Storage environment	2~8℃+80%RH	-

3. Description of characteristics and advantages

The Ustar MultNAT molecular diagnostic testing system adopts real-time fluorescence quantitative PCR technology and can flexibly support a variety of POCT testing consumables to meet the clinical needs for the detection of multiple targets and high-throughput rapid detection of samples. It can cover multiple detection gene targets such as multiple pathogens detection, drug resistance detection, genotyping detection, quantitative detection, etc., and immediately report the comprehensive detection results of pathogens in the sample, facilitating clinical precision treatment.

The molecular diagnostic testing system can be configured with 2/4 independent detection modules. Each detection module has independent temperature control and respective reaction program setting. There is no interference between the modules, and modules can be randomly accessed, without the need to accumulate samples or wait. It can be widely used in various detection scenarios such as medical institutions at all levels, disease control centers, mobile detection vehicles, airports, customs, etc.

Hangzhou Shengting Medical Technology Co. Ltd.

Company Introduction

1. Company Profile

ShengTing Med is a biotechnology company that focuses on the application of **next-generation sequencing** (NGS) technology in precision medicine. It was founded by members from the Broad Institute of Harvard and MIT and Tianyu Pharma Group (A-share market value of $1.5 billion).ShengTing Med provides more than **1000 testing services and kits** across multiple disease areas, including oncology, infectious diseases, personalized medicine, neurological disorders, inherited disease and immune-related conditions.

Shengting attaches great importance to R&D, and has published over 200 high-IF SCI papers ,**107 invention** patents and **40 software copyrights** so far. **In March 2024, TBseq® developed by Shengting Medical was recommended as the first three NGS products for drug resistant tuberculosis detection by 2024 WHO tuberculosis guidelines.**

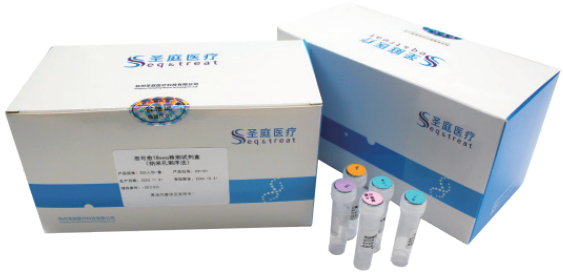
Headquartered in Hangzhou, ShengTing Med has established an R&D center and a GMP production facility for Class III medical devices. It also operates 8 **ISO15189+CAP** certified clinical testing laboratories in China, with a total over **200000 NGS tests** were completed last year.

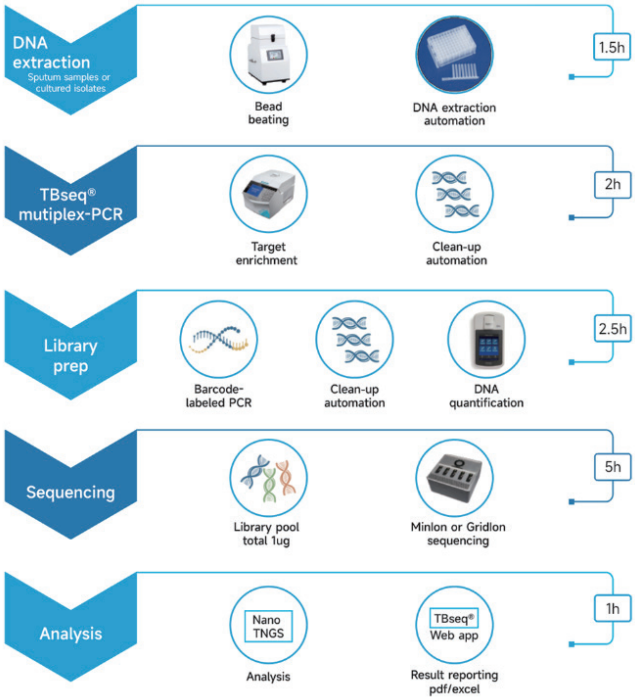
2. Basic Information

Company Name: Hangzhou Shengting Medical Technology Co. Ltd.
Address: Building 5, Liangzhu International Life Science Town, 362 Tongyun Street, Yuhang District, Hangzhou, Zhejiang Province, China.
Official website: www.shengtingmed.com
Email: Info@StengTingGroup.com
Tel: +86-400-7737008

TBseq®-Mycobacterium DNA and M. tuberculosis drug resistance gene detection kits (Sequencing Method)

1. Product appearance and operation flow chart





2. Detailed information

Characteristics	Performance and descriptions	Note
Intended purpose	The kit is designed for the qualitative detection of Mycobacterium DNA and M. tuberculosis (Mtb) drug resistance genes in human sputum, bronchoalveolar lavage fluid, pleural effusion or Mycobacteria-positive culture.	-
Target population	Individuals requiring tuberculosis and drug resistance testing, especially suspected or confirmed TB patients who need drug susceptibility analysis.	-
Number of Preparations	24 tests	-
Regulatory approval of the products	CE marked	-
Sensitivity	95.7% in BALF samples; 90.9% in sputum samples [14].	-
Specificity	97.6% in BALF samples; 100% in sputum samples [14].	-
Sample types	BALF, sputum, cerebrospinal fluid, blood, tissue, urine, and pleural/ascitic fluids.	-
Mycobacterium Detection Range	MTB(8) : Includes Mycobacterium tuberculosis, Mycobacterium bovis, Mycobacterium africanum, etc.	-
	NTM(168): Encompasses Mycobacterium avium, Mycobacterium intra-cellulare, Mycobacterium abscessus, Mycobacterium chelonae, Mycobacterium marinum, Mycobacterium kansasii, etc.	-
Coverage of Resistant Genes	MTB First-Line Drugs (5): Targets genes like Rifampicin(rpoB), Isoniazid (katG,inhA), Pyrazinamide (pncA), Ethambutol(embB), and Streptomycin(rpsL, rrs).	-
	MTB Second-Line Drugs (11): Includes Amikacin (rrs), Fluoroquinolones (gyrA, gyrB), Isonicotinamide Ethothione (inhA), Propyl Isonicotinamide (inhA), Sodium p-Aminosalicylate (folC, thyA), Kanamycin(rrs), Capreomycin (rrs), Cycloserine (alr), Clofazimine (Rv0678, atpE), Bedaquiline (Rv0678, atpE), and Linezolid (rplC).	-
	NTM Drugs (6): Clarithromycin (erm, rrl), Azithromycin (erm, rrl), Amikacin (rrs), Kanamycin (rrs), Gentamicin(rrs), and Rifampicin(rpoB).	-
Time to result	Less than 12 hours from DNA extraction to report	-
Shelf life	Valid for 12 months.	-
Storage environment	Store and transport at –20°C in light-protective packaging	-

3. Description of characteristics and advantages

TBseq® is a specialized diagnostic solution developed by Shengting Medical for mycobacterial identification and drug resistance gene detection, based on third-generation nanopore sequencing technology integrated with the company's proprietary patented technologies and bioinformatics algorithms.

Key Features:

Comprehensive detection of:

- Mycobacterium tuberculosis complex (MTB)
- 168 species of nontuberculous mycobacteria (NTM)
- Over 35,000 genomic loci associated with 22 antimycobacterial drugs
- Unique "Drug Resistance Confidence Score" algorithm to assess the clinical relevance of detected mutations
- Human NAT2 genotyping to guide isoniazid therapy
- Screening for 126 common pathogens to assess co-infection risks
- Spoligotyping for MTBC lineage classification
- MIRU-VNTR analysis for molecular epidemiological tracing
- Fully automated nucleic acid extraction and library preparation workflows are available.
- The analysis platform is highly integrated and supports one-click generation of comprehensive diagnostic reports.
- The drug resistance mutation database is continuously updated and optimized on a quarterly basis.

Notable Recognition:

In 2023, TBseq® participated in the development of China's first NGS-based tuberculosis diagnostic guidelines. In 2024, the TBseq® kit obtained CE certification in the European Union and has since been marketed in over 10 countries. In March 2024, TBseq® was included in the updated World Health Organization (WHO) TB diagnostic guidelines as one of only three targeted next-generation sequencing (tNGS) solutions recommended globally—and the only product from China.

Clinical research article on TBseq®

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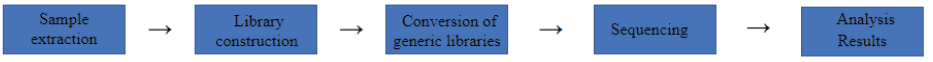
Multi-Cancer Detection Blood Test Kit

1. Product appearance and operation flow chart



2. Detailed information

Characteristics	Performance and descriptions	Note
Intended purpose	This kit is designed for the qualitative in vitro detection of cfDNA methylation and fragmentation profiles in blood samples. It calculates a Cancer Score (CS Score) using the companion software PRIME Multi-Cancer Screening and Analysis Software. A positive score suggests increased cancer risk and predicts the potential organ of origin, supporting early cancer screening in high-risk individuals.	-
Target population	Individuals aged 45 or above who are at high risk for cancer, based on clinical guidelines in China. This test does not replace standard screening procedures (e.g., colonoscopy, gastroscopy) and is not intended for use in patients undergoing anti-cancer therapy, pregnant women, transplant recipients, or individuals with bleeding or autoimmune disorders.	-
Number of Preparations	96 tests	-

Characteristics	Performance and descriptions	Note
Regulatory approval of the products	CE marked	-
Sensitivity	≥81.5%(The sensitivity of lung cancer is 87%.)	-
Specificity	≥98%	-
positive predictive value	82.4%	-
Sample types	Blood	-
Detection Range	12 cancer types: lung, colorectal, liver, stomach, breast, esophageal, pancreatic, bladder, prostate, kidney, ovarian, and lymphoma	-
Shelf life	Valid for 12 months.	-
Storage environment	The kit is stored at -20±5℃ and protected from light.	-

3. Description of characteristics and advantages

PRIME is a next-generation blood-based multi-cancer early detection test co-developed with leading methylation researchers. It combines two core technologies:

(1) Ultra-low-input micro-sequencing (as low as 100 pg cfDNA) [12]

(2) A proprietary tumor-specific methylation signal traceability system

Built on a proprietary RRBS (Reduced Representation Bisulfite Sequencing) platform, the test analyzes over 5 million CpG sites and captures over 70% of tumor-derived signals in key genomic regions. Advanced AI algorithms further enable early cancer detection and precise tissue-of-origin prediction.

Key Advantages:

(1) Earlier Detection

High sensitivity for early-stage cancers (80% for Stage I–II;) allows earlier intervention and better outcomes.

(2) High Accuracy

Trained on large-scale Chinese population data, PRIME achieves ≥81.5% sensitivity, The sensitivity of lung cancer is 87%, ≥98% specificity, and 82.4% accuracy in organ site identification. Validated through national projects and peer-reviewed publications [15]

(3) Comprehensive Coverage

Simultaneous screening for 12 high-incidence cancers with one blood test, combined with accurate lesion traceability.

(4) Non-Invasive and Patient-Friendly

Requires only 10 mL of peripheral blood, with no radiation exposure—suitable for mass screening initiatives.

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Epilogue

As one of the three pillars of the END-TB strategy, technological innovation plays a pivotal role in achieving the milestones and realizing the TB control and prevention target outlined by the United Nations Sustainable Development Goals (UN SDGs).

In recent two decades, China has witnessed groundbreaking technological advances in artificial intelligence (AI), microfluidics and point-of-care testing (POCT). These innovations, in turn, have translated to benefit the field of TB diagnostics R&D. A number of novel TB diagnostic solutions that are efficacious, peripheral level deployable and with cost-effectiveness have been successfully hatched. A number of these solutions have been validated and studied under trial or programmatic conditions across vast regions of China to probe their potential in optimizing the existing cascade of TB care or creating novel strategies and models of case detection.

As TB case detection deficit has been identified by the WHO as the greatest challenge faced by the End-TB roadmap today. In order to reinvigorate the existing TB IVD landscape which has been dominated by the western legacy brands for more than 20 years, the WHO has opened Prequalification channels for several classes of TB IVDs since 2021 in hoping to find TB IVD solutions that are accurate in performance and feasible as well as affordable when deployed to high burden resource constraint regions. Against the backdrop of this rapid transition of TB IVD guideline recommendation and procurement, IATB is working with its industrial partners to capitalize on this opportunity by raising their awareness on the WHO TPPs as well as the latest development of the WHO IVD PQ program, so that Chinese manufacturers with an eye on the global public health market may be well poised in terms of their TB IVD products' diagnostic accuracy, operational characteristics as well as cost-effectiveness when competing on an international level.

More importantly, IATB understands the significance of high-quality clinical evidence generation to backing up these products' claims of performance excellence as we are engaging actively with our industrial partners in real-world and clinical validation studies of these technologies. Therefore, IATB is committed fully to the mission of 'Serving China and Contributing to the World at Large.'

With IATB's extensive network of TB hospitals and industrial partners, we stand ready to meet major clinical needs by fostering R&D in safe and effective TB technological solutions, and in term, making China's contribution to the 2035 END-TB targets.