



A Quick Glance of Innovative Tuberculosis Technologies from China 2026



INNOVATION ALLIANCE ON TUBERCULOSIS
DIAGNOSIS AND TREATMENT (BEIJING)

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Forewords

In 2024, tuberculosis (TB) remains the deadliest infectious disease caused by a single pathogen across the globe, leaving over 1.2 million deaths in its wake. 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.

Persistent gap of TB case detection, technical challenges in finding those sub-clinical/incipient TB cases who are asymptomatic, inherent limitations of traditional sputum based bacteriological tests have prompted the World Health Organization (the WHO) to move toward research and development as well as roll-out of accurate in vitro diagnostics that are capable of deploying to the peripheral of the health system with a quick turn-around time, non-sputum sample processability, versatile operational characteristics and ideal health economics.

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). Some of these IVD products have demonstrated their versatility in processing sample types other than sputum, most notably the tongue swabs.

In order to systematically introduce Chinese developed TB IVD technologies and products to the world. In 2024 and 2025, IATB had edited and published the first and second handbook under the title of 'A Quick Glance of Innovative Tuberculosis Diagnostic Technologies from China.' These two editions made in-depth introduction of 18 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 third edition of the handbook with a broader scope in which six indigenously

manufactured anti-TB drugs are added on top of another ten Chinese developed novel TB IVD products (some of the products appeared in the first and second editions but have been updated in the third 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 accuracy, operational characteristics as well as health-economics for IVD products and safety, effectiveness for pharmaceutical products 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. Yuhong Liu

Yuhong Liu

Chair, Innovation Alliance on Tuberculosis Diagnosis and Treatment (Beijing)

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Introduction of IATB

In August 2016, the Innovation Alliance on Tuberculosis Diagnosis and Treatment (hereinafter, the alliance) was founded on the initiative of the Beijing Chest Hospital, Capital Medical University with founding members including the Tianjin Haihe Hospital, Shannxi Provincial Hospital of Tuberculosis Control and Prevention as well as the Wuhan Pulmonary Hospital. As a non-gov and not-for-profit civil organization, the alliance operates under the jurisdiction of the Beijing Municipal Civil Affairs Authority. The membership of the alliance is mainly consisting of China's TB designated hospitals, TB control and prevention institutions, scientific research institutions, industrial enterprises as well as other stakeholders involved in TB R&D and individual members. Now the alliance has grown to include 131 institution members including 88 TB designated hospitals, 43 industrial members and 761 individual members. Its operation scope is as following: theoretical research; scientific research; technological R&D; technological translation; market development; construction of big data repository; academic exchanges; consultation; philanthropic activities; publication of internally circulated materials; conferencing and exhibition; 3rd party commissioning; international cooperation.

Aspiration of the alliance is to be a pioneer in TB diagnostic and treatment technological innovation; a hatchery in promising TB technology translation and a facilitator in professional and academic exchanges.

Founding mission of the alliance 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, the alliance operates the following five departments, namely education and training, laboratory quality assurance, remote and online medical services, international cooperation and clinical research along with a nation-wide clinical trials consortium (the China Tuberculosis Clinical Trials Consortium).

Autobio Diagnostics Co., Ltd.

Company Introduction

1. Company Profile

Autobio Diagnostics Co., Ltd. was founded in 1998. A high-tech enterprise specialized in the R&D, manufacturing, integrated solutions and suppliers of IVD reagents and instruments. Its products cover immunoassay, microbiology, biochemistry, molecular diagnostics and coagulation, and have expanded into sequencing, mass spectrometry, quality control products, intelligent medical laboratories and medical treatment combination. It is able to provide comprehensive product solutions and integrated services for medical laboratories. The company launched its first Initial Public Offerings (IPOs) on September 1, 2016, making it the first domestic IVD R&D and manufacturing enterprise in China listed on the Main Board of the Shanghai Stock Exchange.

Autobio boasts strong innovation capabilities, undertaking a number of national-level scientific and technological projects and participating in the formulation of more than 100 industrial standards. Its products are used in over 10,000 medical institutions in China and exported to more than 100 countries overseas. The Autobio IVD Industrial Park covers a land of 167,333 m² with a total construction floor area of over 720,000 m². It has become one of the largest IVD industrial parks in China. Adhering to its mission, Autobio drives high-quality development through innovation and aims to build an integrated IVD enterprise.

2. Basic Information

Company Name: Autobio Diagnostics Co., Ltd.

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Autobio TB-IGRA Solution

1. Product Appearance and Operation Flow

(1) TB-IGRA CLIA Microparticles Kit



IVDD (28Tests, include Reagent pack, Calibrators, 3-hole Cell Culture Strip, Positive Control Medium, Negative Control Medium, Test Medium)

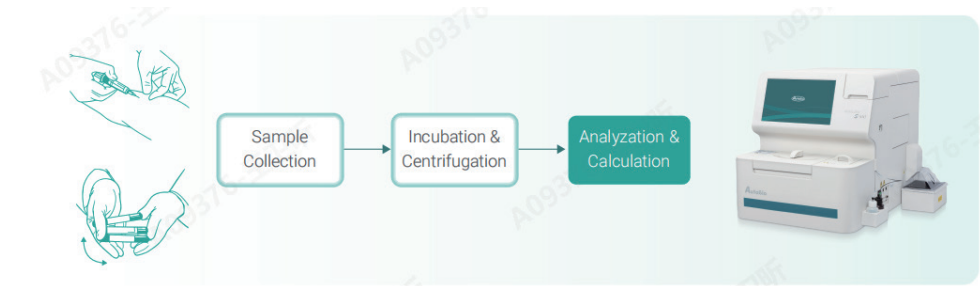


IVDR (28Tests, include Reagent pack, Calibrators, Sample Release Reagent(N/P/T), Quality Control)

(2) AutoLumo S900



(3) Operation Flow



- **Sample collection:** Whole blood samples should be collected via standard aseptic phlebotomy vacuum blood collection tubes pre-coated with sodium heparin or lithium heparin anticoagulant.
- **Incubation & centrifugation:** Gently invert culture tubes of Sample Release Reagent (N/P/T) and mix for 3-5 times, then quickly put them into an electric thermostat incubator (37 °C) and incubate at 37°C for 16-24 hours. After cooling to room temperature, centrifuge each culture tube at 1800-3000rpm for 10 minutes to use for subsequent IFN- γ detection.
- **Analyzation & Calculation:** After centrifugation, load the sample directly into the analyzer. The analyzer will complete the subsequent IFN- γ content detection according to the established procedure.

2. Detailed Information

Characteristics	Performance and descriptions	Notes
Intended purpose	This TB-IGRA CLIA Microparticles and AutoLumo TB-IGRA Calibrators are used together based on the fully automated chemiluminescent immunoassay microparticle (CLIA Microparticles) system for the qualitative detection of MTBC specific T cell immune response in fresh peripheral venous anticoagulant blood. Using specific antigen representing to MTBC peptides to stimulate cells in the sample to release IFN- γ (interferon-gamma release assay, IGRA) and quantitative detection of IFN- γ is used to identify specific T-cells immunological reaction to those peptide antigens that are associated with MTBC infection. Clinical determination of this assay is used as an aid to diagnosis the presence of MTBC infection.	-

Characteristics	Performance and descriptions	Notes
Target population	Individuals aged 12 years and older, who have not received treatment for latent tuberculosis infection or active tuberculosis disease within the preceding 12 months, and have not taken antimycobacterial medicines in the prior 14 days. Subjects are indicated for testing if they are either clinically presumptive of pulmonary tuberculosis (e.g., presenting with new-onset or persistent cough lasting ≥ 2 weeks) or belong to populations at elevated risk of MTBC infection, including people living with HIV, individuals with self-reported close contact with microbiologically confirmed active TB patients, persons with occupational silica exposure associated with mining, and other priority high-risk cohorts defined by WHO 2025 TB diagnostic guidance.	[1],[2],[3]
Intended users	High-throughput public health center screening; Decentralized tuberculosis surveillance network.	-
Regulatory approval of the products	CE IVD for Reagent and Tube Russia FDA Brazil FDA China NMPA Indonesia FDA Mexico FDA Saudi FDA	In progress: WHO ERPD, CE IVDR(Reagent).
Regulatory requirements of manufacture	ISO 14001 ISO 13485 ISO 9001	-
*Sensitivity	97.84%	-
*Specificity	98.25%	

Characteristics	Performance and descriptions	Notes
Multiplexing, multi-disease plat form	Automatic Luminescence Immunoassay Analyzer (AutoLumo S900 series) Automatic Luminescence Immunoassay Analyzer is strictly intended for professional In-vitro Diagnostic use. It is an automat-ed instrument which is clinically used for qualitative and quantitative assay of ana-lyte derived from human samples. The test items including tumor-related antigens, liv-er disease, hormones, infectious diseases, immune function, autoantibodies, proteins and peptides, cardiomyopathies, vitamins, amino acids and blood concentrations, al-lergens, kidney disease, clotting tests, and other enzymes. Sample type: serum, plasma, whole blood, urine, saliva, sputum, cerebrospinal fluid, alveolar lavage fluid, swab eluate, swab processing fluid and feces. It consists of sample reagent management module, RV supply module, sample load-ing module, incubation module, cleaning module, mixing module, gripper module, photometry module, circuit control mod-ule, liquid circuit module, data processing module, display module and software.	-
Sample types	Whole blood.	Sterile blood collec-tion tubes (lithium heparin or sodium heparin).

Characteristics	Performance and descriptions	Notes
Manual prep of samples	Sample collection: whole blood samples should be collected using correct medical techniques, using aseptically processed vacuum blood collection tubes with sodium heparin or lithium heparin as anticoagulant. Whole blood sample dispensing: After whole blood samples are collected, gently invert tubes 3-5 times. Dispense 1.0mL whole blood samples into Sample Release Reagent (N), Sample Release Reagent (T), and Sample Release Reagent (P), respectively, within 24 hours, and tighten the tube caps carefully. Incubation: Gently invert culture tubes of Sample Release Reagent (N), Sample Release Reagent (T), and Sample Release Reagent (P) and mix for 3-5 times, then quickly put them into an electric thermostat incubator (37°C) and incubate for 16-24 hours. Supernatant collection: After incubation and returning to room temperature, centrifuge each culture tube at 1800-3000rpm for 10 minutes to collect supernatant, which is used for subsequent IFN-γ detection.	-
Turn Around Time (TAT)	First report time:34 minutes; continuous random access sampling mode, one sample every 60 seconds.	-
Throughput per test	60 samples/hour, 180 tests/h.	-
Power requirement	Voltage:100-230 V Frequency:50/60 Hz Voltage Fluctuation: Not more than $\pm 10\%$ Power Consumption: 1.0 kVA Overvoltage Category: II	-
Operation environment	Room temperature.	-
Reagent kits transport	2-8 °C .	-
Shelf life	18 months.	-

Characteristics	Performance and descriptions	Notes
AutoLumo S900 Parameters	Sample capacity: 51 (include 3 independent physical STAT emergency sample slots) - Continuous sample loading with an appointment - Sample tube with a diameter of 10-13 mm, 16 mm, test tube with a height of 65-100 mm, and 2 mL micro cuvette - Remarks: Test tubes with a diameter of 16 mm require a special adapter Barcode Scanning: Built-in barcode scanner for samples and reagent Reagent Positions: 16, continuous reagent loading with an appointment 2-8 °C 24 h independent cooling in sleep mode Reagent identification via built-in RFID Scanning RV Capacity: 1000, continuous loading Incubation Tray: 107 - Incubation temperature: 37 ± 0.3 °C Substrate pre-heating function Touch-screening operation Weight: 85 kg Size: 576 x 796 x 654 mm	-

* A comparison study was performed where samples were tested using this assay and a commercially available immunoassay kit.

3. Description of Characteristics & Advantages

(1) Reliable Clinical Performance

The clinical performance of this product has been recognized in the following areas:

- Provides reliable routine diagnostic support for patients with presumptive tuberculosis;

A retrospective study by Suzhou Fifth People’s Hospital ^[4] (involving 331 people with presumptive TB) showed that, among the 199 patients diagnosed with tuberculosis, the TB-IGRA positive detection rate (83.92 %) was significantly higher than that of sputum smear microscopy (21.61%; $\chi^2= 155.000$, $P < 0.01$); Of these 199 tuberculosis diagnosed patients, old pulmonary tu-

berculosis (66.67% vs 6.67%, $\chi^2 = 11.630$, $P < 0.01$) and active pulmonary tuberculosis (83.83% vs 24.55%, $\chi^2 = 118.200$, $P < 0.01$) were also significantly higher than those of sputum smear testing, thereby lowering the risk of false-negative diagnoses resulting from the low analytical sensitivity of sputum smear microscopy. Its sensitivity (83.92%), specificity (68.18%) and accuracy (77.64%) meet clinical requirements; when used in combination with sputum smear testing, sensitivity rises to 87.44%, further reducing the risk of missed diagnoses. Furthermore, the positive detection rate of TB-IGRA in patients with other respiratory diseases was only 31.82%, significantly lower than that in tuberculosis patients ($\chi^2 = 92.570$, $P < 0.01$). This can assist in distinguishing between diseases, providing a basis for the screening and diagnosis of presumptive cases.

- **Specialised Diagnosis of Pathogen-Negative Tuberculous Pleurisy**

A study by Puyang Fifth People's Hospital ^[5] (involving 229 patients with negative pathogen results, 298 patients with positive pathogen results, and 207 patients with non-tuberculous pleurisy) showed that: there was no statistically significant difference in the TB-IGRA positivity rate between the pathogen-negative and pathogen-positive groups ($P > 0.05$), but a significant difference was observed compared with the non-tuberculous pleurisy group ($P < 0.001$), indicating that it can effectively distinguish between tuberculous and non-tuberculous pleurisy. Its sensitivity (89.96%), specificity (75.85%) and accuracy (83.26%) were superior to those of individual tests for tuberculosis antibodies (TB-Ab) and adenosine deaminase (ADA) in pleural effusion; compared with pairwise combinations of TB-Ab and ADA, or a combination of all three tests, the diagnostic performance of the three-marker combination was superior to that of any single test; in particular, the three-marker combination achieved a sensitivity of 98.25% (with specificity reduced to 61.84%), thereby meeting the clinical requirements for high-sensitivity diagnosis and serving as a key diagnostic tool for this condition.

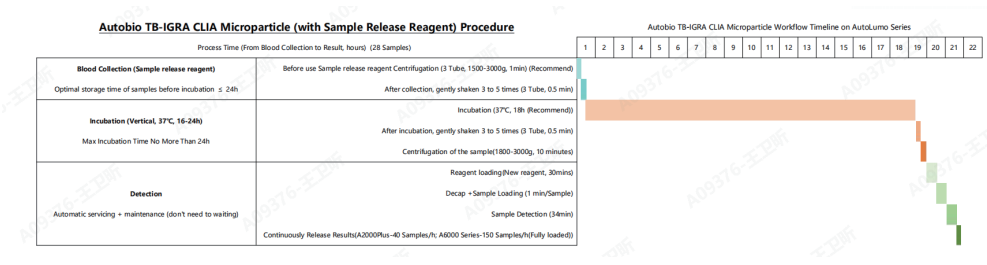
- **Prognosis Assessment in Patients with Smear-Negative Pulmonary Tuberculosis**

A prospective study conducted by the Department of Respiratory Medicine at Guizhou Aerospace Hospital ^[6] (involving 90 patients with sputum-negative pulmonary tuberculosis and 90 healthy controls) showed that logistic regression analysis indicated a positive TB-IGRA result was an adverse factor for

patient survival ($P < 0.05$), whilst anti-tuberculosis treatment was a favorable factor. This suggests that TB-IGRA-positive patients require enhanced monitoring and the formulation of active treatment regimens; Age $\geq$ 40 years and a diagnosis of a false-positive TB-IGRA result were identified as risk factors ($P < 0.05$), which may guide clinicians in interpreting results in conjunction with age to avoid overtreatment. Furthermore, the sensitivity and specificity of the TB-IGRA test for sputum-negative pulmonary tuberculosis showed no significant difference compared with the healthy control group ($P > 0.05$). It can therefore be used for the dynamic monitoring of patients' conditions, prognostic risk stratification and the optimization of treatment regimens, thereby enhancing the standard of clinical management.

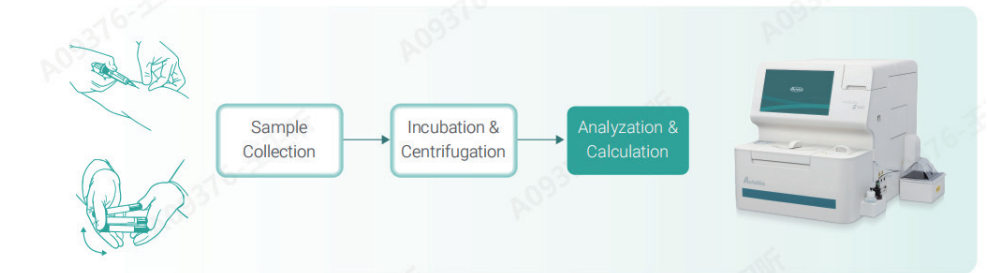
(2) Rapid Turnaround Time

The Autobio TB-IGRA CLIA Microparticle can complete the entire testing process in as little as 22 hours (from sample collection - sample preparation - analysis).



(3) Decentralized Design

This solution features a compact design which, through its integrated sample pre-processing system and fully automated mini analysis system (<0.5 m²), significantly reduces operational complexity. This enables tuberculosis immunological screening to transcend the limitations of traditional laboratory settings, allowing it to be deployed closer to the grassroots level, thereby shortening the information chain from disease detection to management and enhancing the operational efficiency of the public health system.



(4) User-Friendly Design

“Pre-barcoded Sample Tubes”

Autobio Sample Release Reagent is supplied with a unique, identifiable barcode already affixed at the factory. This pre-bar-coded design significantly simplifies the management of experimental samples and reduces training costs for laboratories, enabling operators to easily achieve seamless identification and management within the Autobio system.



“Dual Quantitative & Qualitative Result Auto-Output”

The software integrated into the fully automated analysis platform can automatically generate the final qualitative results and directly provide three quantitative results for each sample. The entire process requires no manual recalculation, thereby reducing the workload on the laboratory and minimising the risk of errors arising from human intervention.

(5) 10 years’ Technical expertise and clinical recognition

Autobio launched ELISA-based products in 2014, followed two years later in 2016 by CLIA Microparticles-based products. After more than 10 years of product operation, Autobio has gained widespread market recognition and accumulated extensive market feedback. With this high-quality feedback, Autobio has continuously optimized its products to better meet clinical needs.



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- [6] Zhao ZL, Liao JR, Chen X. Interferon-gamma release assay for evaluating prognosis in patients with sputum smear-negative pulmonary tuberculosis and analysis of risk factors for false-positive interferon-gamma release assay results. *Chinese Remedies & Clinics.*, 2022,22(1):45-48.

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 solutions for clinical applications, covering mycobacterial identification, antimicrobial resistance (AMR) profiling, adventitious virus screening and food safety testing. 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 4 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 more than 198 peer-reviewed publications with a combined cumulative Impact Factor exceeding 800. Additionally, Hugobiotech's targeted NGS (tNGS) assay for TB drug resistance profiling was featured in a 2024 global analysis published in *The Lancet Infectious Diseases* as the only evidence-based platform with a 24-hour 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

Company Name: Hugobiotech Co., Ltd.

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TB-EASY Kit

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 both tongue swabs and sputum specimens, enabling rapid and accurate tuberculosis diagnosis. The product is open-platform compatible, supporting full-scenario deployment especially at primary health-care facilities. It can detect 48 samples within 4 hours and be compatible with automated liquid handlers, suitable for both population screening and clinical confirmatory diagnosis.	-
Target population	- Adults and adolescents (over 10 years) in need of evaluation for TB; - Populations and groups at risk of TB.	-
Intended users	Professional users, laboratory technicians, or healthcare workers with training in conducting moderately complex lab tests in laboratory settings.	-
Regulatory approval of the products	- NMPA - CE	Only for tongue swab specimen
Regulatory requirements of manufacture	- ISO 13485 - ISO 14971	-
Sensitivity	Tongue swab - Compared to sputum Xpert MTB/RIF: 89.6% - Compared to microbiological reference standard: 87.4%^[1] Sputum: under evaluation	[1]

Characteristics	Performance and descriptions	Notes
Specificity	Tongue swab: • Compared to sputum Xpert MTB/RIF: 96.2% • Compared to microbiological reference standard: 98.0%^[1] Sputum: under evaluation	[1]
Multiplexing, multi-disease platform	Compatible on open PCR platforms, such as QuantStudio 5/7, ABI7500, SLAN-96S, etc.	-
Sample types	Tongue swabs, Sputum.	-
Manual prep of samples	Five manual sample pre-processing steps are required, as detailed below: • Place the sampling tube into the dry bath for incubation • Take the sample for beads beating • Place the tube into the EASYLab for DNA extraction and PCR mix preparation • After the process is completed, seal the PCR plate manually • Put the plate on the PCR machine for qPCR detection	-
Time to Result	< 4 hours	-
Throughput per test	48 tests	-
POC or near POC	Moderate complexity	-
Power requirement	Continuous electrical power	-
Operation environment	2°C to 40°C with up to 50% humidity	-
Reagent kits transport	2°C to 40°C (No cold chain required)	-
Shelf life	12 months at 2°C to 40°C with up to 85% humidity	-

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 and sputum 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, a human housekeeping gene 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. De- signed for use with a wide range of clinical samples, including sputum, bronchoalveolar lavage fluid (BALF), blood, and cerebrospinal fluid (CSF) etc., TB-Pro en- ables species-level identification and relative quanti- fication of MTBC and non-tuberculous mycobacteria (NTM), alongside the detection of drug-resistance mutations in tuberculosis-associated genes. This com- prehensive 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 strat- egies, improve patient outcomes, and combat the growing threat of drug-resistant tuberculosis.	-
Target popula- tion	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	Research for use only. Registration is undergoing	-

Characteristics	Performance and descriptions	Notes
Regulatory requirements of manufacture	ISO 13485 and ISO 14971	-
Sensitivity	> 95%	Compared with WGS method
Specificity	> 98%	-
Sample types	Sputum, bronchoalveolar lavage fluid (BALF), blood, and cerebrospinal fluid (CSF).	-
Time to Result	The time from sample collection to result is under 24 hours.	-
Reagent kits trans- port	-15°C ~ -25°C	-
Shelf life	Valid for 12 months.	-
Storage environment	-15°C ~ -25°C	-

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 enables the prediction of resistance to 27 anti-mycobacterial drugs, including 4 first-line and 14 second-line anti-tuberculosis drugs (including BDQ and DLM).
- (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 >95% and 98%^[2-3].
- (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

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- [2] Wu XC, Liang RB,Xiao YQ, et al.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., 2023,86(4):399-401.
- [3] Ou XC, Pei SJ, Li HR, et al. A comprehensive evaluation of a novel targeted-sequencing workflow for *Mycobacterium* species identification and anti-tuberculosis drug-resistance detection. Front Cell Infect Microbiol., 2025,15:1584237.

Coyote Bioscience Co., Ltd.

Company Introduction

1. Company Profile

Founded in 2009, Coyote Bioscience is a leading biotechnology company specializing in the research, development, production, and commercialization of point-of-care testing (POCT) and rapid molecular diagnostic products. Driven by the mission of “Molecular Diagnostics for Everyone,” the company is committed to making high-quality nucleic acid testing accessible, affordable, and simple for use in diverse real-world healthcare environments.

At the core of Coyote’s platform is the FlashDetect™ System, which integrates automated sample preparation, nucleic acid extraction, and real-time PCR (qPCR) technology into a single workflow. Utilizing closed, single-use disposable cartridges with pre-loaded lyophilized reagents, the system minimizes hands-on time and cross-contamination risks. These features, combined with high-speed thermal cycling (reaching ramp rates up to 34°C/s), enable a “sample-in, result-out” experience in typically less than 30 minutes, making the platform ideal for frontline healthcare, community screening, and decentralized settings.

Coyote Bioscience holds over 130 patents and maintains dedicated manufacturing facilities that adhere to ISO 13485 quality management systems and GMP standards. The company’s products have reached over 65 countries and more than 150 million tests delivered to date. Coyote’s history of innovation includes launching the world’s first portable real-time qPCR device Mini8 Plus, deployed in support of Ebola emergency response activities. These efforts are supported by ongoing collaborations with major international health partners, including the WHO, FIND, Stop TB Partnership, and the Aurum Institute, helping accelerate the clinical evaluation and implementation, and scale-up for tuberculosis, respiratory, and STI diagnostic pipelines.

2. Basic Information

Company Name: Coyote Bioscience Co., Ltd.

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Tel: +86-10-64844237

FlashDetect™ LyocartE Assay

1.Product Appearance and workflow

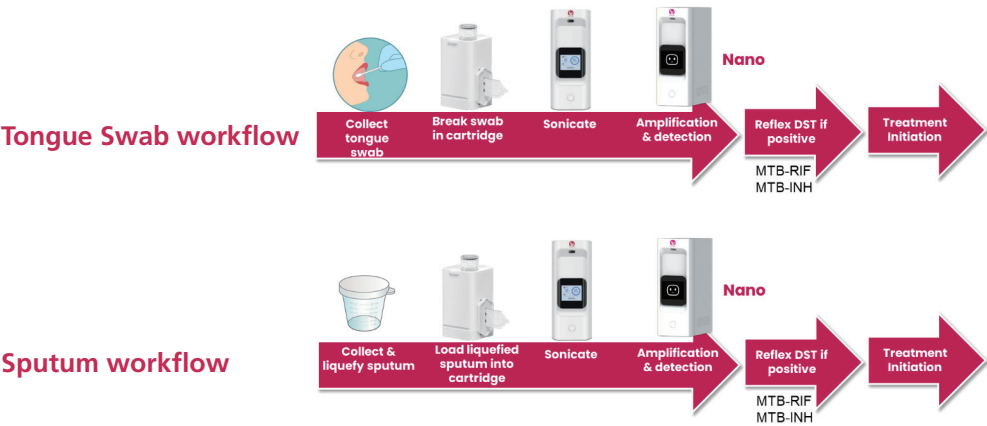


FlashDetect™ Nano

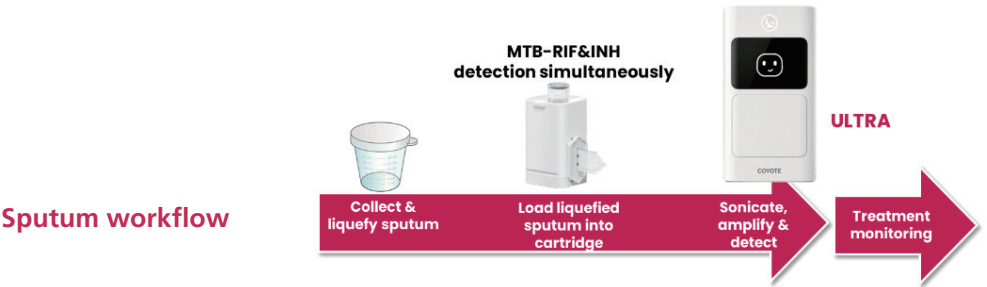


FlashDetect™ Ultra

Pathway 1 – Rapid TB Screening



Pathway 2 – Integrated TB & Drug-Resistance Detection



2. Detailed Information

Characteristics	FlashDetect™ LyocartE MTB Assay	FlashDetect™ LyocartE MTB&RIF Assay	FlashDetect™ Lyo- cartE MTB/RIF&INH Assay
Intended Purpose	Qualitative detection of <i>Mycobacterium tuberculosis</i> complex (MTBC) DNA.	Simultaneous qualitative detection of MTBC DNA and Rifampicin (RIF) resistance-associated genes.	Rapid molecular in vitro diagnostic test for the simultaneous qualitative detection of <i>Mycobacterium tuberculosis</i> (MTB) complex DNA, Rifampicin (RIF) resistance genes, and Isoniazid (INH) resistance genes.
Target Population	Individuals presumptive of pulmonary TB.	Individuals presumptive of TB or at high risk for MDR-TB or RR-TB.	Individuals with presumptive or confirmed pulmonary TB, or those at high risk for Multi-drug-Resistant TB (MDR-TB).
Intended Users	Trained healthcare workers and/or laboratory professionals proficient in molecular testing.		
Regulatory Approval	CE-IVD	CE-IVD	CE-IVD
Regulatory Requirements of Manufacture	Manufactured under ISO 13485 quality systems and GMP standards.		
Analytical Sensitivity (LoD)	LoD:10 CFU/mL	LoD: 10 CFU/mL	MTB: 10 CFU/mL; RIF & INH resistance mutants: 300 CFU/mL
Sensitivity	Sputum specimens: 98.95%; Tongue Swab specimens: 89.20%	Under development	Under development
Specificity	Sputum specimens: 98.69%; Tongue Swab specimens: 86.97%	Under development	Under development

Characteristics	FlashDetect™ LyocartE MTB Assay	FlashDetect™ LyocartE MTB&RIF Assay	FlashDetect™ Lyo- cartE MTB/RIF&INH Assay
Multiplexing	Targets IS6110 and IS1081 genes; internal control.	Targets IS6110, IS1081, and the 81bp RRDR of the rpoB gene; sample processing control; internal control.	Targets MTBC, RIF (rpoB), and INH (katG, inhA, ahpC); sample processing control; internal control.
Sample Types	Sputum or Tongue Swabs	Sputum	Sputum
Manual Prep of Samples	Liquefaction (~1 min) for sputum; direct swab transfer to cartridge for tongue swabs.	Liquefaction (~1 min)	Liquefaction (~1 min)
Turn Around Time	Sonication: 2 mins; TAT: 30 mins	Sonication: 2 mins; TAT: 60 mins	60 mins
Throughput Per Test	Nano: 1-16; Ultra: 1-32; Ultra (built in sonicator).		High-throughput matrix with 1 to 32 scalable modules.
POC or Near POC	Designed for near-POC, clinics, and community screening.	Designed for front-line healthcare and district hospitals.	Designed for near-POC
Power Requirement	Supports external mobile power supply options.		
Operating Environment	Approximately 10°C to 40°C; 50%-80% Humidity Corresponding to FlashDetect™ instrument requirements.		
Reagent Transportation	Stable at room temperature, no cold chain required.		
Shelf Life	12 months when stored at 2-28°C		

3. Product Highlights

- Near-point-of-care molecular testing with results in approximately 30 minutes.
- Supports both sputum and tongue swab specimens.
- Closed-cartridge workflow with minimal hands-on time.
- Compatible with portable FlashDetect™ Nano and FlashDetect™ Ultra platforms.
- Scalable to higher-throughput configurations on the Nano and Ultra platforms.

4. Clinical Evidence and Field Performance

1. Multicenter Diagnostic Accuracy Study^[1]

- **Study Design:** A prospective multicenter diagnostic accuracy trial was carried out to evaluate the diagnostic performance of the FlashDetect™ LyocartE MTB Assay using two specimen types: sputum and non-invasive tongue swabs.
- **Participants:** 689 consecutive, prospectively enrolled individuals with presumptive TB were enrolled across three clinical sites in China: Beijing Chest Hospital, Heilongjiang Provincial Institute of Infectious Disease Prevention and Control, and Shenyang Tenth People's Hospital.
- **Key Findings (vs. Cepheid MTB/RIF Ultra):**
 - **Sputum Performance:** The LyocartE Assay demonstrated 95.2% sensitivity and 98.6% specificity compared to the Cepheid Xpert Ultra assay.
 - **Tongue Swab Performance:** When using tongue swabs, the assay achieved 87.4% sensitivity and 99.7% specificity.
 - **High-Burden Groups:** The assay showed 99.6% sensitivity in smear-positive TB cases.
- **The optimized workflow offers three key advantages:**
 - **Rapid Results:** Achieving a sample-to-result time of 27 minutes.
 - **Extreme Portability:** The FlashDetect™ Nano platform supports external mobile power supply options, allowing for field use where stable power is unavailable.
 - **Low Barrier to Entry:** Requires minimal infrastructure; the fully automated, enclosed cartridge system workflow minimizes manual han-

dling and reduces infrastructure requirements, supporting testing in decentralized and near-point-of-care settings.

2. Community Screening

The platform has been successfully deployed in multiple large-scale community TB screening programs across China using non-invasive tongue swabs, demonstrating feasibility for decentralized molecular screening in resource-limited settings.

Field Deployment: The system has been validated through large-scale community screenings in remote regions, including:

- **Yulongkashi Town:** 2,000 residents screened over 5 days.
- **Inner Mongolia:** 1,200 residents screened in 6 days.
- **Liangshan, Sichuan:** 1,500 residents and students screened in 3 days.
- **Impact:** These evaluations demonstrate that **non-invasive tongue swab molecular testing** allows for rapid, scalable TB detection (27-minute sample-to-result) in decentralized settings with minimal infrastructure, supporting the growing role of NPOC NAATs and non-sputum sampling approaches in **decentralized TB screening** and diagnostic pathways.

5. References

- [1] Ma Z, Yu X, Yu Y, et al. Near-point-of-care diagnosis of tuberculosis with LyocartE MTB Assay: a multicentre diagnostic accuracy study. *Clinical Infectious Diseases.*, 2026,83(2):250-259.

Hangzhou ShengTing Medical Technology Co., Ltd.

Company introduction

1. Company Profile

Hangzhou ShengTing Medical Technology Co., Ltd. is a National High-Tech Enterprise founded in 2013 by a team of expats with backgrounds at the Broad Institute of MIT and Harvard University, together with the chairman of Zhejiang Tianyu Pharmaceutical Co., Ltd. (300702.SZ). The company integrates independent clinical laboratory services with the development and commercialization of innovative in vitro diagnostic (IVD) solutions, focusing on cancer screening, precision infectious disease diagnostics, and chronic disease management.

ShengTing Medical has built an integrated precision diagnostics platform spanning technology development, reagent manufacturing, automated laboratory systems, bioinformatics analysis, clinical testing, and medical services. The company operates under a comprehensive quality management system and has obtained ISO 13485 certification, while its clinical laboratory operations have achieved College of American Pathologists (CAP) accreditation and ISO 15189 accreditation.

Over the past decade, ShengTing Medical has established end-to-end capabilities in precision diagnostics, covering assay development, NGS automation, sequencing workflows, bioinformatics pipelines, and AI-assisted data interpretation. The company has developed more than 1,000 precision medicine testing services and serves over 1,300 healthcare institutions. Multiple products have received Class II or Class III IVD registration approval from the relevant medical products regulatory authorities in China.

In infectious disease diagnostics, ShengTing Medical has developed TBseq[®], a targeted NGS solution for the identification of mycobacteria and the detection of drug-resistance-associated mutations in the *Mycobacterium tuberculosis* complex. Lungseq[®] integrates broad-range pathogen detection with lung can-

cer risk assessment in a single assay, supporting the differential diagnosis of infectious and neoplastic causes of pulmonary cavitary lesions.

TBseq[®] became China's first nanopore sequencing-based diagnostic product to enter the National Medical Products Administration's Special Review Procedure for Innovative Medical Devices. In 2023, 2024 and 2025, TBseq[®] was recommended by the "WHO consolidated guidelines on tuberculosis. Module 3: diagnosis – rapid diagnostics for tuberculosis detection"^[1,2].

TBseq[®] and Lungseq[®] have been introduced or evaluated in multiple markets across Southeast Asia, Central Africa, and Southern Africa. ShengTing Medical also collaborates with global health organizations including the WHO, the Bill & Melinda Gates Foundation and FIND, supporting the validation and implementation of infectious disease diagnostic solutions.

2. Basic Information

Company Name: Hangzhou ShengTing Medical Technology Co., Ltd.

Address: Building 5, Liangzhu Life Town, Yuhang District, Hangzhou, Zhejiang, China

Official Website: www.seqtreat.com

Email: Info@ShengTingGroup.com

Tel: +86-400-773-7008

TBseq[®]

1. Product Appearance and Operation Flow

(1) TBseq[®]



(96 Tests/kit, suitable for bronchoalveolar lavage fluid, sputum, tissue, purulent discharge, cerebrospinal fluid, pleural effusion and ascites)

(2) Automated Library Preparation System

Dual Independent Zones

Each zone has 8 channels operating independently without interference.

Exhaust System

Connectable ventilation duct for controlled air exhaust.

8-Channel Pipetting Head

Precise positioning, fast movement, and flexible, efficient operation.

Automated PCR Instrument

Accurate temperature ramp control with interchangeable heated lid to prevent physical cross-contamination in each run.

Sealed Reagent Strips

Easy handling while minimizing reagent loss.

UV Sterilization & Ventilation

Equipped with UV lamps for comprehensive irradiation, strictly controlling contamination.

Air Intake Filtration System

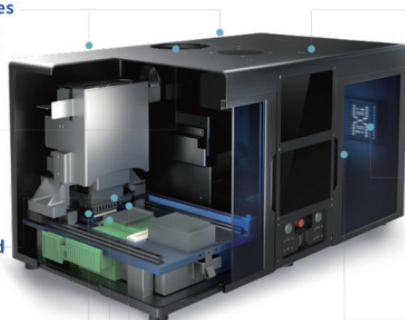
Self-suction negative pressure HEPA filtration for clean air intake.

Camera Monitoring

Dynamic video recording ensures traceability of all experimental steps.

Multi-Zone Magnetic Purification System

: Lateral adsorption of reaction and heating zones maximizes selectable magnetic capture range



(3) Sequencing Instruments

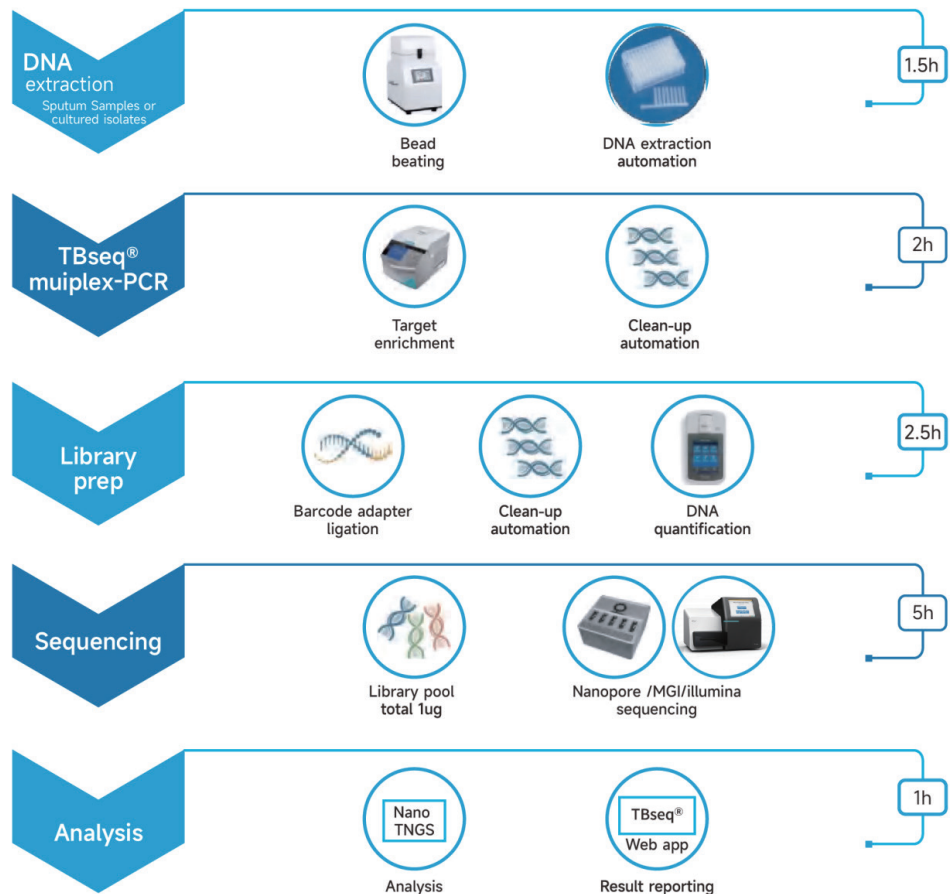
1) Third-generation sequencers



2) Second-generation sequencers



(4) Operation Flow



2. Detailed Information

Characteristics	Performance and descriptions	Notes
Intended purpose	TBseq [®] is a qualitative in vitro diagnostic assay designed to detect MTB complex DNA directly in primary specimens, such as sputum and bronchoalveolar lavage fluid (BLAF), and to identify mutations associated with resistance to five first-line and 12 second-line anti-tuberculosis drugs.	-
Target population	Individuals who have not received treatment for TB infection or TB disease within the previous 12 months and have not taken medications with antimycobacterial activity within the past 2 weeks, and who are either clinically presumptive of having pulmonary tuberculosis (e.g., those with a new or persistent cough lasting more than 2 weeks) or at increased risk of tuberculosis (TB) (including individuals living with HIV, those reporting close contact with a person with TB, and those with a history of occupational exposure in mining).	-
Intended users	Trained users working in laboratory.	-
Regulatory approval of the products	CE-IVD.	In progress: NMPA
Regulatory requirements of manufacture	ISO13485.	-
Sensitivity	Yu et al. reported TBseq [®] clinical sensitivity 90.9% across BALF, sputum, tissue, pus, CSF, pleural effusion and ascites (95% CI: 88.9–93.0%) vs. reference standard ^[3] .	[3]
Specificity	Yu et al. reported TBseq [®] clinical specificity 93.0% across BALF, sputum, tissue, pus, CSF, pleural effusion and ascites (95% CI: 97.2–99.5%) vs. reference standard ^[3] .	[3]
Multiplexing, multi-disease platform	TBseq [®] supports the identification of 168 species of both common and rare mycobacteria, including Mycobacterium avium, M. abscessus, and M. marinum.	-
Sample types	BALF, sputum, tissue, Pus, CSF, pleural effusion and ascites.	-

Characteristics	Performance and descriptions	Notes
Manual prep of samples	The manual preparation among the automated operation of the instrument takes 100 minutes.	-
Turn around time	Turnaround time of less than 12 hours.	-
Throughput per test	96 sample max for per run.	-
Power requirement	Power requirement refers to the compatible analyzer, reagent kit itself contains no electrical components.	-
Operation environment	Controlled room temperature (20–26 °C), RH 30%–70%.	-
Reagent kits transport	-20 °C--cold chain required.	-
Shelf life	Valid for 12 months.	-

3.Description of Characteristics & Advantages

(1) Broad Mycobacterial Detection

A single test simultaneously detects the MTBC complex and 168 species of nontuberculous mycobacteria (NTM).

(2) Simultaneous Detection of Drug Resistance in the MTBC and NTM.

It detects resistance to 5 first-line and 12 second-line anti-tuberculosis drugs, as well as resistance to nine drugs used in the treatment of NTM disease, targeting over 40 resistance-associated genes and more than 30,000 mutation loci.

(3) NAT2 Genotyping for Individualized Isoniazid Dosing Guidance

Detection of NAT2 gene polymorphisms enables prediction of the patient's acetylator phenotype, thereby supporting individualized isoniazid dosing decisions.

(4) Rapid Results and High Accuracy

Rapid workflow TAT is less than < 12 hours, standard balanced sequencing workflow delivers results within 17 hours

The assay achieves a diagnostic sensitivity of 90.9%, representing a 68% higher sensitivity than conventional mycobacterial culture and 12% higher than Xpert MTB/RIF.

For drug-resistance detection, the assay achieves an AUC of 97.3%, with prediction accuracy exceeding 90% for resistance to seven first- and second-line anti-tuberculosis drugs. The positive predictive value is 89.2%, reducing the likelihood of false-positive resistance calls and potentially avoiding unnecessary changes to treatment regimens.

(5) Compatible with Multiple Clinical Specimen Types

The assay supports a wide range of clinical specimens, including sputum, BALF, tissue, blood, cerebrospinal fluid, and synovial fluid. Its streamlined sample-processing workflow enables testing directly from primary clinical specimens.

(6) Automated Report Generation

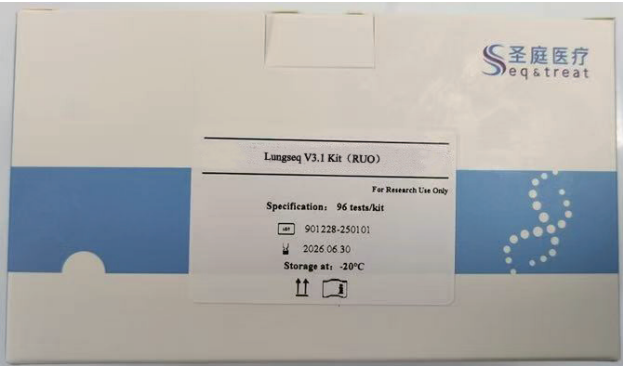
Our proprietary automated reporting system analyzes sequencing data and presents generates a standardized report summarizing mycobacterial identification, drug-resistance predictions, and relevant molecular findings.

(7) Cross-Platform Compatibility

The assay is compatible with multiple sequencing platforms, including both second-generation (NGS) and third-generation sequencing technologies. Validation studies have demonstrated consistent analytical performance across different platforms.

1. Product Appearance and Operation Flow

(1) Lungseq[®]



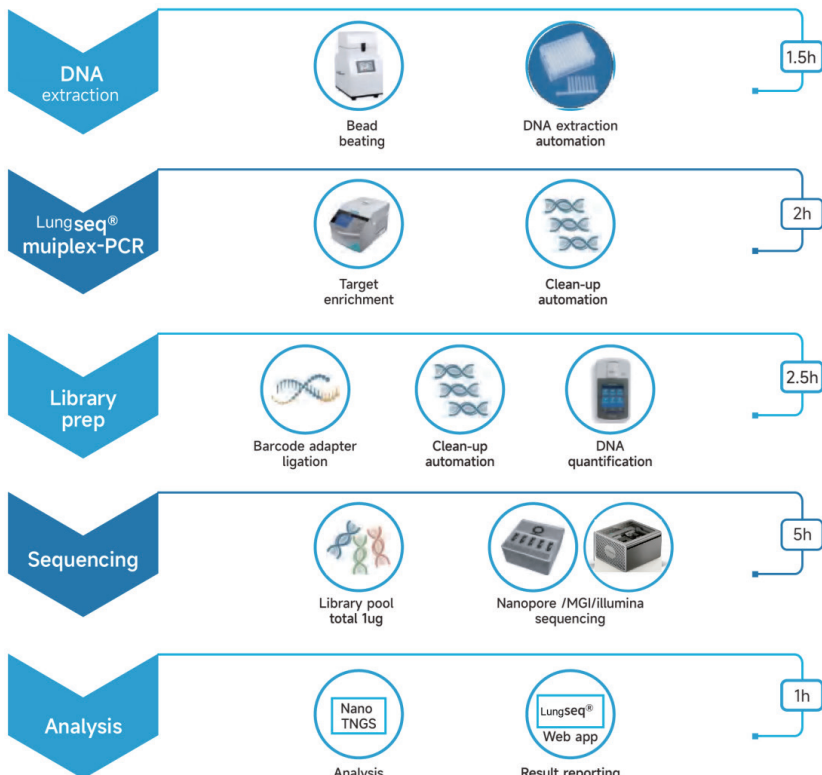
(2) Automated Library Preparation System



(3) Third-generation sequencers



(4) Operation Flow



2. Detailed Information

Characteristics	Performance and descriptions	Notes
Intended purpose	Lungseq [®] is a qualitative in vitro diagnostic assay designed to detect of 637 bacterial species, 345 fungal species, 24 atypical pathogens, and 174 mycobacterial species in raw BALF, lung tissue, and pleural/ascitic fluid samples. Additionally, the assay analyzes host DNA methylation signatures, lung cancer-associated driver gene mutations, and human copy number variations (CNVs).	-
Target population	1. Individuals with imaging findings suggestive of pulmonary cavitory lesions requiring etiological investigation. 2. Individuals requiring differentiation between malignant and infectious pulmonary cavitory lesions (e.g., tuberculosis-associated cavities). 3. Individuals with pulmonary cavitory lesions of complex, mixed, or undetermined etiology. 4. Individuals requiring detection of infections with a low microbial burden.	-
Intended users	Trained users working in a laboratory.	-
Regulatory approval of the products	-	-
Regulatory requirements of manufacture	ISO13485.	-
Sensitivity	Analytical performance shows that Lungseq [®] achieves a sensitivity of 95%, as determined by internal laboratory validation studies.	-
Specificity	Analytical performance shows that Lungseq [®] achieves a specificity of 99%, as determined by internal laboratory validation studies.	-
Multiplexing, multi-disease platform	Lungseq [®] simultaneously detects 637 bacterial species, 345 fungal species, 24 atypical pathogens, and 174 mycobacterial species, along with genomic DNA methylation signatures, lung cancer driver gene mutations and human copy number variations (CNVs).	-
Sample types	BALF, tissue, pleural and ascitic fluid.	-

Characteristics	Performance and descriptions	Notes
Manual prep of samples	The manual preparation among the automated operation of the instrument takes 100 minutes.	-
Turn around time	Turnaround time of less than 12 hours.	-
Throughput per test	96 sample max for per run.	-
Power requirement	Power requirement refers to the compatible analyzer, reagent kit itself contains no electrical components.	-
Operation environment	Controlled room temperature (20–26 °C), RH 30%–70%.	-
Reagent kits transport	-20 °C --cold chain required.	-
Shelf life	Valid for 12 months.	-

3. Description of Characteristics & Advantages

(1) Broad Pathogen Identification

A single test simultaneously detects 637 bacterial species, 345 fungal species, 24 atypical pathogens, and 174 mycobacterial species, along with genomic DNA methylation signatures, lung cancer driver gene mutations and human copy number variations (CNVs), enabling comprehensive etiological assessment of pulmonary cavitory lesions and differentiation between infectious and malignant causes.

(2) Integrated Lung Cancer Risk Assessment

Nanopore adaptive sequencing directly sequences DNA molecules retaining native methylation modifications, enabling simultaneous profiling of both DNA methylation signatures, cancer-associated mutations, and copy number variations. Bioinformatic algorithms calculate a Lung Cancer Risk Score, supporting early lung cancer risk assessment and clinical decision-making.

(3) Rapid Results and High Accuracy

The rapid workflow provides results in less than 12 hours, while the standard balanced-sequencing workflow delivers results within 17 hours.

The assay achieves a diagnostic sensitivity of 94.4%, compared with 30.0% for conventional culture, with enhanced performance in detecting fungi, viruses and atypical pathogens.

(4) Compatible with Multiple Clinical Specimen Types

The assay supports a wide range of clinical specimens, including ascitic fluid, BLAF and tissue samples. Its streamlined sample-processing workflow enables testing directly from primary clinical specimens.

(5) Automated Report Generation

Our proprietary automated reporting system analyzes sequencing data and presents the results in a standardized report format.

4. References

- [1] World Health Organization. WHO consolidated guidelines on tuberculosis: module 3: diagnosis. Geneva: World Health Organization; 2024.
- [2] World Health Organization. WHO consolidated guidelines on tuberculosis: module 3: diagnosis. Geneva: World Health Organization; 2025.
- [3] Yu S, Liu N, Xie Z, et al. Nanopore sequencing for precise detection of *Mycobacterium tuberculosis* and drug resistance: a retrospective multicenter study in China. *Journal of Clinical Microbiology*, 2025, 63(4):e01813-24.

Rocgene Co.,Ltd

Company information

1. Company Profile

Founded in 2016, Rocgene is a biotechnology company specializing in the development, manufacture, and commercialization of molecular diagnostic products based primarily on real-time PCR technology. Its portfolio spans conventional nucleic acid testing and automated molecular diagnostic solutions, including real-time PCR systems of different capacities, the iFIND low-complexity molecular POCT system, and the Atlas120 On-Demand Automated Molecular Diagnostics System. Assay menus cover tuberculosis, respiratory and fungal infections, diarrheal diseases, antimicrobial resistance, tropical diseases, and veterinary applications.

Headquartered in Beijing, RocGene (Beijing) Technology Co., Ltd. houses corporate operations and the R&D centers for instrument and reagent development, and holds over 100 patents covering microfluidics, real-time PCR, software, and associated technologies. The dedicated manufacturing base, RocGene (Xuzhou) Technology Co.,Ltd. operates under ISO 9001 and ISO 13485 quality management systems. The company currently holds 8 NMPA registrations, 36 CE-IVD certificates, 4 MHRA approvals, 4 US FDA clearances, and 3 Indonesian NADFC registrations.

Rocgene instrument platforms have been installed in more than 30 countries. To support broader international adoption, the company is conducting clinical studies in over 10 countries covering high-, middle-, and low-income regions, in collaboration with global partners including FIND, and is expanding collaboration with global health organizations to improve access in low-income countries.

2. Basic Information

Company Name: RocGene (Beijing) Technology Co., Ltd.

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Email: sale@rocgene.com

Tel: +86-010-86229225

iFIND TBR&IFQ

1. Product Appearance and Operation Flow

(1) Product Appearance



(2) Operation Flow

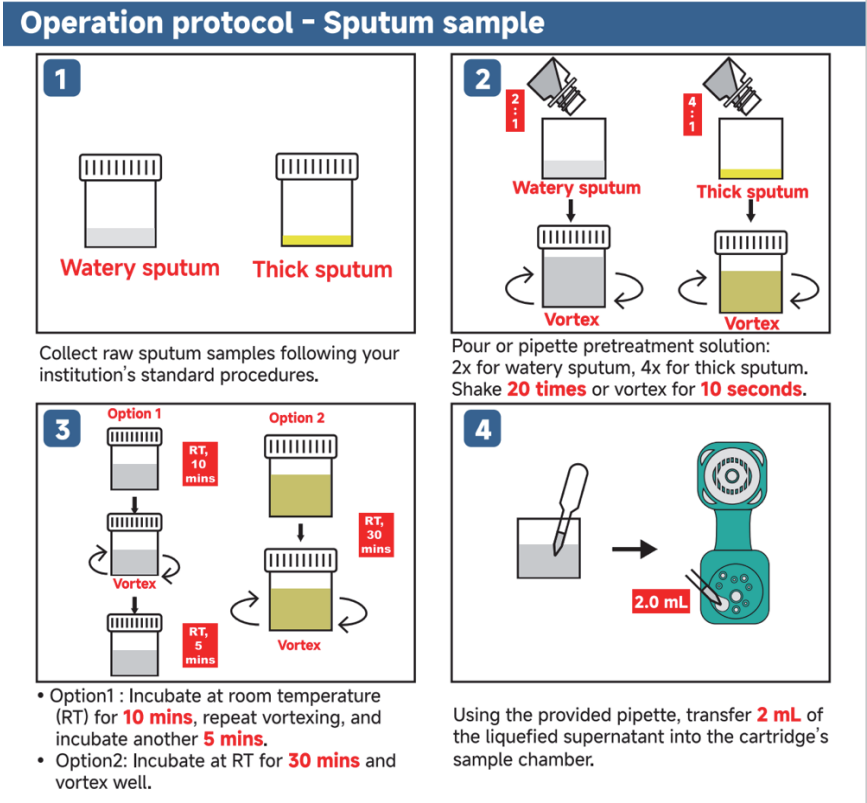


Step 1 — Sample addition.

Step 2 — Cartridge loading.

Step 3 — Automatic Result Report Generation.

(3) Sputum Sample Pretreatment Flow



Characteristic	Performance and description		Notes
Intended users	Trained laboratory professionals or trained healthcare workers in laboratory or near-point-of-care settings, LC-aNAAT.		-
Regulatory status	CE-IVD; NMPA (China). CE-IVD; NMPA (China).		-
Manufacturing quality system	ISO 9001; ISO 13485.		-
Target genes	IS6110, IS1081; rpoB RRDR ^[2,5] .	katG, inhA ; gyrA ^[4] .	-
Methodology	Nested real-time fluorescence PCR with molecular beacon probes melting-curve analysis ^[5,6] .		[2],[4]
Clinical sensitivity (positive percent agreement,PPA)	MTB 98.55% (613/622); RIF 95.58% (108/113) vs WHO-recommended molecular assays.	INH-R 94.17% (194/206); FQ 93.15% (136/146) vs phenotypic DST.	-
Clinical specificity (negative agreement)	MTB 92.76% (282/304); RIF 97.37% (370/380) vs WHO-recommended molecular assays.	INH 98.02% (595/607); FQ 98.20% (655/667) vs phenotypic DST.	-
Limit of Detection (LoD, probit analysis)	MTB: 13.34 CFU/mL; RIF-R (100% mutant): 109.79 CFU/mL.	INH: 20.79 CFU/mL; FQ: 9.34 CFU/mL.	-
Multiplexing / multi-disease platform	>10-plex capability on 6-channel optics; shared iFIND platform hosts NTM, respiratory, fungal, GI, tropical, and HAI panels.		-
Manual sample preparation	One-step sample liquefaction and inactivation ($\approx$ 15 min); only 2 mL supernatant is transferred to the cartridge with no separate nucleic acid extraction or manual reagent manipulation required.		-
Turn Around Time (TAT)	$\leq$ 135 min from sample loading ($\approx$ 120 min instrument runtime).	$\leq$ 165 min from sample loading ($\approx$ 150 min on-instrument).	-
POC or near-POC	near POCT.		-
Sample types	Sputum, sputum sediment, BALF, pleural fluid, ascites, pus, CSF, gastric aspirate, urine, stool, tissue, bacterial isolates.		-
Storage conditions	2–28 °C, protected from light, do not freeze; 12-month shelf life ^[5,6] .		[5],[6]

3. Description of characteristics and advantages

(1) iFIND TBR & IFQ

The iFIND TBR (*Mycobacterium Tuberculosis* and Rifampicin Resistance Gene Test Kit) and iFIND IFQ (*Mycobacterium Tuberculosis*, Isoniazid and Fluoroquinolone Resistance Mutation Test Kit) are fluorescence PCR-based assays designed for use on the iFIND fully automated nucleic acid detection and analysis system. Both assays use disposable hermetically sealed cartridges integrating sample pre-processing, nucleic acid extraction, target amplification, and automated result interpretation into a unified streamlined workflow.

TBR is intended for the qualitative detection of MTBC DNA and rifampicin-resistance-conferring mutations in the *rpoB* gene. IFQ is designed for the qualitative detection of isoniazid- and fluoroquinolone-resistance-conferring mutations (*katG*, *inhA*, and *gyrA*) in MTBC-positive samples.

While sputum is the primary sample types, both assays have been validated across a broad range of clinical specimens-including sputum sediment, bronchoalveolar lavage fluid (BALF), pleural fluid, ascites, pus, cerebrospinal fluid (CSF), gastric aspirate, urine, stool, tissue, and bacterial isolates — enabling testing across pulmonary, extrapulmonary, and pediatric tuberculosis.

Used together, TBR and IFQ provide complementary information that supports comprehensive tuberculosis diagnosis and drug-resistance assessment. TBR detects active tuberculosis and screens for rifampicin resistance, a surrogate marker for multidrug-resistant tuberculosis (MDR-TB); IFQ extends profiling to isoniazid and fluoroquinolones, two drug classes critical for treatment regimen selection. This sequential or parallel strategy lets clinicians rapidly evaluate both the presence of disease and the resistance pattern guiding therapy.

(2) A Highly Compact and Automated PCT Platform

- Cartridge-based sample enrichment and purification after a simple, locally performed specimen-liquefaction step.
- Built-in ultrasonication for lysis, followed by nucleic acid release and automated transfer through the closed microfluidic cartridge.
- Fluorescence PCR amplification, melting-curve acquisition where applicable, and software-based result interpretation.
- Independent testing modules on iFIND S2, S4, and S8 analyzers, supporting on-demand operation without batching.

4. References

- [1] World Health Organization. Target product profiles for tuberculosis diagnosis and detection of drug resistance. Geneva: WHO; 2024. ISBN 978-92-4-009769-8.
- [2] Ou X, Song Z, Xing R, et al. Development and preliminary assessment of the iFIND TBR: all-in-one molecular diagnostic assay for rapid detection of *Mycobacterium tuberculosis* and rifampicin resistance. *Front Cell Infect Microbiol*. 2024;14:1439099.
- [3] Ou X, Zheng H, Li Y, et al. Real-world performance of iFIND-TBR for rapid detection of *Mycobacterium tuberculosis* and rifampicin resistance in China. *Front Microbiol*. 2026;17:1757837.
- [4] Ou X, Ma Y, Zheng H, et al. iFIND INH/FQ: a LC-aNAAT assay for rapid simultaneous detection of isoniazid and fluoroquinolone resistance in *Mycobacterium tuberculosis*. *Microbiol Spectr*. 2026;14(3):e03743-25.
- [5] Rocgene. *Mycobacterium Tuberculosis and Rifampicin Resistance Gene Test Kit (Fluorescence PCR Method)*: approved Chinese Instructions for Use. Effective 20 June 2025.
- [6] Rocgene. *Mycobacterium Tuberculosis Isoniazid and Fluoroquinolone Resistance Gene Test Kit (Fluorescent PCR Method)*: approved Chinese Instructions for Use. Effective 14 April 2026.

Shenyang Hongqi Pharmaceutical Co., Ltd.

Company Introduction

1. Company Profile

Shenyang Hongqi Pharmaceutical Co., Ltd. was established in 1964 and has focused on the research and development, manufacturing, marketing, and professional services of anti-tuberculosis agents since the 1980s. Hongqi Pharma has provided quality medicines and services to more than 15 million patients with tuberculosis. In 2010, Hongqi Pharma became a member company of Shanghai Fosun Pharmaceutical (Group) Co., Ltd.

With the mission of “Making humans no longer suffer from tuberculosis” and the vision of becoming an internationally leading anti-tuberculosis pharmaceutical enterprise, Hongqi Pharma continues to invest in pharmaceutical innovation and research and development. The company is recognized as a medical translational innovation base of the Chinese Antituberculosis Association, an innovative drug research and development base associated with the National Clinical Research Center for Infectious Diseases in Shenzhen, and an enterprise technology center in Liaoning Province.

Hongqi Pharma has expanded its anti-tuberculosis portfolio through the introduction and development of products including rifampicin for injection, isoniazid injection, linezolid tablets, and pretomanid (PA-824). The company has built a tuberculosis medicine production line in accordance with the WHO Prequalification (WHO-PQ) specifications, with capacity to support supply sufficient medicines to treat over five million tuberculosis patients annually.

The company holds a portfolio (including both marketed drugs and candidates in the pipeline) that covers more than 90% of all the anti-TB agents recommended by the WHO tuberculosis treatment guidelines, spanning key products for both drug-susceptible and drug-resistant tuberculosis. Hongqi Pharma also established an anti-tuberculosis medicine supply coordination reserve in cooperation with the Chinese Antituberculosis Association to support continuity of medicine supply.

Beyond tuberculosis, the company is developing additional product lines in urology and andrology through its Hainan platform, while tuberculosis remains its principal strategic therapeutic field.

2. Basic Information

Company Name: Shenyang Hongqi Pharmaceutical Co., Ltd. (Hongqi Pharma)

Address: No. 6 Xinluo Street, Hunnan District, Shenyang, Liaoning Province, China

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Email: hongqi@hongqipharma.com

Tel: +86-24-23786268

Tuberculosis Product Portfolio

- Drug-susceptible TB: ethambutol hydrochloride tablets and capsules; pyrazinamide tablets and capsules; rifampicin capsules and rifampicin for injection; isoniazid tablets and isoniazid injection; rifapentine capsules; rifampicin and isoniazid tablets/capsules; and fixed-dose combination tablets.
- Drug-resistant TB: pretomanid tablets; bedaquiline fumarate tablets; cycloserine capsules; linezolid tablets; and moxifloxacin hydrochloride tablets.

1. Product Appearance and Portfolio Overview

The supplied materials present a broad pharmaceutical portfolio, with tuberculosis as the company's core therapeutic field. The tuberculosis portfolio includes both drug-susceptible and drug-resistant TB products, together with selected active pharmaceutical ingredients.

HONGQI PHARMA
A FOSUN PHARMA Company

Extensive TB product pipeline covering key drugs of DS-TB and DR-TB treatment

Category	Product Name	Description
DS-TB	怡诺尼康® Ethambutol Hydrochloride, Pyrazinamide, Rifampicin and Isoniazid Tablets (II)	
	Rifampin and Isoniazid Tablets/ Capsules	
	Isoniazid Tablets/Pyrazinamide Tablets/ Ethambutol Hydrochloride Tablets/ Rifampicin Capsules	
	复和® Rifampicin Capsules (II)/天再欣® Rifampicin for Injection	
DR-TB	Pretomanid Tablets (PA-824)	The core drug of the 6-month short-course regimens for DR-TB treatment (BPoLM/BPaL recommended by WHO guidelines)
	Moxifloxacin Hydrochloride Tablets	
	安斯诺康® Cycloserine Capsules	
	Linezolid Tablets	
	Bedaquiline Fumarate Tablets	

Figure 1. Hongqi Pharma tuberculosis product portfolio and selected product appearance.

2. Detailed information

(1) Bedaquiline

Characteristics	Performance and descriptions	Notes
Indication for use	As part of an appropriate combination regimen for the treatment of pulmonary tuberculosis caused by <i>Mycobacterium tuberculosis</i> resistant to at least rifampicin and isoniazid in adults and adolescents aged 12 to <18 years and weighing ≥ 30 kg. Reserved for cases where an alternative effective therapeutic regimen is unavailable.	-
Target population	Adults and adolescents aged 12 to <18 years and weighing ≥ 30 kg with pulmonary tuberculosis caused by <i>M. tuberculosis</i> resistant to at least rifampicin and isoniazid.	-
Mechanism of action	Bedaquiline is a diarylquinoline antimycobacterial agent that inhibits mycobacterial ATP synthase by binding to subunit c, thereby disrupting the energy generation required by <i>M. tuberculosis</i> .	-
Safety	The most common adverse reactions in adult clinical studies included nausea, arthralgia, headache, haemoptysis and chest pain. Key identified safety risks include QTc interval prolongation and hepatotoxic potential, an imbalance in mortality observed in one placebo-controlled trial, and drug interactions mediated by CYP3A4. Treatment should be discontinued if clinically significant ventricular arrhythmia occurs or QTc exceeds 500 ms on repeat ECG.	-
In vitro activity	Bedaquiline is active against most <i>M. tuberculosis</i> isolates in vitro and in clinical infection. Susceptibility testing may use 7H9 broth microdilution or agar methods over a concentration range of 0.008–2.0 $\mu\text{g/mL}$. Interpretive criteria for bedaquiline susceptibility testing have not been established.	-
Efficacy	In Study 1, bedaquiline added to a background regimen shortened the median time to sputum culture conversion at Week 24 compared with placebo (83 days versus 125 days) and increased the proportion of patients with culture conversion ^[1] .	[1]
Regulatory approval of the products	Approved in China on 7 May 2026. Marketing authorisation number: H20264244.	-

Characteristics	Performance and descriptions	Notes
Pharmacokinetics	Median time to maximum plasma concentration is approximately 5 hours after a single oral dose. A high-fat meal approximately doubles C _{max} and AUC; therefore, bedaquiline should be taken with food. Bedaquiline is a CYP3A4 substrate. Renal excretion of unchanged bedaquiline is minimal ($\leq 0.001\%$).	-
Route of administration	Oral administration. Swallow the tablet whole with water and take with food.	-
Formulation/presentation	Bedaquiline fumarate tablets, 100 mg (expressed as bedaquiline). White to off-white tablets. Blister pack: 8 tablets per blister, 3 blisters per carton.	-
Dose regimen	400 mg oral once daily for the initial 2 weeks, then 200 mg oral three times weekly for the subsequent 22 weeks (minimum 48-hour interval between doses).	-
Co-administration	Use only in combination with other antimycobacterial agents. Combine with at least three drugs to which the patient's isolate is susceptible; if in vitro susceptibility results are unavailable, combine with at least four drugs likely to be active. Avoid moderate or strong CYP3A4 inducers. Monitor safety when used with CYP3A4 inhibitors or other QTc-prolonging drugs.	-
Product stability and storage	Protect from light. Store in a tightly closed container at a temperature not exceeding 30°C. Shelf life: 24 months.	-

(2) Additional information for Bedaquiline paediatric formulation

Characteristics	Performance and descriptions	Notes
Target population	Adolescents aged 12 to <18 years and weighing ≥ 30 kg with pulmonary tuberculosis caused by <i>M. tuberculosis</i> resistant to at least rifampicin and isoniazid. Safety and efficacy have not been established in patients aged <12 years and/or weighing <30 kg.	-
Efficacy and safety	In the single-arm, open-label C211 study, 15 adolescents aged 14 to <18 years received bedaquiline with a background regimen. Among baseline culture-positive patients, the Week 24 culture conversion rate was 75.0% (6/8). The most common adverse reactions were arthralgia (40%), nausea (13%) and abdominal pain (13%); no deaths occurred during bedaquiline treatment ^[2] .	[2]

Characteristics	Performance and descriptions	Notes
Pharmacokinetics	In 15 adolescents aged 14 to <18 years receiving the adult dosing regimen, bedaquiline pharmacokinetic parameters were comparable to those in adults. Body weight had no effect on pharmacokinetics within the studied range of 38–75 kg. Pharmacokinetics have not been evaluated in patients aged <14 years or weighing <38 kg ^[2] .	[2]
Formulation/presentation	Bedaquiline fumarate tablets, 100 mg (expressed as bedaquiline).	-
Dose regimen	Same as the adult regimen: 400 mg orally once daily for 2 weeks, followed by 200 mg orally three times per week for 22 weeks, with at least 48 hours between doses. Total treatment duration: 24 weeks.	-

(3) Pretomanid

Characteristics	Performance and descriptions	Notes
Indication for use	As part of a combination regimen with bedaquiline and linezolid for the treatment of adult pulmonary tuberculosis caused by <i>Mycobacterium tuberculosis</i> that is resistant to isoniazid, rifamycins, any fluoroquinolone and at least one second-line injectable anti-TB drug, or adults with isoniazid- and rifampicin-resistant pulmonary TB who are intolerant of or non-responsive to standard treatment.	-
Target population	Adults with highly drug-resistant pulmonary TB meeting the approved indication.	-
Mechanism of action	Nitroimidazooxazine antimycobacterial. Inhibits mycolic acid biosynthesis in actively replicating M. tuberculosis and releases nitric oxide under anaerobic conditions to kill non-replicating bacilli after Ddn/ F420-dependent activation.	-
Safety	Common adverse reactions: nausea, vomiting, elevated transaminases. Important risks: hepatotoxicity, QT prolongation (with bedaquiline), myelosuppression, peripheral/optic neuropathy (mainly linezolid-related) ^[3,4] .	[3],[4]
In vitro activity	Active against the M. tuberculosis complex. Baseline MIC in clinical isolates: 0.06–1 µg/mL.	-
Efficacy	Nix-TB: favorable outcome 90%. ZeNix: favorable outcomes 84.1–93.2% depending on linezolid dose/duration ^[6] .	[5],[6]

Characteristics	Performance and descriptions	Notes
Regulatory approval of the products	Approved for the restricted indication described in the label.	-
Pharmacokinetics	t _{max} 4–5 h; food increases exposure; protein binding 86.4%; t _{1/2} about 17 h; partly metabolized by CYP3A4 ^[3,4] .	[3],[4]
Route of administration	Oral.	-
Formulation/presentation	200 mg uncoated oval tablet.	-
Dose regimen	Pretomanid 200 mg once daily orally for 26 weeks, administered concomitantly with bedaquiline and linezolid; oral intake with food is required ^[3,4] .	[3],[4]
Co-administration	Must be co-administered with bedaquiline and linezolid ^[3,4] .	[3],[4]
Product stability and storage	Store below 30°C in a tightly closed container.	-

(4) FDC_HRZE

Characteristics	Performance and descriptions	Notes
Indication for use	For the initial 2-month intensive phase of short-course chemotherapy for pulmonary tuberculosis. The product should be taken daily during this phase.	-
Target population	Patients with pulmonary tuberculosis requiring the initial intensive phase of treatment. The product is not suitable for patients weighing less than 30 kg.	-
Mechanism of action	Fixed-dose combination of rifampicin, isoniazid, pyrazinamide and ethambutol. The four active ingredients act against <i>Mycobacterium tuberculosis</i> through different mechanisms, including inhibition of mycobacterial RNA synthesis, mycolic-acid/cell-wall synthesis and other essential metabolic processes.	-
Safety	Adverse reactions described in the package insert include hematologic disorders, neuropsychiatric and visual disorders, gastrointestinal reactions, skin reactions, hepatobiliary disorders, hyperuricemia/gout and other reactions associated with rifampicin, isoniazid, pyrazinamide and ethambutol. Important precautions include monitoring liver function and visual function, and avoiding use in patients with relevant contraindications stated in the package insert.	-

Characteristics	Performance and descriptions	Notes
In vitro activity	The active ingredients have antimycobacterial activity against <i>Mycobacterium tuberculosis</i> .	-
Efficacy		-
Regulatory approval of the products	Chinese drug approval number: National Medical Product Approval No. H20061903.	-
Route of administration	Oral.	-
Formulation/ presentation	Film-coated fixed-dose combination tablet. Each tablet contains rifampicin 150 mg, isoniazid 75 mg, pyrazinamide 400 mg and ethambutol hydrochloride 275 mg.	-
Dose regimen	Once daily according to body weight: 30-37 kg, 2 tablets; 38-54 kg, 3 tablets; 55-70 kg, 4 tablets; above 70 kg, 5 tablets. The tablets should be taken as a single daily dose.	-
Co-administration	-	-
Product stability and storage	Store in a tightly closed container, protected from light.	-

(5) Rifampin and Isoniazid Capsules

Characteristics	Performance and descriptions	Notes
Indication for use	For the 4-month continuation phase of treatment in patients with newly diagnosed tuberculosis or non-multidrug-resistant tuberculosis.	-
Target population	Adults weighing less than 50 kg (excluding 50 kg) who require continuation-phase treatment for newly diagnosed or non-multidrug-resistant tuberculosis.	-
Mechanism of action	Rifampin inhibits the DNA-dependent RNA polymerase of <i>Mycobacterium tuberculosis</i> and thereby suppresses bacterial RNA synthesis. Isoniazid inhibits the synthesis of mycolic acids in the mycobacterial cell wall.	-

Characteristics	Performance and descriptions	Notes
Safety	Adverse reactions described in the package insert include gastrointestinal reactions, hepatotoxicity, hypersensitivity reactions, hematologic abnormalities, peripheral neuritis and other nervous-system reactions. Liver function should be monitored, and pyridoxine may be considered in patients at increased risk of peripheral neuropathy.	-
In vitro activity	Rifampin and isoniazid have antibacterial activity against MTBC. Rifampin acts on both intracellular and extracellular organisms, while isoniazid is bactericidal against actively dividing mycobacteria.	-
Efficacy	-	-
Regulatory approval of the products	Chinese drug approval number: National Medical Product Approval H21023354.	-
Pharmacokinetics	Following oral administration of rifampin 10 mg/kg on an empty stomach, peak plasma concentration is reached in approximately 2-4 hours, with an elimination half-life is approximately 3-5 hours. Following oral administration of isoniazid 300 mg, peak plasma concentration is reached in approximately 1-2 hours and the elimination half-life is approximately 1-3 hours.	-
Route of administration	Oral.	-
Formulation/ presentation	Capsules. Each capsule contains rifampin 0.15 g and isoniazid 0.10 g.	-
Dose regimen	For adults weighing less than 50 kg: 3 capsules once daily, providing rifampin 0.45 g and isoniazid 0.30 g per dose.	-
Co-administration	-	-
Product stability and storage	Store in a tightly closed container, protected from light, in a dry and cool place.	-

(6) Rifampin and Isoniazid tablets

Characteristics	Performance and descriptions	Notes
Indication for use	For the treatment of various types of tuberculosis.	-
Target population	-	-

Characteristics	Performance and descriptions	Notes
Mechanism of action	Rifampin inhibits DNA-dependent RNA polymerase in susceptible mycobacteria, thereby suppressing RNA synthesis. Isoniazid acts mainly against actively growing mycobacteria; its mechanism of action is thought to involve inhibition of mycolic acid synthesis and disruption of the bacterial cell wall.	-
Safety	Adverse reactions described in the package insert include hepatotoxicity, gastrointestinal reactions, hypersensitivity reactions, hematologic abnormalities, peripheral neuritis and other neurologic reactions. Liver function should be monitored during treatment. The product is contraindicated in patients with hypersensitivity to rifamycins or isoniazid and in patients with severe hepatic dysfunction.	-
In vitro activity	-	-
Efficacy	-	-
Regulatory approval of the products	Chinese drug approval number: National Medical Product Approval H20103325.	-
Pharmacokinetics	Rifampin is rapidly absorbed after oral administration; peak blood concentration is reached in approximately 2-4 hours, and the elimination half-life is approximately 5.1 hours. Isoniazid is rapidly and almost completely absorbed after oral administration; peak blood concentration is reached in approximately 1-2 hours. Its elimination half-life is approximately 0.5-1.6 hours in fast acetylators and 2-5 hours in slow acetylators.	-
Route of administration	Oral.	-
Formulation/ presentation	Film-coated tablets. Each tablet contains rifampin 0.3 g and isoniazid 0.15 g.	-
Dose regimen	Take 30 minutes before a meal or 2 hours after a meal. Adults weighing more than 50 kg: 2 tablets once daily. Continue treatment until bacteriological conversion and maximum improvement of clinical symptoms, or as directed by the physician.	-
Co-administration	-	-
Product stability and storage	Store in a tightly closed container, protected from light, in a dry place.	-

3. Description of Characteristics & Advantages

(1) Long-standing focus on tuberculosis

Founded in 1964, Hongqi Pharma has maintained tuberculosis as a central therapeutic field. Its stated mission and vision position TB control and anti-tuberculosis drug manufacturing as long-term corporate priorities.

(2) Broad coverage of drug-susceptible and drug-resistant TB medicines

The supplied portfolio covers major first-line anti-tuberculosis agents and several key medicines used for drug-resistant TB, allowing the company to present a relatively complete TB-focused product offering.

(3) Portfolio support for contemporary short-course DR-TB regimens

The materials include pretomanid, bedaquiline, linezolid, and moxifloxacin, which are core components of BPaL/BPaLM regimens. This portfolio structure is relevant to the development and supply of modern all-oral short-course treatment options for drug-resistant TB^[7].

(4) Combination of finished products and selected APIs

The product list includes finished pharmaceutical products as well as selected APIs, including bedaquiline fumarate and pretomanid. This demonstrates that the company's supplied portfolio extends beyond a single finished dosage form.

(5) Quality and regulatory foundation in China

According to the supplied company profile, all first-line anti-tuberculosis products have passed China's generic drug consistency evaluation. This provides a documented domestic quality and regulatory foundation for the company's established TB portfolio.

(6) International orientation

The company profile explicitly states that Hongqi Pharma is based in the domestic market while looking globally. Its mission and vision also emphasize an international first-class anti-tuberculosis drug manufacturing enterprise.

4. References

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Shanghai MicuRx Pharmaceuticals Co., Ltd.

Company Introduction

1. Company Profile

Shanghai MicuRx Pharmaceuticals was founded in 2007 as an innovative biopharmaceutical company focused on treating infectious diseases, with globally independent intellectual property rights and international competitiveness. Upholding the philosophy of “Better Therapy Through Superior Medicine.” the company addresses the growing global challenge of bacterial resistance by providing patients with differentiated and superior treatment options. With R&D centers established in both China and the United States, MicuRx boasts an international core R&D team and an integrated antibacterial new drug development system.

The company's first product, Contezolid Tablets, was approved for marketing in June 2021 through the NMPA's priority review and approval process, and was included in the National Reimbursement Drug List in December of the same year. It was successfully renewed in 2023 and 2025, and clinical trials to expand its indication to pediatric populations have been completed. The company also has multiple product candidates in clinical stages, including MRX-4 (Contezolid Acefosamil Sodium for injection; Phase III clinical trial in China for complicated skin and soft tissue infections [cSSTI] has been successfully completed, and the New Drug Application [NDA] has been accepted by the CDE and is currently under review), MRX-5 (for the treatment of non-tuberculous mycobacterial infections; Phase I first-in-human trial completed in Australia; the healthy subject portion of Phase I in China has been completed, and a patient cohort with Mycobacterium abscessus pulmonary disease is currently being enrolled; the U.S. FDA has approved the IND and a Phase IIa clinical trial is about to be initiated, with Orphan Drug Designation granted), and MRX-8 (for the treatment of multidrug-resistant Gram-negative bacterial infections; Phase I clinical trials in both the U.S. and China have been completed). In addition, the company has several preclinical-stage novel anti-resistant bacterial drugs, as well as pipeline candidates for renal cancer and nephritis.

2. Basic Information

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Introduction to Anti-Tuberculosis Drugs

1. Product Appearance



2. Detailed Anti-Tuberculosis Drug Information

Characteristic	Description	Notes
Indication	Treatment of complicated skin and soft tissue infections caused by susceptible strains of Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant strains), Streptococcus pyogenes, or Streptococcus agalactiae ^[1] .	According to the Expert Consensus on All-Oral Short-Course Regimens for Drug-Resistant Tuberculosis and the Expert Consensus on Contezolid for the Treatment of Tuberculosis, this drug is recommended for TB patients in the following situations ^[2,3] : 1. When initial treatment regimens fail to constitute an effective and adequate therapeutic combination. 2. When patients experience adverse reactions such as myelosuppression or neuritis leading to drug intolerance. 3. When patients are anticipated to have a high risk of linezolid-related adverse reactions or elevated potential for drug-drug interactions.
Target Population	Patients with infections meeting the above criteria.	Adult and pediatric patients meeting the above criteria.

Characteristic	Description	Notes
Mechanism of Action	Contezolid exerts its antibacterial effect through the same mechanism as other oxazolidinone antimicrobials, i.e., by inhibiting the formation of the functional 70S initiation complex essential for bacterial protein synthesis^[1].	[1]
Safety	- The most common adverse reactions observed in clinical trials are gastrointestinal reactions (nausea, vomiting, abdominal discomfort), most of which are mild to moderate in severity, transient, and resolve spontaneously without pharmacological intervention^[1]. - A prospective study demonstrated that the incidence of myelosuppression and neurotoxic adverse reactions in the contezolid-containing anti-TB regimen group was 0% (only gastrointestinal reactions were observed). In contrast, the linezolid group showed a myelosuppression rate of 30.8% and a peripheral neuropathy rate of 53.8%^[4].	[1],[4]
In Vitro Activity	- The MICs of contezolid against clinical isolates of drug-susceptible and drug-resistant <i>M. tuberculosis</i> ranged from 0.125 to 4 mg/L, demonstrating anti-TB activity comparable to that of linezolid^[5,6,7]. - The intracellular antibacterial activity of contezolid against <i>M. tuberculosis</i> was significantly superior to that of linezolid^[6].	[5],[6],[7]

Characteristic	Description	Notes
Efficacy	Early Bactericidal Activity (EBA) Study: In a 14-day EBA study comparing the bactericidal activity of contezolid (800 mg BID) and linezolid (600 mg QD) as monotherapy in treatment-naïve pulmonary TB patients, the EBA_{0–14} for contezolid was similar to that of linezolid (0.08 vs. 0.03 log₁₀CFU/mL/day, respectively). Although the initial bactericidal activity of contezolid was lower than that of linezolid in the first few days, its efficacy surpassed that of linezolid after the first week of treatment^[8]. Clinical Efficacy Studies: • A prospective, randomized, active-controlled study showed that during a 2-month treatment period for drug-resistant pulmonary TB, sputum culture conversion rates and lesion absorption rates were comparable between the contezolid and linezolid groups^[4]. • A retrospective study on drug-resistant TB showed that the treatment success rate was 96.3% in the contezolid group and 98.15% in the linezolid group (P=0.491). Sputum culture conversion rates within 6 months exceeded 92% in both groups, with no statistically significant difference. Symptom improvement and radiological resolution were also comparable between the two groups^[9].	[4],[8],[9]
Regulatory Approval	Approved for the indications as stated in the approved labeling.	-

Characteristic	Description	Notes
Pharmacokinetics	• Absorption and Distribution: Following oral administration with food at steady state, the median time to maximum plasma concentration (T_{max}) is approximately 2.5 hours. Systemic exposure increases proportionally with dose. Food enhances the absorption of contezolid; therefore, it is recommended to be taken with or within 30 minutes after a meal. The drug is widely distributed in healthy subjects, with a mean apparent volume of distribution of approximately 0.61 L/kg^[1]. • Metabolism and Elimination: Metabolism is primarily catalyzed by flavin-containing monooxygenase 5 (FMO5) and cytosolic reductases, without interfering with cytochrome P450 (CYP450) isoenzymes. No significant accumulation of the parent drug or its major metabolite M2 was observed after 7-14 days of BID dosing. The cumulative urinary and fecal excretion of the parent drug accounts for less than 5% of the administered dose^[1].	[1]
Route of Administration	Oral ^[1] .	[1]
Dosage Form/Appearance	400 mg white, film-coated tablets ^[1] .	[1]
Dosage Regimen	800 mg of contezolid, administered orally twice daily, with or within 30 minutes after a meal ^[1] .	[1]
Combination Therapy	Should be administered in combination with other anti-TB drugs.	-
Stability and Storage	Store in a closed container at a temperature not exceeding 25°C. Shelf life: 48 months.	-

Information Relevant to Pediatric Use

Characteristic	Description	Notes
Target Population	Pediatric TB patients for whom initial treatment regimens fail to constitute an effective and adequate therapeutic combination, or who experience adverse reactions such as myelosuppression or neuritis leading to drug intolerance, or who are anticipated to have a high risk of linezolid-related adverse reactions or elevated potential for drug-drug interactions ^[3,10] .	[3],[10]
Efficacy and Safety	Although large-scale efficacy and safety evaluations of contezolid in pediatric TB patients are lacking, clinical case reports indicate favorable efficacy and safety profiles in children: • A 6-year-old patient with tuberculous pleurisy was successfully treated with contezolid at a dose of 200 mg every 12 hours^[11]. • A 4-month-old infant with pre-extensively drug-resistant TB (pre-XDR-TB) was successfully treated with a regimen containing contezolid at a dose of 16 mg/kg every 12 hours^[12].	[11],[12]
Pharmacokinetics	-	-
Dosage Form/Appearance	400 mg white, film-coated tablets.	-
Dosage Regimen	Based on limited evidence, the reference pediatric dosage for contezolid is as follows (administered orally, with or within 30 minutes after a meal, twice daily) ^[1,10] : • Body weight ≥50 kg and 12 years ≤ age < 18 years: 800 mg • 35 kg ≤ body weight < 50 kg and 6 years ≤ age < 18 years: 600 mg • 20 kg ≤ body weight < 35 kg and 6 years ≤ age < 12 years: 400 mg • Body weight < 20 kg or age < 6 years: Calculate dose at 12-20 mg/kg.	[1],[10]

3. Description of Characteristics & Advantages

1) Potent Antibacterial Activity and Proven Efficacy: Conte zolid exhibits superior intracellular bactericidal activity against M. tuberculosis compared to linezolid^[6]; its in vitro anti-TB activity is comparable to that of linezolid^[5,6,7]. Its clinical efficacy in treating drug-resistant pulmonary TB is comparable to that of linezolid^[4].

2) Significantly Improved Safety Profile: Among marketed oxazolidinones, contezolid has demonstrated the most favorable therapeutic index^[13]. It is associated with a lower risk of myelosuppression, optic neuropathy, and peripheral neuropathy^[11]. Gastrointestinal reactions are mostly transient, mild to moderate, and generally resolve without the need for pharmacological intervention^[11].

3) Fewer Drug-Drug Interactions and Broad Applicability: Metabolized primarily by FMO5, independent of the CYP450 enzyme system, resulting in fewer drug-drug interactions^[1,14] and reduced concerns for concomitant medication at therapeutic doses^[1,14]. No dose adjustment is required in special populations such as the elderly, patients with renal impairment, or patients with mild-to-moderate hepatic impairment¹. Routine therapeutic drug monitoring (TDM) is not required.

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Some supporting evidence is derived from Chinese-language package insert and Chinese expert consensus documents^[1-3,10].

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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).

Over the past two decades, China has witnessed groundbreaking technological advances in artificial intelligence (AI), microfluidics, 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 accurate in diagnostic performance, rapid in turn-around time, peripheral level deployable and with cost-effectiveness have been successfully developed. A number of these solutions have been validated and studied under trial or programmatic conditions across vast regions of China or even outside 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 deploy 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 of 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.

In recent years, China has seen a wave of significant development in reshaping its presence in the global innovative drug sector. Most notably, the adaptation of GCP standards and ICH guidelines in conducting clinical trials for the purpose of registering innovative pharmaceuticals as well as meeting the bench-

marks of the WHO Listed Authorities (WLAs) by streamlining and fast-tracking regulatory processes for drugs that are of great public health benefits and urgently needed by its indicative patient populations. A number of indigenously developed novel anti-TB compounds, repurposed TB drugs as well as generic versions of novel drugs like Bedaquiline and Pretomanid have been either advancing steadily in pre-clinical and clinical pipelines or already being manufactured and marketed domestically. As China's overall TB burden continues to fall, its pharmaceutical capacity may well be poised to provide the rest of the world, especially other high TB burden countries with therapeutic choices that are safe and effective.

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 (be it IVD or drug or vaccine). 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.



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