A Quick Glance of Innovative Tuberculosis Diagnostic Technologies from China

INNOVATION ALLIANCE ON TUBERCULOSIS DIAGNOSIS AND TREATMENT (BEIJING)

October 2024

Forewords

Tuberculosis (TB) is a major public health challenge faced by all humanity. According to the World Health Organization's (WHO) latest estimates, there were nearly 10.6 million new incident TB cases and more than 1.3 million people dying from TB in 2022. As a high TB burden country, China still faces a number of challenges in TB prevention and care common across the world despite remarkable achievements.

Early detection of TB is not only a prerequisite in terms of prescribing appropriate treatment and improving treatment outcomes, but key to effective containment of on-going transmission of mycobacterium tuberculosis (Mtb). Due to their inherent limitations, traditional radiological and bacteriological means of detection could not meet the needs of active case finding among at risk populations. Therefore, development and clinical uptake of novel TB screening and diagnosing tools that are suitable for different use cases is urgently needed.

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

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 prophylaxis 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 diagnostics, international cooperation, digital medical platform and services, academic promotion as

well as capacity building. This handbook comprehensively introduces the basic mechanism, diagnosing performance, use cases as well as advantages and limitations of 12 novel TB IVD and computer aided detection (CAD) products developed by 6 Chinese innovators. In doing so, we demonstrate China's resolve in advancing the eradication of TB in China and beyond. While IATB stands ready to be a bridging force introducing the most promising of China's innovative TB solutions that are safe, effective and affordable to the world, especially those resource constraint high burden countries.

Dr. Li Liang Li Liang

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

Introduction of IATB

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

Under the leadership of a board and a secretariat, IATB operates in the following domains, namely a clinical research consortium, education and training, laboratory quality assurance, remote and online medical services as well as international cooperation. Since its founding, IATB has been operating the China Tuberculosis Clinical Trials Consortium (CTCTC) which was founded in collaboration with the US National Institute of Health (NIH) in September 2013. The research network now covers 29 TB hospitals (all CFDA certified site compliant with GCP standards) and has conducted a number of important clinical researches on novel anti-TB drugs and regimens among Chinese patients. In terms of training and education, IATB organizes a series of important academic events in China, namely the annual China TB R&D Collaboration International Forum, the annual China Tuberculosis International Forum, a co-organizer to the annual National Tuberculosis Academic Forum and the annual Tuberculosis International Training Workshop under the Belt & Road initiative. IATB also conducts cross laboratory quality assurance works, including DST QA, among membership hospitals, and validation studies for innovative TB diagnostics developed by our industrial partners. Since 2017, IATB has been working on a number of online and remote medical platforms, some for clinical data harmonization, the others for remote clinical services for under-developed high-burden regions. IATB recognizes the importance of international cooperation in advancing technological R&D innovation in the field of TB prevention and control. The alliance also recognizes that China has much to offer to the END-TB course through its indigenous innovations and technologies. In this course, IATB has been a driving force for promoting and showcasing Chinese innovative TB solutions on the world stage.

CONTENTS

Jiangxi JF Healthcare Technology Co., Ltd.

Company Introduction

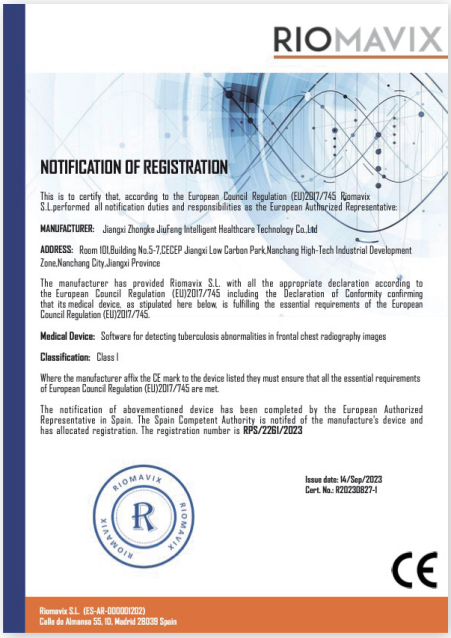
1.Company Profile

Founded in 2015, with a comprehensive partnership with the Chinese Academy of Sciences, JF Healthcare is committed to build a comprehensive remote diagnosis platform that integrates radiology imaging, genetics, hematology, pathology, and computer-aided detection to provide remote diagnostic services for diseases like emphysema, fractures, chronic bronchitis, tumors and of course pulmonary tuberculosis.

The "Pulmonary Tuberculosis X-ray Image Computer-aided Detection Software" (generic name JF-CXR 1 and JF-CXR 2) developed by Jiangxi JF Healthcare Technology Co., Ltd. uses deep learning technology to assist in radiological interpretation in distinguishing among various pathologies such as active pulmonary tuberculosis diseases or residual of past lesions, various infectious pulmonary lesions, pulmonary nodules, and other common and multiple chest and orthopedics lesions. The software can instantly generate likelihood scores and reports in turn, improve diagnostic accuracy and turn-around times through AI-assisted imaging reading, and is suitable for active TB case finding in areas with limited medical resources. The software can be deployed in various ways such as local workstations, remote cloud platforms, mobile clinic vans, portable and ultra-portable DR, etc.

Computer-aided detection has the characteristics of low cost, rapid, high accuracy, and simple deployment, with no need for a complex laboratory facility and consumables. The higher the volume of CAD reading, the lower the cost per reading.

- In October 2022, our JF-CXR 1 became the very first TB CAD software to obtain Class III medical device registration certificate from the National Medical Products Administration (NMPA) in China. Findings of a clinical



RIOMAVIX

NOTIFICATION OF REGISTRATION

This is to certify that, according to the European Council Regulation (EU)2017/745 Riomavix S.L.performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: Jiangxi Zhongke JiuFeng Intelligent Healthcare Technology Co.,Ltd

ADDRESS: Room 101,Building No.5-7,CECEP Jiangxi Low Carbon Park,Nanchang High-Tech Industrial Development Zone,Nanchang City,Jiangxi Province

The manufacturer has provided Riomavix S.L. with all the appropriate declaration according to the European Council Regulation (EU)2017/745 including the Declaration of Conformity confirming that its medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Regulation (EU)2017/745.

Medical Device: Software for detecting tuberculosis abnormalities in frontal chest radiography images

Classification: Class I

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Regulation (EU)2017/745 are met.

The notification of abovementioned device has been completed by the European Authorized Representative in Spain. The Spain Competent Authority is notified of the manufacture's device and has allocated registration. The registration number is **RPS/2261/2023**

Issue date: 14/Sep/2023
Cert. No.: R20230827-I

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

DEPARTAMENTO DE PRODUCTOS SANITARIOS

N/REF: PS/RPS/2261/2023

O F I C I O

Comunicación: RPS/2261/2023
Nº AEMPS: 23-03706
Fecha: 14/09/2023
Asunto: **Anotación de la comunicación en el Registro de Responsables de la puesta en el mercado de Productos Sanitarios**

RIOMAVIX SL
Calle de Almansa 55,1D
28039 - Madrid
MADRID
Madrid, Comunidad de

Con fecha **14/09/2023** ha sido **registrada** en la aplicación de Registro de Responsables de la puesta de mercado de Productos Sanitarios (RPS) de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) la comunicación presentada por **RIOMAVIX SL**, con la siguiente información:

1. Número de identificación asignado en el registro

RPS/2261/2023

2. Responsable de la puesta en el mercado de los productos sanitarios

Empresa **RIOMAVIX SL**
Calle de Almansa 55,1D
28039 - Madrid (MADRID)
Madrid, Comunidad de

En calidad de **Representante**

3. Legislación que declara cumplir:

PS - Reglamento (EU) 2017/745.

4. Página(s) adicional(es) de productos sanitarios incluidos en esta comunicación.

REGISTRO DE RESPONSABLES DE LA PUESTA EN EL MERCADO DE PRODUCTOS SANITARIOS
DEPARTAMENTO DE PRODUCTOS SANITARIOS

Nota.- Esta notificación no tiene el carácter de una autorización sanitaria de comercialización, ni entraña un juicio sobre la conformidad del producto con la legislación vigente.Únicamente avala el cumplimiento del Registro de Responsables según el artículo 24 del RD 1591/2009 por el que se regulan los Productos Sanitarios.

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
Fecha de la firma: 14/09/2023
Puede comprobar la autenticidad del documento en la sede de la AEMPS:https://localizador.aemps.es

CSV: XP2SBQ37A4

Página 1 de 2

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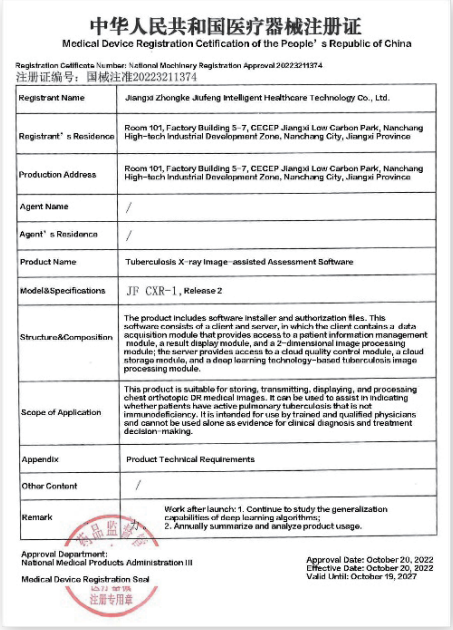
Fax: 91 822 52 99



中华人民共和国医疗器械注册证

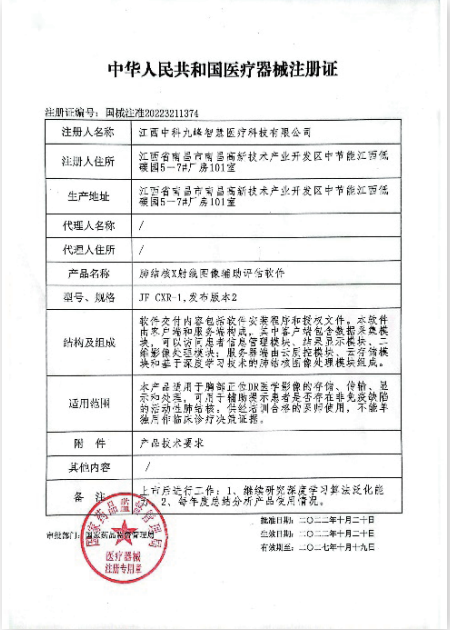
Medical Device Registration Cetification of the People' s Republic of China

Registration Cetificate Number: National Machinery Registration Approval 20223211374
注册证编号：国械注准20223211374

Registrant Name	Jiangxi Zhongke Jiufeng Intelligent Healthcare Technology Co., Ltd.
Registrant' s Residence	Room 101, Factory Building 5-7, CECEP Jiangxi Low Carbon Park, Nanchang High-tech Industrial Development Zone, Nanchang City, Jiangxi Province
Production Address	Room 101, Factory Building 5-7, CECEP Jiangxi Low Carbon Park, Nanchang High-tech Industrial Development Zone, Nanchang City, Jiangxi Province
Agent Name	/
Agent' s Residence	/
Product Name	Tuberculosis X-ray Image-assisted Assessment Software
Model&Specifications	JF CXR-1, Release 2
Structure&Composition	The product includes software installer and authorization files. This software consists of a client and server, in which the client contains a data acquisition module that provides access to a patient information management module, a result display module, and a 2-dimensional image processing module; the server provides access to a cloud quality control module, a cloud storage module, and a deep learning technology-based tuberculosis image processing module.
Scope of Application	This product is suitable for storing, transmitting, displaying, and processing chest orthotopic DR medical images. It can be used to assist in indicating whether patients have active pulmonary tuberculosis that is not immunodeficiency. It is intended for use by trained and qualified physicians and cannot be used alone as evidence for clinical diagnosis and treatment decision-making.
Appendix	Product Technical Requirements
Other Content	/
Remark	Work after launch: 1. Continue to study the generalization capabilities of deep learning algorithms; 2. Annually summarize and analyze product usage.

Approval Department:
National Medical Products Administration III
Medical Device Registration Seal

Approval Date: October 20, 2022
Effective Date: October 20, 2022
Valid Until: October 19, 2027



中华人民共和国医疗器械注册证

注册证编号：国械注准20223211374

注册人名称	江西中科九峰智慧医疗科技有限公司
注册人住所	江西省南昌市南昌高新技术产业开发区中节能江西低碳园5-7#厂房101室
生产地址	江西省南昌市南昌高新技术产业开发区中节能江西低碳园5-7#厂房101室
代理人名称	/
代理人住所	/
产品名称	肺结核X射线图像辅助评估软件
型号、规格	JF CXR-1，发布版本2
结构及组成	软件交付内容包括软件安装程序和授权文件。本软件由客户端和服务端构成。其中客户端包含数据采集模块，可以访问患者信息管理模块、结果显示模块、二维影像处理模块；服务端提供云质控模块、云存储模块和基于深度学习技术的肺结核图像处理模块模块。
适用范围	本产品适用于胸部正位DR医学影像的存储、传输、显示和处理，可用于辅助提示患者是否存在非免疫缺陷的活动性肺结核。经经过训练的医师使用，不能单独作为临床诊疗决策证据。
附　件	产品技术要求
其他内容	/
备　注	上市后进行工作：1、继续研究深度学习算法泛化能力；2、每年度总结分析产品使用情况。

审批部门：国家药品监督管理局
批准日期：二〇二二年十月二十日
生效日期：二〇二二年十月二十日
有效期至：二〇二七年十月十九日

trial in 6 China's TB hospitals where JF-CXR 1 was deployed as a TB triage and screening tool have demonstrated the CAD software is on par with human radiologist in terms of imaging reading accuracy.

- In September 2023, the product obtained the European CE certification and met the EU standards for sale in the wider market;

- In 2019, JF CXR-1 was evaluated by the Stop TB partnership as part of a systematic review of available TB CAD software in the world, findings of which suggest that the accuracy of the software is on par or even performed better than mainstream international brands. JF CXR-1 and 2 have been included by the AI4Hlth website run by the Stop-TB partnership in which development and regulatory approval updates of major TB CAD software are tracked. It was also incorporated into the Foundation of Innovative Diagnostics (FIND) resource center files.

2.Basic Information

Company Name: Jiangxi JF Healthcare Technology Co., Ltd.

Address: Room 101, Building 5-7, CECEP Jiangxi Low Carbon Park, Nanchang National High-tech Industrial Development Zone, Nanchang City, Jiangxi Province

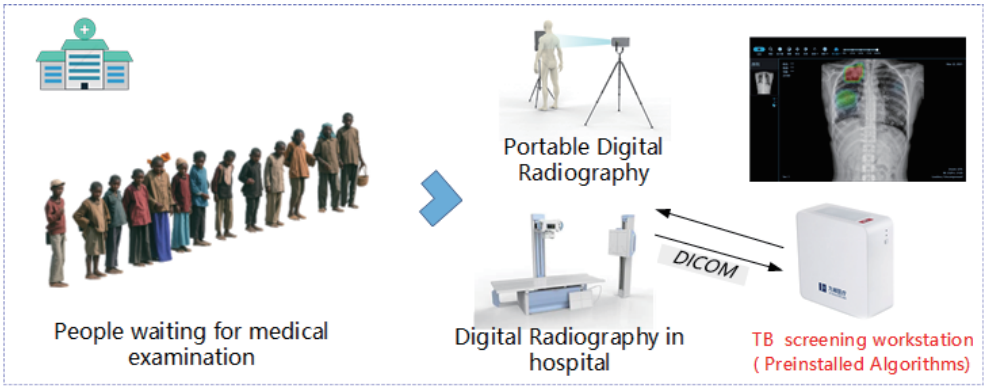
Official website: https://intl.jfhealthcare.com/

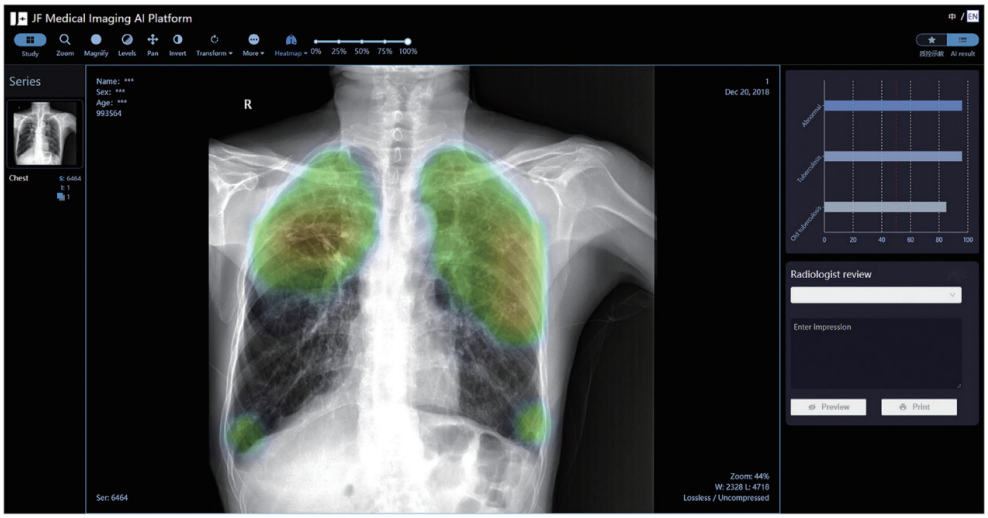
Email address: JF@jfhealthcare.com

Telephone: 0791-88389791

Jiangxi JF Healthcare Pulmonary Tuberculosis X-ray Computer-aided Detection Software

1. Product appearance and operation flow chart





2. Performances and operational characteristics

Characteristics	Performance and descriptions	Notes
Intended purpose	Triage and screening, suitable for deployment in primary medical institutions.	–
Target population	≥15 years.	–
Intended users	Medical practitioners, imaging Technician.	–
Regulatory approval of the products	CE, NMPA.	–
Regulatory requirements of manufacture	ISO13485, ISO27001.	–
Software version	V2.0	–
Please report an area under Receiver Operating Curve (ROC) of the latest software version	0.98	–
Sensitivity	94.19%	–
Specificity	91.17%	–
Projections of digital X-ray accepted	Default is PA, AP can also be projected.	–
Compatible radiograph format	DICOM.	–
Ability to provide abnormality score for TB AND dichotomous outcome for TB based on predefined threshold score	Yes.	–
Score pre-set for TB screening with the option for user to adjust threshold score	Yes.	–
Ability to provide abnormality map where abnormalities are located or a heat map showing areas of abnormality	Yes.	–
Ability to de-identify/anonymize patient's DICOM data	Yes.	–
Ability to operate offline and interpret radiographs without internet connection on image database	Yes.	–
Data backup system on a server chosen by user, with flexibility for local server locations.	Yes.	–

Time to result	At least 60 CXRs can be processed and reported on whether there are imaging manifestations of presumed pulmonary TB within one minute.	–
Operation complexity	Easy to learn, minimum training, suitable for primary health care personnel.	–
Power requirement	NO.	–
Operation environment	Temperature 5℃~50℃, humidity 30%~80%. The data acquisition box has a metal shell, stable performance and dustproof.	–

3. Description of characteristics and advantages

(1). High precision: The AI-assisted TB diagnosis system uses advanced deep learning technology to accurately identify and analyze lung images and improve the accuracy of diagnosis;

(2). High efficiency: The system can automatically analyze and process a large amount of lung imaging data, greatly improving doctors' work efficiency and shortening the diagnosis time;

(3). Objectivity: The system can reduce the influence of human factors on the diagnosis results and thus provide more objective and fair diagnosis results;

(4). Traceability: The system can record the process and results of each diagnosis, making it convenient for doctors to review and study;

(5). Easy to use: The system has a friendly interface and is easy to operate. Doctors can easily get started without the need for professional IT skills.

(6). Continuous learning: The system can self-learn and optimize, and can continuously improve the accuracy of diagnosis based on new data and information;

(7). Privacy protection: The system strictly abides by medical data protection regulations to ensure the security of patients' personal information;

(8). Cost reduction: Through automation and intelligent technologies, the system can help reduce labor and material costs of hospitals.

(9). Decision support: By providing detailed imaging analysis reports and

possible diagnostic suggestions, the system can assist doctors in making more accurate treatment decisions;

(10). Remote diagnosis capability: Supported by cloud computing technology, experts can remotely access and analyze imaging data, especially those from remote areas, which can effectively solve the problem of uneven distribution of medical resources;

(11). Early detection: The system is highly sensitive to tiny lesions and early lesions, which helps to achieve early detection and early treatment of diseases, improve cure rates and patients' quality of life;

(12). Patient management: The system can integrate patients' medical history and examination results to help doctors track changes in their condition and optimize long-term management and follow-up plans;

(13). Education and training: The system can be used as a medical education tool to help medical students and young doctors master diagnostic skills faster through actual cases and AI analysis processes;

(14). Disease prediction and prevention: The system can identify disease trends and high-risk groups by analyzing big data, , providing a scientific basis for public health strategies.

4. References

[1] Yang Y, Xia L, Liu P, et al. A prospective multicenter clinical research study validating the effectiveness and safety of a chest X-ray-based pulmonary TB screening software JF CXR-1 built on a convolutional neural network algorithm[J]. Front Med (Lausanne). 2023; 10:1195451.

[2] Qin ZZ, Ahmed S, Sarker MS, et al. TB detection from chest x-rays for triaging in a high TB-burden setting: an evaluation of five artificial intelligence algorithms[J]. Lancet Digit Health. 2021;3 (9): e543-e554.

[3] Codlin AJ, Dao TP, Vo LNQ, et al. Independent evaluation of 12 artificial intelligence solutions for the detection of TB[J]. Sci Rep. 2021;11(1):23895.

[4] Qin, ZZ., Walt MV, Moyo S., et al. Computer-aided detection of TB from chest radiographs in a TB prevalence survey in South Africa: external validation and modeled impacts of commercially available artificial intelligence software [J]. The Lancet. Digital health, 2024, 6(9), e605–e613.

[5] Liao Q, Feng H, Li Y, et al. Evaluation of an artificial intelligence (AI) system to detect TB on chest X-ray at a pilot active screening project in Guangdong, China in 2019[J]. J Xray Sci Technol. 2022;30(2):221-230.

Coyote Bioscience Co., Ltd.

Company Introduction

1.Company Profile

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

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

Honors and Achievements

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

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

Research and Development Status of Existing TB Products

(1).Sample Pre-processing System

Coyote is developing an innovative sample pre-processing system designed to handle complex samples like sputum, fungi, and Gram-positive bacteria. This system focuses on rapid sputum liquefaction and effective wall-breaking of Mycobacterium tuberculosis (MTB). After evaluating various processing methods (chemical, enzymatic, and mechanical lysis), the company has selected non-contact ultrasonic treatment. The integration of mechanics, electronics, materials, and biology has defined the key parameters for ultrasonic processing. The prototype is currently in small-scale trial production, with ongoing performance verification and NMPA registration.

(2).MTB Nucleic Acid Detection Cartridge

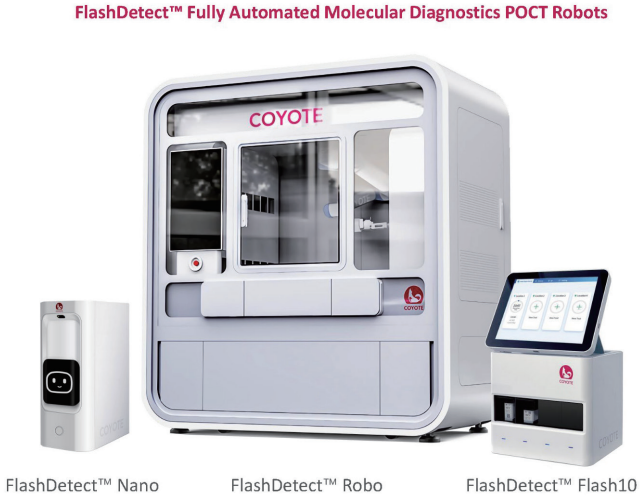
The company has also created an integrated nucleic acid detection cartridge tailored for detecting MTB in sputum and tongue swab samples. Following thorough research on primers, probes, and reaction program optimization, the cartridge has successfully completed finalization and performance verification testing. The manual process is simplified to "sample loading-ultrasonic-machine detection," yielding results in under 30 minutes. This cartridge is currently undergoing clinical trials for NMPA registration.

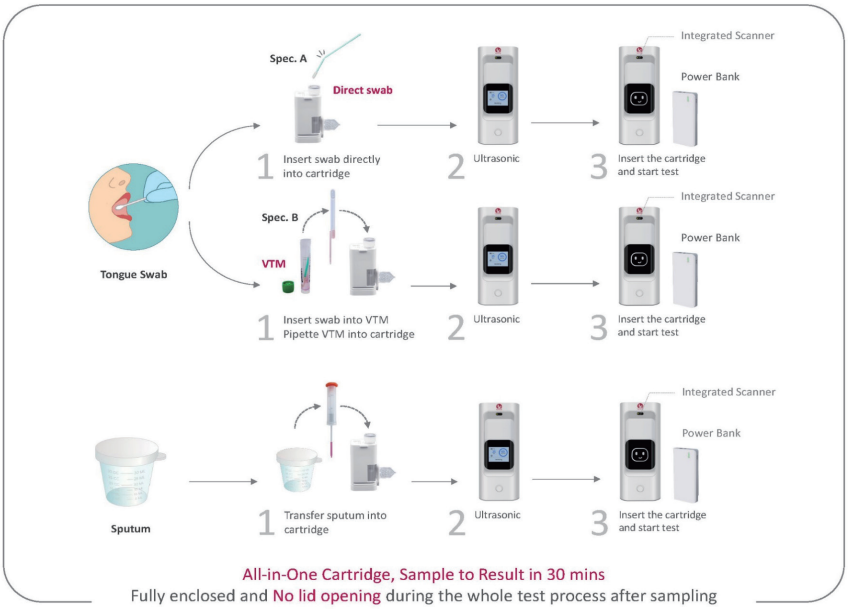
2.Contact Information

Company Name: Coyote Bioscience Co., Ltd.
Address: Building 22, Zone 3, Gaolizhang Road, Haidian District, Beijing 100095, China
Official Website: www.coyotebio.com
Email: sales@coyotebio.com
Telephone: +86 10 64844237

Coyote FlashDetect™ Fully Automated Molecular Diagnostics POCT Robots

1. Product appearance and operation flow chart





2. Detailed information

Characteristics	Performance and description	Notes
Intended purpose	This product is user-friendly and enables rapid detection, making it ideal for primary healthcare settings. It specifically targets tuberculosis (TB), with test results available within one hour of the patient's visit to a medical facility.	–
Target population	Testing is available for individuals with presumed or confirmed tuberculosis (TB), including those showing symptoms or signs of the disease, as well as their close contacts. The clinical research phase will also include children under 14 years old.	–
Intended users	Medical staff with basic testing skills, as well as community health workers and nursing staff without specialized training, can operate the product after receiving brief training.	–
Regulatory approval of the products	CE certification. Currently at the stage of clinical trial of NMPA	–
Regulatory requirements of manufacture	ISO13485.	–
Limit of detection	10 CFU/mL.	–
Sensitivity	Clinical trials are currently in progress, with data expected to be available by the end of October.	–
Specificity	Clinical trials are currently in progress, with data expected to be available by the end of October.	–

Multiplexing, Mult disease platform	FlashDetect™ Flash 10 and FlashDetect ™ Robo have multiple independent modules that can respectively detect different pathogens or different samples	–
Sample types	Sputum/Tongue swab	–
Manual prep of samples	Low workload	–
Time to result	It only takes 30 minutes from sample collection to results	–
Throughput per test	Flash10 Model: This model consists of four independent detection modules that can simultaneously analyze different pathogen samples. It also supports the connection of up to 10 devices, allowing for the detection of 40 samples at once. FlashDetect™ Nano Model: This model features a single detection module, offering efficient testing for individual samples. FlashDetect™ Robo Model: With 16 or 32 independent detection modules, this model can simultaneously detect multiple pathogen samples, significantly increasing testing capacity and efficiency.	–
POC or near POC	Yes	–
Power requirement	Flash10/FlashDetect™ Robo: Power supply required FlashDetect ™ Nano: Compatible with rechargeable batteries (power bank)	–
Operation environment	Operating Conditions: •Temperature: 10°C to 40°C •Relative Humidity: Maximum 80% at temperatures below 31°C, 50% relative humidity at 40°C. Dust Prevention Measures: A dust cover is available as an optional accessory.	–
Reagent kits transport	Test kits and quality control products should be transported at room temperature (2-28°C) and must not exceed a transportation time of 5 days.	–
Shelf life	Valid for 12 months.	–
Storage environment	The test kits and sample processing quality control products should be stored at 2-28°C, protected from light. Reference quality control products should be stored at 2-8°C, also away from light.	–

3.Description of Characteristics and Advantages

Unique Highlights

(1).Innovative Sample Types

This product is designed for both tongue swabs and sputum samples. Unlike other sample types (such as alveolar lavage fluid, gastric fluid, blood, and feces), tongue swabs are non-invasive, easy to collect, and pose lower infection risks. This makes them ideal for self-sampling and large-scale screenings, while

also reducing sample contamination. This feature is particularly advantageous for a broader demographic, especially children under 14, and has promising applications in clinical diagnostics.

(2).Rapid and Efficient Testing

The system provides results in under 30 minutes from sample input to output. It is perfect for immediate testing and point-of-care diagnostics, allowing patients to receive timely results and minimizing the risk of hospital-acquired infections. This system is the first based on QPCR technology to achieve such a quick turnaround time, working effectively with both tongue swab and sputum samples.

(3).Fully Enclosed Design

The integrated test kit features a fully enclosed design that eliminates the need to open the lid throughout the testing process (including ultrasonic treatment, nucleic acid extraction, and PCR testing) after the tongue swab or sputum sample is inserted. This significantly reduces the risk of cross-contamination, ensuring both tester safety and accurate results.

(4).High Accuracy

Utilizing efficient ultrasonic treatment, the system can liquefy sputum samples and lyse MTB in just 2 minutes. Its sensitivity and specificity surpass those of similar products, enhancing diagnostic reliability.

(5).Integrated Sampling and Testing

The system is designed for ease of use, requiring only minimal training for operators, which means extensive professional skills are not necessary. This makes it suitable for deployment in primary healthcare facilities, community settings, and underdeveloped areas, thereby expanding access to essential diagnostics.

Ustar Biotechnologies (Hangzhou) Ltd.

Company Introduction

1. Company Profile

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

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

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

2. Basic Information

Company Name: Hangzhou Ustar Biotechnologies Co., Ltd.

Address: 6th Floor, Building 2, No. 611, Dongguan Road, Binjiang District, Hangzhou

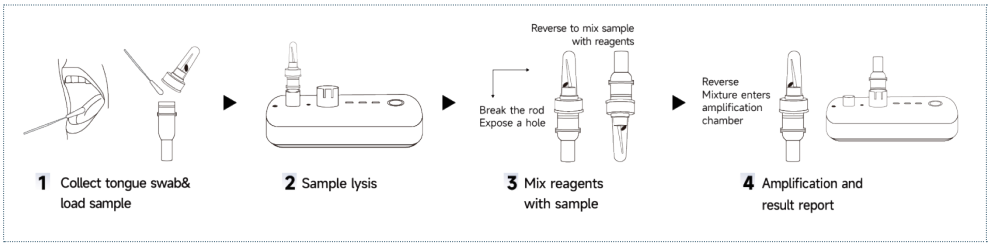
Official website: www.bioustar.com

Email: sales@bioustar.com

Telephone: 0571-88939388

Ustar PortNAT Nucleic Acid Testing System

1. Product appearance and operation flow chart



2. Detailed information

Characteristics	Performance and description	Notes
Intended purpose	Suitable for deployment at primary institutions, the target diseases for diagnosis is pulmonary TB. It allows patients to get the results on the same day of visiting a medical institution and allows clinicians to make decisions on whether to include anti-TB chemotherapy.	–
Target population	Applicable population for testing: adults, adolescence, children. Plan to include children (under 14 years old) in the validation study or clinical research phase.	–
Intended users	Suitable for community health workers or caregivers with no skills at all.	–
Regulatory approval of the products	CE.	–
Regulatory requirements of manufacture	ISO13485, MDSAP.	–
Sensitivity and Specificity	Hunan Chest Hospital and Ustar Biotechnologies (Hangzhou) Ltd. conducted a study on the detection of TB in tongue swabs. The study compared the detection performance of Ustar PortNAT TB Assay and Xpert MTB/RIF Ultra on tongue swabs. The study included 125 tongue swab samples from people with presumed TB. Among all the samples, PortNAT TB Assay detected 56 TB positives and 69 negatives. The control reagent Xpert MTB/RIF Ultra detected 60 TB positives and 65 negatives. The positive coincidence rate of PortNAT TB Assay and Xpert MTB/RIF Ultra was 93.3%, the negative coincidence rate was 100%, and the overall coincidence rate was 96.8%.	–
Multiplexing, multidisease platform	While testing for TB, other pathogens cannot be tested simultaneously.	–
Sample types	In addition to tongue swab samples, sputum samples can also be tested.	–
Manual prep of samples	Low workload, self-testing by patient is applicable.	–
Time to result	About 30 minutes.	–
Throughput per test	Each test can process one sample, and one test cannot process samples for multiple different pathogens.	–
POCT or near POCT	POCT Device.	–
Power requirement	Need to use external rechargeable battery.	–
Operation environment	Ambient temperature: 5~40℃ Ambient humidity: 25~90%RH Dust prevention measures: There is a dust cover (and there is no fan inside this product to reduce dust entry).	–

Reagent kits transport	Can be transported at normal temperature (-25~37℃).	–
Shelf life	18 months.	–
Storage environment	2~8℃ + 80% RH.	–

3. Description of characteristics and advantages

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

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

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

4. References

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

Ustar EasyNAT Nucleic Acid Amplification and Detection Analyzer

1. Product appearance and operation flow chart

①Load sample ②Test ③Report

2. Detailed information

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

Regulatory approval of the products	CE, NMPA, FDA.	–
Regulatory requirements of manufacture	ISO13485, MDSAP.	–
Sensitivity and Specificity	**TB project testing data** Ustar EasyNAT and Cepheid GeneXpert were used simultaneously to test sputum samples of 169 confirmed cases of pulmonary TB from Beijing Chest Hospital. The sensitivity results of each method were: 32.54% for smear method, 53.85% for culture method, 61.54% for Cepheid GeneXpert, and 72.19% for Ustar EasyNAT. In the simultaneous testing of 74 pulmonary TB patients in Beijing Chest Hospital by Ustar EasyNAT and Cepheid GeneXpert, the proportion of positive cases detected by Cepheid GeneXpert and Ustar EasyNAT was 22.97% and 44.59%, respectively. EasyNAT and GeneXpert were used to test gastric juice samples from 239 children from Beijing Children's Hospital (National Children's Medical Center) affiliated to Capital Medical University. The two detection methods showed similar sensitivity in the total active TB cases [22.6% (31/137) vs. 26.3% (36/137)], and the sensitivity in bacteriologically confirmed TB cases was 60% (9/15). The two methods showed similar specificity at 98.0% (100/102) and 99.0% (101/102) respectively. Ustar EasyNAT and RT-PCR were used to simultaneously test 151 pathological tissue samples from Beijing Chest Hospital affiliated to Capital Medical University. Among all the samples, Ustar EasyNAT detected 90 positive MTB samples and 61 negative samples. RT-PCR detected 91 positive MTB samples and 60 negative samples. The positive coincidence rate of Ustar EasyNAT and RT-PCR was 97.80%, the negative coincidence rate was 98.33%, and the overall coincidence rate was 98.01%. The Shanghai Pulmonary Hospital affiliated to Tongji University and Ustar Biotechnologies (Hangzhou) Ltd. conducted a study on the detection of MTBC in 197 bronchoalveolar lavage fluid samples, and compared the detection performance of Ustar EasyNAT and Cepheid GeneXpert. The results showed that Ustar EasyNAT detected 120 positive cases of MTB and 77 negative cases. Cepheid GeneXpert detected 121 positive cases of MTB and 76 negative cases. The positive coincidence rate of Ustar EasyNAT and Cepheid GeneXpert was 97.52%, the negative coincidence rate was 97.37%, and the overall coincidence rate was 97.46%.	Reference*(2-3)*

Sensitivity and Specificity	**TB/NTM test data** Beijing Chest Hospital Affiliated to Capital Medical University, Hangzhou Red Cross Hospital, Hunan Chest Hospital, Wuhan Pulmonary Hospital, and Ustar Biotechnologies (Hangzhou) Ltd. conducted a study on the detection of MTBC and NTM in sputum samples. The study compared the detection performance of Ustar EasyNAT MTC/NTM Assay and Chengdu CapitalBio Mycobacterium Nucleic Acid Detection Kit (PCR-fluorescent probe method) for sputum samples. Using a multicenter clinical research method, a total of 1,453 sputum samples of persons of presumed TB or NTM disease were included from 4 different hospitals. Among all the samples, Ustar EasyNAT MTC/NTM Assay detected 712 MTB positive cases and 741 MTB negative cases; 353 NTM positive cases and 1,100 NTM negative cases. Chengdu CapitalBio's control reagent detected 705 MTB positive cases and 748 MTB negative cases; 344 NTM positive cases and 1,109 NTM negative cases . For the detection of MTBC, the positive coincidence rate of EasyNAT MTC/NTM Assay and Chengdu CapitalBio Mycobacterium Nucleic Acid Detection Kit (PCR-fluorescent probe method) was 100%, the negative coincidence rate was 99.06%, and the overall coincidence rate was 99.52%. For the detection of NTM, the positive coincidence rate of EasyNAT MTC/NTM Assay and Chengdu CapitalBio Mycobacterium Nucleic Acid Detection Kit (PCR-fluorescent probe method) was 100%, the negative coincidence rate was 99.19%, and the overall coincidence rate was 99.38%. In addition, Beijing Chest Hospital affiliated to Capital Medical University and Ustar Biotechnologies (Hangzhou) Ltd. have conducted research on the detection of MTBC in sputum samples. The study compared the detection performance of Ustar EasyNAT MTC/NTM Assay and Xpert MTB/RIF for sputum samples. The study included 145 sputum samples from persons with presumed TB. Among all the samples, Ustar EasyNAT MTC/NTM Assay detected 62 positive MTB and 83 negative MTB. The control reagent Xpert MTB/RIF detected 61 positive MTB and 84 negative MTB. Ustar EasyNAT The positive coincidence rate of MTC/NTM Assay and Xpert MTB/RIF was 98.36%, the negative coincidence rate was 97.62%, and the overall coincidence rate was 97.93%.	Reference*(2-3)*
Multiplexing, multi-disease platform	Besides testing for TB, other pathogens can be tested simultaneously.	

Sample types	In addition to sputum, it can also support tongue swabs, alveolar lavage fluid samples, pleural effusion, urine, feces, gastric juice, pathological tissue sections, and cerebrospinal fluid testing	–
Manual prep of samples	Low workload, self-testing by patient is not applicable	–
Time to result	MTC: about 45 minutes MTC/NTM: about 54 minutes	–
Throughput per test	Each test can process up to 16 samples, and one test can process samples for multiple different pathogens	–
POCT or near POCT	No auxiliary equipment required, Is POCT Device	–
Power requirement	External power supply, Or connect to an external UPS that can be charged multiple times.	–
Operation environment	Ambient temperature: 5~40℃ Relative humidity: 25~95%RH Dust prevention measures: With dust net	–
Reagent kits transport	Can be transported at normal temperature (-25~30℃)	–
Shelf life	MTC: 12 months MTC/NTM: 12 months	–
Storage environment	2~8℃ + 80%RH	–

3. Description of characteristics and advantages

Ustar's molecular POCT laboratory testing solutions include nucleic acid amplification detection analyzer and fully automatic medical PCR analyzer, both of which are highly integrated, fully automatic and integrated molecular POCT products. They combine sample lysis, nucleic acid extraction and purification, amplification, and detection in an independent enclosed test tube, realizing "sample in, result out". After loading the sample, the test tube does not need to be opened during the entire testing process, which is biologically safe and can prevent contamination.

Ustar EasyNAT Nucleic Acid Amplification and Detection Analyzer was certified by the National Medical Products Administration (NMPA) through the fast approval channel in 2019.

EasyNAT Nucleic Acid Amplification and Detection Analyzer has a broad detection menu, covering respiratory tract, reproductive tract, gastrointestinal tract, blood infection and other detection items. It is easy to operate and can quickly produce test reports. The Nucleic Acid Amplification and Detection Analyzer

can be configured with 4/8/16 independent modules. Each detection module has independent temperature control and respective reaction program setting. There is no interference between the modules, and samples can be tested as soon as they arrive, without the need to accumulate samples or wait. It can be widely used in various detection scenarios such as medical institutions at all levels, disease control centers, mobile detection vehicles, airports, customs, etc.

4. References

[1] Global TB report 2018. Geneva: World Health Organization; 2018. License: CC BY-NC-SA 3.0 IGO.

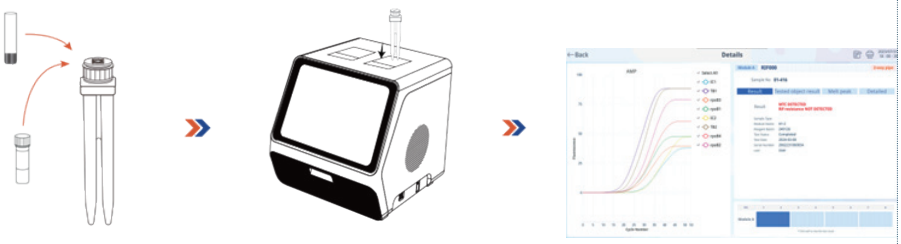
[2] Zhang Z, Du J, Liu T, et al. EasyNAT MTC assay: A simple, rapid, and low-cost cross-priming amplification method for the detection of mycobacterium TB suitable for point-of-care testing. Emerg Microbes Infect. 2021 Dec;10(1):1530-1535. doi : 10.1080/22221751.2021.1959271 . PMID: 34288833; PMCID: PMC8330774.

[3] Quan S, Jiang T, Jiao w, et al. (2022) A Novel Cross-Priming Amplification-Based Assay for TB Diagnosis in Children Using Gastric Aspirate. Front. Microbiol. 13:819654.doi: 10.3389/fmicb.2022.819654

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

Ustar MultNAT Molecular diagnostic testing system Automatic PCR Analyzer

1. Product appearance and operation flow chart



①Load Sample ②Test ③Report

2. Detailed information

Characteristics	Performance and descriptions	Notes
Intended purpose	Suitable for deployment at primary institutions, the target diseases for diagnosis are pulmonary TB and extrapulmonary TB. It allows patients to get the results on the same day of visiting a medical institution and allows clinicians to make decisions on whether to include anti-TB chemotherapy.	–
Target population	Applicable population for testing: adults, adolescence, children. Plan to include children (under 14 years old) in validation studies or clinical research.	–
Intended users	Suitable for medical personnel with basic testing skills (non-precision pipetting and minimal sample preparation skills).	–
Regulatory approval of the products	CE, NMPA, FDA .	–
Regulatory requirements of manufacture	ISO13485, MDSAP.	–
Sensitivity and Specificity	Hangzhou Red Cross Hospital (Zhejiang Provincial Hospital of Integrated Traditional Chinese and Western Medicine), Hunan Chest Hospital, Guangzhou Chest Hospital, and Ustar Biotechnologies (Hangzhou) Ltd. conducted a study on the detection of MTBC and rifampicin resistance genes in 966 sputum samples. For the detection of MTBC, Ustar MultNAT MTB/RIF kit detected 585 cases of MTB positive, of which the control reagent Xpert MTB/RIF Ultra detected 583 cases of MTB positive and 2 cases of negative, Ustar MultNAT MTB/RIF kit detected 381 cases of MTB negative, of which the control reagent Xpert MTB/RIF Ultra detected 4 cases of MTB positive and 377 cases of negative. The consistency analysis of the results of the Ustar MultNAT MTB/RIF kit and the control reagent Xpert MTB/RIF Ultra MTB test was performed, and the positive coincidence rate was 99.32%, 95% CI (98.26%-99.73%), the negative coincidence rate was 99.47%, 95% CI (98.10% -99.86%), the total coincidence rate was 99.38%, 95% CI (98.65%-99.72%), the Kappa value was 0.9870, 95% CI (0.9766-0.9974), $P < 0.01$, and the overall consistency was good. For the detection of rifampicin resistance genes, there were 966 effective cases in this clinical trial, and 532 cases were reported to be RIF resistant or sensitive by both the control reagent and the assessment reagent. The consistency analysis of the Ustar MultNAT MTB/RIF kit and the control reagent Xpert MTB/RIF Ultra for detecting RIF resistance was performed, and the positive coincidence rate was 100.00%; the negative coincidence rate was 100.00%, and the overall coincidence rate was 100.00%.	–

Sensitivity and Specificity	Hangzhou Red Cross Hospital (Zhejiang Provincial Hospital of Integrated Traditional Chinese and Western Medicine), Hunan Chest Hospital, Guangzhou Chest Hospital, and Ustar Biotechnologies (Hangzhou) Ltd. conducted a study on the detection of MTBC and rifampicin resistance genes in 108 tongue swab samples. Out of all the samples, Ustar MultNAT MTB/RIF kit detected 65 positive MTB cases and 43 negative MTB cases. The control reagent Xpert MTB/RIF Ultra detected 65 positive MTB cases and 43 negative MTB cases. For the detection of MTBC, the positive coincidence rate of Ustar MultNAT MTB/RIF Assay and Xpert MTB/RIF Ultra was 98.46%, the negative coincidence rate was 97.67%, and the overall coincidence rate was 98.15%. Among the 64 MTB positive samples, the Ustar MultNAT MTB/RIF kit detected RIF resistance in 15 cases and did not detect RIF resistance in 30 cases. The control reagent Xpert MTB/RIF Ultra detected RIF resistance in 15 cases and did not detect RIF resistance in 31 cases. For the detection of rifampicin resistance genes, the positive coincidence rate of Ustar MultNAT MTB/RIF Assay and Xpert MTB/RIF Ultra was 100.00%, the negative coincidence rate was 100.00%, and the overall coincidence rate was 100.00% (Note: In one sample, the test result of the assessment reagent was MTB positive and RIF was unclear, the test result of the control kit was that MTB detection was extremely low, RIF resistance was not detected. For this sample kit, its clinical sample RIF negative/positive coincidence rate result was not included in the statistics.)	–
Multiplexing, multidisease platform	While testing for TB, other pathogens can be tested simultaneously.	–
Sample types	In addition to sputum samples, it can also support tongue swabs, alveolar lavage fluid, pleural effusion, pathological tissue sections, urine, and cerebrospinal fluid samples.	–
Manual prep of samples	Low workload, self-testing by patient is not applicable.	–
Time to result	About 2 hours and 30 minutes.	–
Throughput per test	Each test can process up to 16 samples, and one test can process samples for multiple different pathogens.	–
POCT or near POCT	No auxiliary equipment required. POCT Device.	–
Power requirement	External power supply, Or connect to an external UPS that can be charged multiple times.	–
Operation environment	Ambient temperature: 5~40℃. Ambient humidity: 25~90%RH. Dust prevention measures: with dust net.	–
Reagent kits transport	Can be transported at normal temperature (2~28℃).	–
Shelf life	12 months.	–
Storage environment	2~8℃+80%RH.	–

3. Description of characteristics and advantages

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

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

Xiamen Zeesan Biotech Co., Ltd.

Company Introduction

1. Company Profile

Founded in 2010, Xiamen Zeesan Biotech Co., Ltd. is a high-tech enterprise integrating the R&D, production, sales and service of molecular diagnostic reagents and instruments. The company is committed to developing the world's leading molecular diagnostic technologies, providing innovative overall solutions, and facilitating early detection, precise treatment and prognosis monitoring of diseases.

Zeesan Biotech has long been dedicated to the R&D of molecular diagnostic technologies for TB, and owns Multicolor Melting Curve Analysis (MMCA®), an innovative technology with completely independent intellectual property rights. Underpinned by this advanced technology, Zeesan Biotech has built a unique multi-target nucleic acid detection platform to meet diverse application needs. Its full-course molecular diagnostic solution for TB not only achieves accurate and efficient detection of TB and its drug-resistant strains, but also effectively identifies nontuberculous mycobacteria (NTM), providing the most comprehensive molecular diagnostic solution for TB and drug-resistant TB on the market.

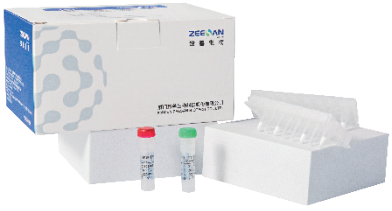
To date, 115 diagnostic reagents of Zeesan have obtained CE-IVD certification. Zeesan are committed to becoming a reliable partner for medical institutions, research institutions and diagnostic laboratories around the world. Its sample-to-result molecular diagnostic solution for TB has been used in nearly 600 top medical institutions in China and have been supplied to dozens of countries including India, Indonesia, Thailand, Malaysia, Iran, Pakistan, South Africa and the United Arab Emirates, contributing to the precision diagnosis and treatment of TB worldwide.

2. Basic Information

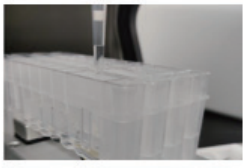
Company Name: Xiamen Zeesan Biotech Co., Ltd.
Address: No. 884-2, Lianting Road, Xiang'an Industrial Area, Torch Hi-Tech Zone Xiamen.
Official website: www.zeesandx.com
Email: info@zsandx.com
Tel: +86-592-7615091

Zeesan MTB/MDR Test Kit (Sanity 2.0)

1. Product appearance and operation flow chart



1. Scan QR code on reagent



2. Add sample

3. Fully automated analysis

2. Detailed information

Characteristics	Performance and descriptions	Notes
Intended purpose	The MDR/MTB-Test Kit is primarily designed for the qualitative detection of mycobacterium tuberculosis complex (MTBC), resistance mutations to rifampicin and isoniazid in sputum samples, enabling rapid and accurate tuberculosis (TB) diagnosis. The product is equipped with the Sanity 2.0 system, which offers simple operation and rapid detection, making it suitable for primary healthcare facilities. The product is designed to test MTB at the DNA level, so it can detect both pulmonary TB and extrapulmonary TB. The precise detection system delivers accurate results to patients and medical professionals, aiding clinicians in making prompt diagnostic decisions, and planning of anti-TB chemotherapy. With fully automated operation, the diagnostic process is shortened to under 3 hours, which improves efficiency and allows patients to receive their test results on the same day.	–
Target population	It is suitable for people who need to undergo TB and related drug resistance testing, especially people with presumed TB or confirmed TB patients, and patients who need drug resistance analysis. The sample type of the product is sputum, so there is no age limit for the test group, and any age group can be tested.	–
Intended users	In the whole testing process, only the sample loading step needs to be performed manually. All the other steps after sample loading are fully automated, and the results can also be automatically read and interpreted. Therefore, it is suitable for operation by medical personnel with basic testing skills (non-precision pipetting and the most basic sample preparation skills).	
Regulatory approval of the products	CE.	–
Regulatory requirements of manufacture	ISO13485.	–
Sensitivity	The product successfully detected rifampicin, isoniazid resistance and MTBC with a sensitivity of 98.3%, 96.4% and 96% respectively.	Reference *(1)*

Specificity	The results of the rifampicin and isoniazid resistance mutation tests and the MTBC tests in 1283 and 1096 patients, respectively, showed that the specificity was higher than 96%.	Reference *(1,2)*
Multiplexing, multi-disease platform	The Sanity 2.0 system can detect not only TB-related pathogens, but also respiratory infection-related pathogens, HPV genotyping, sexually transmitted pathogens, monkeypox virus etc.	–
Sample types	Sputum and MTB cultures, thus having the capability to process sputum or non-sputum samples.	–
Manual prep of samples	Low workload The operation is easy and the whole process is automated. The Sanity 2.0 System is easy to operate and can directly test sputum samples. The manual preparation before the automated operation of the instrument takes less than 5 minutes.	–
Time to result	The time from sample collection to result is under 3 hours.	–
Throughput per test	Each test can process up to 4 samples.	–
POC or near POC	Low-complexity: Only one Sanity 2.0 all-in-one machine is needed to carry out the test, which can complete nucleic acid extraction, detection and result analysis, without the need for other auxiliary equipment.	–
Power requirement	The power supply requirements of the Sanity 2.0 all-in-one system are as follows: Power supply: AC 100V-240V, 50 Hz/60 Hz, power: 600 VA. This means that the Sanity 2.0 system can work in a wide voltage range and adapt to the power supply standards of different countries and regions. It can operate by just plugging in the power supply, without built-in UPS and battery.	–
Operation environment	Since the Sanity 2.0 system has a built-in temperature control system, the testing can be carried out at room temperature. No special dust prevention measures are required.	–
Reagent kits transport	The reagent is lyophilized. It is recommended to transport it at -18℃~37℃. Cold chain transportation is not required.	–
Shelf life	Valid for 18 months.	–
Storage environment	It should be stored at -25~8℃ away from light.	–

3. Description of characteristics and advantages

(1). Integrated design: Sanity 2.0 system simplifies PCR testing by integrating key processes like extraction, pipetting, and nucleic acid detection. Unlike traditional fluorescent PCR instruments, which only perform real-time PCR, Sanity 2.0 reduces the need for a complex laboratory setup. It consolidates the multiple areas of a traditional PCR lab setup into one compact device, thus making PCR testing more accessible and minimizing sample contamination risks.

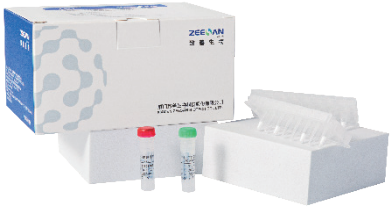
(2). Reliability: The kit provides both positive control and negative control. The design of the assays eliminates the possibility of laboratory contamination;

(3). Convenient and accurate result interpretation: It is equipped with automated interpretation software that presents test results automatically. Additionally, it retains an original data display interface, which shows the results of each experimental stage, including PCR amplification and melting curve analysis, ensuring the most reliable experimental outcomes.

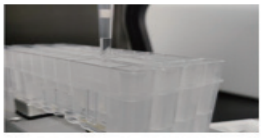
(4). Sanity 2.0 system has comprehensive detection capabilities. It is not only able to detect MTBC and drug-resistant mutations, but also can be used with various applications, such as the detection of respiratory pathogens, monkeypox virus, HPV genotypes and sexually transmitted infections.

Zeesan Mycobacteria Identification Kit (Sanity 2.0)

1. Product appearance and operation process



1. Scan QR code on reagent



2. Add sample

3. Fully automated analysis

2. Detailed information

Characteristics	Performance and descriptions	Notes
Intended purpose	The Mycobacteria Identification Kit (Sanity 2.0) is used to identify 19 clinically relevant mycobacteria in sputum samples, including MTBC and non-tuberculous mycobacteria (NTM). It can be used for both pulmonary TB and extrapulmonary TB. The product is equipped with the Sanity 2.0 system, which offers simple operation and rapid detection. The test result can be acquired on the same day of a patent's visit to a medical institution and allow the clinic to make a decision on whether to include anti-TB chemotherapy.	–

Target population	It is suitable for clinical scenarios where mycobacterial species identification is required, including people with presumed TB or confirmed TB patients and patients with NTM diseases, which helps to distinguish TB and NTM infections, so as to ensure accurate treatment. The sample type is sputum, so there is no age limit for the test group, and any age group can be tested.	–
Intended users	In the whole testing process, only the sample loading step needs to be performed manually. All the other steps after sample loading are fully automated, and the results can also be automatically read and interpreted. Therefore, it is suitable for operation by medical personnel with basic testing skills (non-precision pipetting and the most basic sample preparation skills).	–
Regulatory approval of the products	CE, NMPA.	–
Regulatory requirements of manufacture	ISO13485.	–
Sensitivity	Hu et al further used this system to test 7496 mycobacterium-positive specimens, the study indicates that the kit has concordance rate of 98.15% with WGS and a sensitivity of 99.80%.	Reference *(3)*
Specificity	The specificity was 93.5% .	Reference *(3)*
Multiplexing, multi-disease platform	The Sanity 2.0 system can detect not only TB-related pathogens, but also respiratory infection-related pathogens, HPV genotyping, sexually transmitted pathogens, monkeypox virus etc..	–
Sample types	Sputum and MTB cultures, thus having the capability to process sputum or non-sputum samples.	–
Manual prep of samples	Low workload The operation is easy and the whole process is automated. The Sanity 2.0 System is easy to operate and can directly test sputum samples. The manual preparation before the automated operation of the instrument takes less than 5 minutes.	–
Time to result	The time from sample collection to result is less than 3 hours.	–
Throughput per test	Each test can process up to 4 samples.	–
POC or near POC	Low-complexity: Only one Sanity 2.0 all-in-one machine is needed to carry out the test, which can complete nucleic acid extraction, detection and result analysis, without the need for other auxiliary equipment.	–

Power requirement	The power supply requirements of the Sanity 2.0 all-in-one system are as follows: Power supply: AC 100V-240V, 50 Hz/60 Hz, power: 600 VA. This means that the Sanity 2.0 system can work in a wide voltage range and adapt to the power supply standards of different countries and regions. It can operate by just plugging in the power supply, without built-in UPS and battery.
Operation environment	Since the Sanity 2.0 system has a built-in temperature control system, the testing can be carried out at room temperature. No special dust prevention measures are required.
Reagent kits transport	The reagent is lyophilized. It is recommended to transport it at -18℃~37℃. Cold chain transportation is not required.
Shelf life	Valid for 18 months.
Storage environment	It should be stored at -25~8℃ away from light.

3. Description of characteristics and advantages

(1). Detection capability of mixed infection bacteria: Lin Jian and other researchers conducted mycobacterium identification using Zeesan Mycobacteria Identification Kit and GenoType Mycobacterium CM on strains initially identified as NTM by PNB [4]. The results indicated that, when referring to the result from Sanger sequencing, the concordance rate between Zeesan and Sanger sequencing was 98.9%. The concordance rate between GenoType and Sanger sequencing was 97.7%. Furthermore, Zeesan Mycobacteria Identification Kit is able to detect co-infections and further specify the bacteria species involved in these infections.

(2). Detection capability of multiple targets: Using multicolor melting curve analysis (MMCA) technology, 51 target genes can be screened and 19 types of mycobacteria can be accurately identified from one sample tube.

4. References

[1] Liu ZB, Cheng LP, Pan HQ, et al. Performance of the MeltPro TB assay as initial test for diagnosis of pulmonary TB with drug-resistance detection. Mol Med. 2023 Nov 7;29(1):153.

[2] Hu S, Li G, Li H, et al. Rapid detection of isoniazid resistance in Mycobacterium TB isolates by use of real-time-PCR-based melting curve analysis. Cell journal. 2014, 52(5): 1644-52.

[3] Hu Xiaohong, Han Yu, Zhuang Qian, et al. Analysis of the epidemiological characteristics of nontuberculous mycobacterium infection in Yichang area by fluorescence PCR melting curve method[J]. Chinese Journal of Infection Control, 2023, 22(8): 939-944.
[4] Lin J, Zhao Y, Wei S, et al. Evaluation of the MeltPro Myco Assay for the Identification of Non-Tuberculous Mycobacteria. Infect Drug Resist. 2022 Jun 22; 15:3287-3293.

Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.

Company Introduction

1. Company Profile

Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.(Wantai BioPharm) is a high-tech enterprise specialized in the R&D and production of biological diagnostic reagents and vaccines. It was founded in 1991 and is headquartered in Beijing. The company has a profound technical background in the field of in vitro diagnostic reagents and vaccines, and its product portfolio covers multiple fields such as enzyme immunoassay, Rapid tests, chemiluminescence, PCR, biochemistry, vaccines and quality control products. Wantai BioPharm's products have been sold to more than 60 countries around the world, including the United States, the United Kingdom, Germany, etc., and have been recognized by the international market.

As a powerful force in the industry, Wantai BioPharm has a strong scientific research team composed of top scientists and medical experts, as well as technical platforms such as enzyme immunoassay, chemiluminescence, rapid tests, PCR , virus isolation and large-scale cultivation, genetic engineering, monoclonal antibody and polyclonal antibody preparation and large-scale purification. The company continues to explore into the depth of life sciences and is committed to developing innovative and efficient medical solutions. These efforts have been transformed into fruitful scientific research findings. From vaccine development to precision diagnosis, Wantai BioPharm has always practiced its commitment to "Developing Scientifically , Focusing on Health."

Wantai's TB-IGRA ELISA was launched in April 2012, with about 300 clinical customers and an annual testing volume of about 500,000 samples. Wantai's TB-IGRA ELISA was recommended for use by the WHO in 2022 and is currently the only Chinese IGRA test method recommended by the WHO.

Wantai's luminescent TB-IGRA was launched in China in June 2017. It currently has more than 400 clinical customers and an annual testing volume of approximately 1.5 million samples.

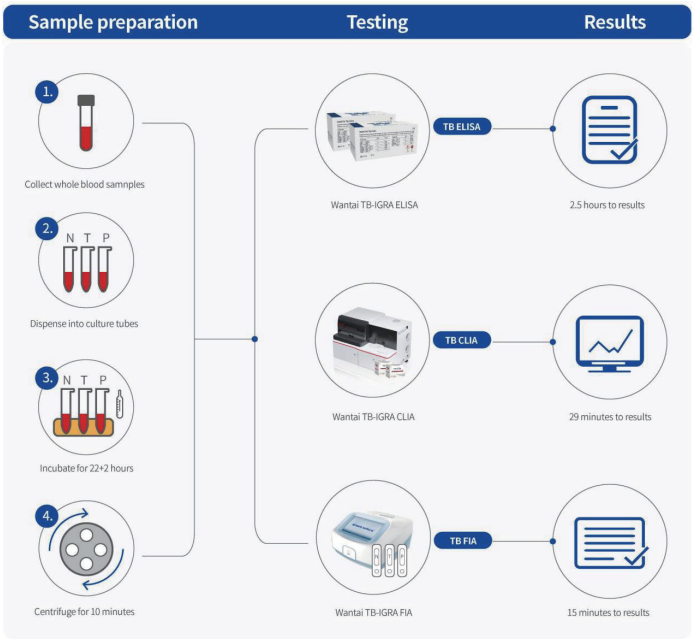
2. Basic Information

Company Name: Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.
Address: No.31 Kexueyuan Road, Changping District, Beijing, China
Official website: www.ystwt.cn
Email: wtexport@ystwt.com
Telephone: +86 10 5952 8888

Wantai TB-IGRA

1.Product appearance and operation flow chart

TB-IGRA ELISA: WHO recommended



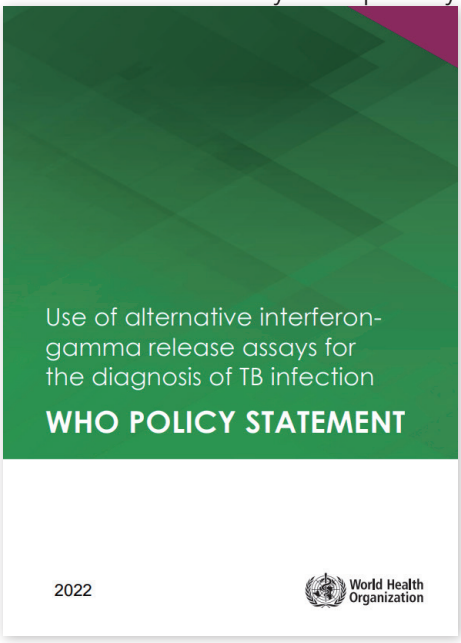
2. Detailed information

Characteristics	Performance and descriptions	Notes
Intended purpose	This test kit tests the recombinant antigens of two genes in the region of deletion 1 (RD1) that are unique to pathogenic MTB and not found in BCG and other mycobacteria. After in-vitro whole blood culture, the TB antigen-specific T cells in the whole blood sample are stimulated to produce an immune response. This kit is used to quantitatively detect the concentration of interferon gamma (IFN-γ) produced by human whole blood samples after in-vitro stimulation with MTB-specific antigens, so as to determine whether it has a T-cell immune response specific to MTB, i.e. TB infection T-cell detection.	Both products are suitable for deployment at primary healthcare institutions and can detect latent TB infection. Both products require the blood sample to be incubated for 22±2 hours, so the results cannot be obtained on the same day of blood draw. Additionally, the product on display herein can also be used for auxiliary diagnosis of TB, especially for auxiliary diagnosis of presumed TB with negative bacteriological result. Reference *(1,2)*
Target population	Applicable to adults, adolescence, and children.	Reference *(1,2)*
Intended users	Medical institutions, and basic testing skills are required.	–
Regulatory approval of the products	TB-IGRA ELISA has obtained CE and NMPA certifications, and is recommended by WHO.	–
Regulatory requirements of manufacture	ISO13485, ISO9001.	–
Sensitivity	ELISA: 95.54%.	–
Specificity	ELISA: 96.12%.	–
Multiplexing, multi-disease platform	Manual Operation.	–
Sample types	Whole blood.	–
Manual prep of samples	High workload.	–
Time to result	The product needs to be incubated for 22±2 hours after sample collection, after which the ELISA methodology requires manual operation and takes 2.5 hours to produce results.	–

Throughput per test	96-well plate, 28 samples can be tested at one time.	TB and other items cannot be performed on the same plate at the same time. Only the same type of pathogens can be tested on a 96-well plate because the incubation time of different items may not be exactly the same.
POC or near POC	Not POCT	–
Power requirement	Manual operation, no power supply required for reagents	–
Operation environment	Operation at room temperature	–
Reagent kits transport	Requires cold chain transportation at 2-8℃	–
Shelf life	12 months	–
Storage environment	Store at 2-8℃	–

3. Description of characteristics and advantages

This product is recommended by the WHO. Based on the analysis of publicly published clinical data and comprehensive consideration of its sensitivity, specificity and other indicators, the performance of Wantai TB-IGRA detection reagent has been recognized by the WHO.



Application scenarios: Clinical auxiliary diagnosis of pulmonary TB and extrapulmonary TB; large-scale screening of various types; custom entry and exit inspections; and daily physical examinations, etc.

Wantai TB-IGRA is fully validated by millions of clinical test data each year and has been widely used and practiced in TB-free community screening in Zheji-

ang Province, TB physical examinations for students entering school in Guangdong Province, and TB screening for outbound students and tourists at Beijing Customs.

4. References

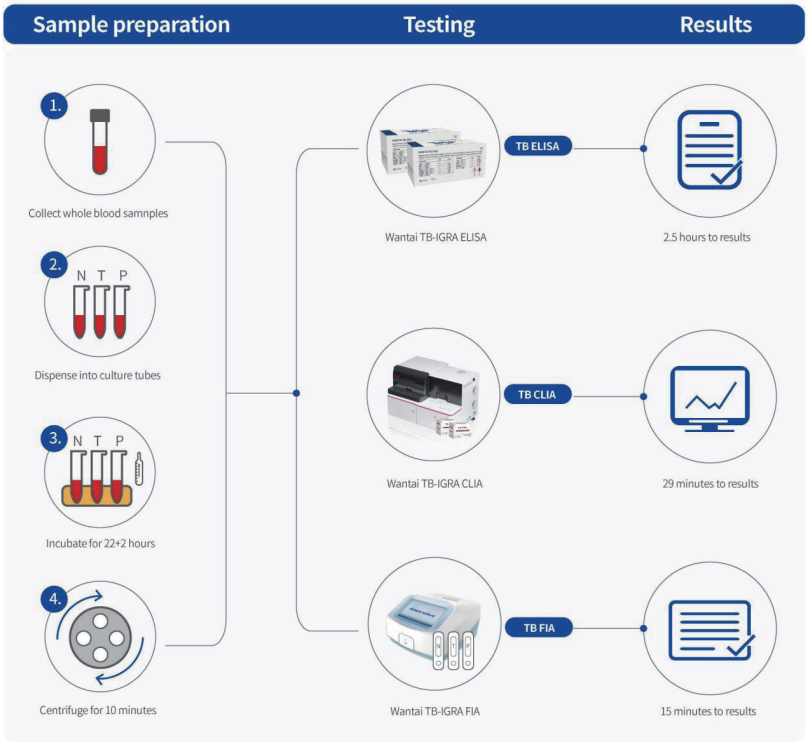
[1] Mu Guangfa, He Hailan, et al. Diagnostic value of interferon-γ release assay for tuberculous meningitis in children. Journal of Clinical Pediatrics, Vol. 33, No. 3, March 2015

[2] Ma Tingting, Yue Ying, Yan Wen. Efficacy of interferon-γ release assay in diagnosing active TB in children in TB clinics. Journal of Clinical Pulmonary Medicine, Vol. 28, No. 6, June 2023

[3] Jiang Ying, Zhao Rong, Zhang Shengnan, et al. Superiority of interferon release enzyme-linked immunosorbent assay (TB-IGRA) for detecting Mycobacterium TB. Practical Preventive Medicine, Vol. 19, No. 1, January 2012

Wantai TB-IGRA CLIA

1. Product appearance and operation flow chart



2. Detailed information

Characteristics	Performance and descriptions	Notes
Intended purpose	This test kit tests the recombinant antigens of two genes in the region of deletion 1 (RD1) that are unique to pathogenic MTB and not found in BCG and other mycobacteria. After in-vitro whole blood culture, the TB antigen-specific T cells in the whole blood sample are stimulated to produce an immune response. This kit is used to quantitatively detect the concentration of interferon gamma (IFN-γ) produced by human whole blood samples after in-vitro stimulation with MTB-specific antigens, so as to determine whether it has a T-cell immune response specific to MTB, i.e. TB infection T-cell detection.	Both products are suitable for deployment at primary healthcare institutions and can detect latent TB infection. Both products require the blood sample to be incubated for 22±2 hours, so the results cannot be obtained on the same day of blood draw. Additionally, the product on display herein can also be used for auxiliary diagnosis of TB, especially for auxiliary diagnosis of presumed TB with negative bacteriological result. Reference*(1,2)*
Target population	Applicable to adults, adolescence, and children.	Reference*(1)*
Intended users	Medical institutions, and basic testing skills are required.	–
Regulatory approval of the products	CE and NMPA.	–
Regulatory requirements of manufacture	ISO13485, ISO9001.	–
Sensitivity	CLIA: 92.66%.	–
Specificity	CLIA: 90.91%.	–
Multiplexing, multidisease platform	While detecting TB, the instrument can detect other pathogens such as hepatitis B, hepatitis C, AIDS, syphilis, etc.	–
Sample types	Whole blood.	–
Manual prep of samples	Low workload.	–
Time to result	The product needs to be incubated for 22±2 hours after sample collection, after which the CLIA methodology is fully automatic chemiluminescence and the results can be reported in 29 minutes.	–
Throughput per test	150 samples can be loaded at one time, and can be added continuously. The product can handle samples of different pathogens.	–
POC or near POC	Not POCT.	–

Power requirement	AC220 V, 50 Hz, single-phase power supply. Dedicated circuit: dedicated circuit is required (the instrument should be the only device connected to the circuit). Circuit outlet: within 10 m from the system, must be compatible with the socket buckle on the instrument. AC power outlet: must be protected with a circuit breaker rated at 20 amps (250 VAC circuit). Instrument circuit fuse: T10A, 240V. Circuit voltage fluctuation: not more than ±10%VAC of rated working voltage per cycle. The maximum resistance between the safety ground wire and the accessible building safety ground: no more than 0.1ohm No built-in UPS	–
Operation environment	Ambient temperature: 10℃ ～ 30℃. Maximum change in ambient temperature during operation: within ±2°C Relative humidity: ≤85%. Ambient air pressure: 75~106kPa. Altitude: below 2000m Power supply: AC220V 50Hz. Machine power: 1000VA.	–
Reagent kits transport	Requires cold chain transportation at 2-8℃.	–
Shelf life	12 months.	–
Storage environment	Store at 2-8℃.	–

3. Description of characteristics and advantages

Acridinium esters is used to emit light without the need for catalysts, offering good linearity of the light signal and a wide dynamic range.

Instrument: Wantai TB-IGRA is fully validated by millions of clinical test data each year and has been widely used and practiced in TB-free community screening in Zhejiang Province, TB physical examinations for students entering school in Guangdong Province, and TB screening for outbound students and tourists at Beijing customs.

Application scenarios: Clinical auxiliary diagnosis of pulmonary TB and extrapulmonary TB; large-scale screening of various types; custom entry and exit inspections; and daily physical examinations, etc.

4. References

[1] Clinical practice guidelines for early detection of pulmonary TB in comprehensive medical institutions. Chinese Journal of Anti-TB, Vol. 46, No. 2, February 2024

[2] GAI Linlin, LI Haibo, CHU Jinjin, et al. The value of chemiluminescent interferon-γ release test in auxiliary diagnosis of pulmonary TB. Laboratory Medicine, Vol. 38, No. 3, March 2023

Leide Biosciences Co., Ltd.

Company Introduction

1. Company Profile

Leide Biosciences Co., Ltd. (LDEBIO), based in Guangzhou, China, is committed to providing innovative in-vitro diagnostic solutions for immune-mediated diseases. Our offerings include reagents, instruments, core raw materials, and immunoassay services. LDEBIO has a modern R&D, production, and sales network, exemplified by the AIMDX research center in Maryland, USA, and the Leide Clinical Service Lab in Guangzhou. The company holds ISO13485, ISO15189, NMPA, CE, and other professional qualifications and certifications. Our business spans infection, tumors, organ transplantation, and immunotherapy, with a strong commitment to delivering efficient and accurate diagnostic services to advance global health innovation. Currently, in the tuberculosis diagnostic pipeline, LDEBIO has interferon-γ release assays (IGRAs) and urine lipoarabinomannan (LAM) tests, both based on multiple platforms.

The company's IGRAs (AIMTB) for diagnosing latent TB infection, which utilize chemiluminescence (CL), enzyme-linked immunosorbent assays (ELISA), and fluorescence lateral flow (FLF), have all received NMPA Class III certifications. AIMTB offers comprehensive solutions for the auxiliary diagnosis of TB in general hospitals, primary healthcare centers, and disease control settings, along with solutions for LTBI screening and outbreak management. In comparison with the clinical diagnostic results, AIMTB (CL) shows a sensitivity of 96.67% and a specificity of 97.56%, the AIMTB (ELISA) shows a sensitivity of 85.9% and a specificity of 93.6%, with an overall concordance rate of 95% with the WHO recommended product. AIMTB (FLF) exhibits a sensitivity of 95.56%, and a specificity of 96.34%, with an overall concordance rate of 95% with the WHO recommended product.

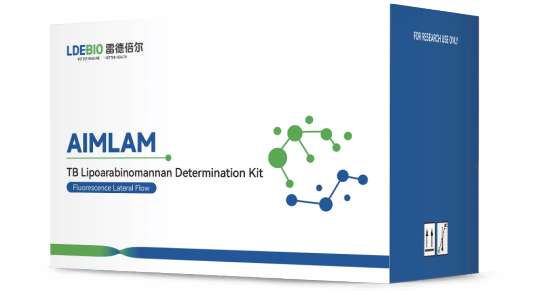
The urine lipoarabinomannan tests (AIMLAM), which employs chemiluminescence and fluorescence lateral flow, are used for the diagnosis of active tuberculosis. The sensitivity of AIMLAM (CL) for active TB is approximately 72% (MRS as a reference, HIV-negative), and the sensitivity of AIMLAM (FLF) is 70% (MRS as a reference, PLHIV).

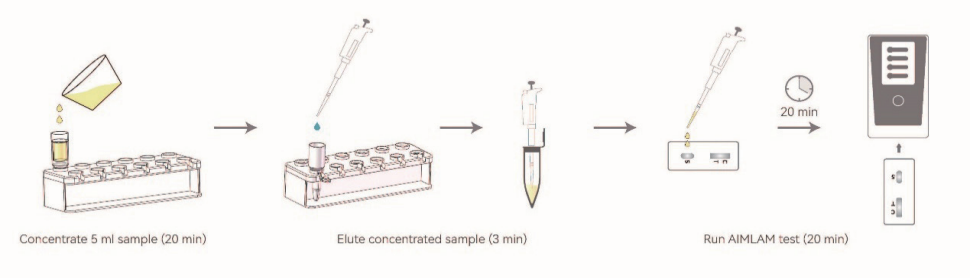
2. Basic Information

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

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

1. Product appearance and operation flow chart





2. Detailed information

Characteristics	Performance and descriptions	Notes
Intended purpose	Used for auxiliary diagnosis of pulmonary TB and extrapulmonary TB.	Results can be obtained on the same day, and chemotherapy can be performed based on positive results
Target population	General population (regardless of HIV status) including adults, adolescence, children.	–

Intended users	Medical personnel with basic testing skills.	Requires 1 pipetting by pipette, others are non-precise pipetting, basic sample preparation skills
Regulatory approval of the products	CE.	–
Regulatory requirements of manufacture	ISO13485.	–
Sensitivity	76.00% (HIV+).	Reference to the instruction manual
Specificity	97.14%.	Reference to instruction manual
Multiplexing, multidisease platform	Can be used to detect other pathogens.	–
Sample types	Urine.	–
Manual prep of samples	Low workload.	–
Time to result	1 hour.	–
Throughput per test	Single sample, single pathogen.	–
POC or near POC	Near POCT.	–
Power requirement	Built-in rechargeable lithium battery.	–
Operation environment	**Test kit:** Temperature 18~28℃, humidity below 80%. Chromatography: Temperature -40℃ ～ 55℃, humidity not higher than 93%.	–
Reagent kits transport	2-30℃, no humidity requirement, no cold chain required.	–
Shelf life	24 months.	–
Storage environment	Temperature 2-30℃, no humidity requirement.	–

3. Description of characteristics and advantages

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

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

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

and those with extrapulmonary TB, thereby expanding the test's scope of application.

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

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

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

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

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

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


RIOMAVIX

NOTIFICATION OF REGISTRATION

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

MANUFACTURER: Leide Biosciences Co., Ltd.

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

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

IVD Devices: TB Lipoarabinomannan Determination Kit (Immunochromatography)

Classification: Others

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

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

RIOMAVIX R RIOMAVIX

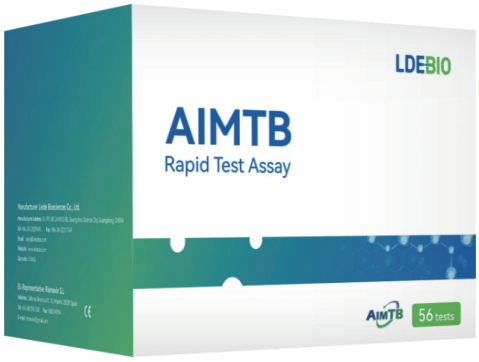
Issue date: 29/Apr/2022
Cert. No.: R20210202-6

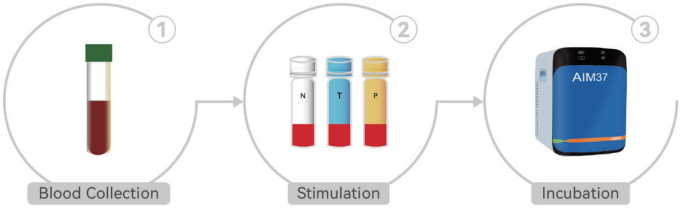
CE

Riomavix S.L. (ES-AR-000001202)
Calle de Alimansa 55, 10, Madrid 28039 Spain

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

1. Product appearance and operation flow chart

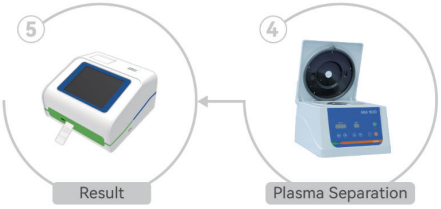




2-3mL

0.6 mL/ Tube
Within 18 h

37°c,20+4 h

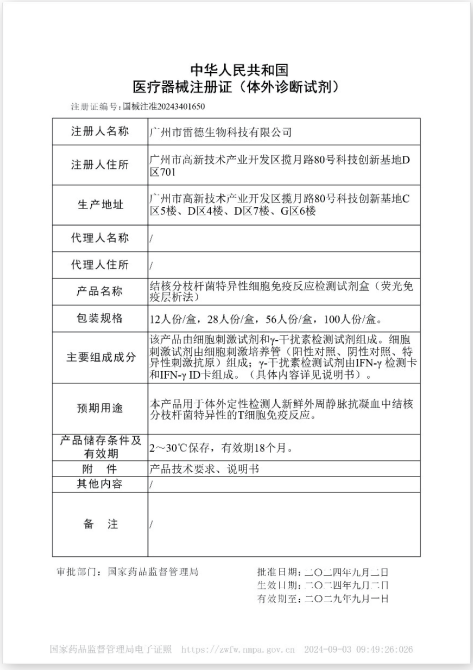


2. Detailed information

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

3. Description of characteristics and advantages

The overall coincidence rate of this product with QFT-Plus is 94.52% (based on 511 samples), and it is widely used in auxiliary diagnosis of TB and screening for latent TB infection. This product can be used with mIGRA, a mobile TB detection system. mIGRA is the world's first portable TB detection system, which includes test kits, incubators, chromatographs, centrifuges, pipettes, sterile tips, and blood collection tubes, providing an integrated solution for IGRA TB detection. Its functions encompass sampling, stimulation, incubation, plasma separation and detection. mIGRA enables on-site detection and management of sporadic TB outbreaks, clustered outbreaks, and public health emergencies. It is particularly suitable for scenarios such as emergency close-contact screening and management, as well as screening key populations at the primary level. Additionally, it can be utilized to enhance TB prevention and care capabilities in primary medical and public health institutions.



中华人民共和国
医疗器械注册证（体外诊断试剂）

注册证编号：国械注准20243401650

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

审批部门：国家药品监督管理局

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

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

RIOMAVIX

NOTIFICATION OF REGISTRATION

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

MANUFACTURER: Leide Biosciences Co., Ltd.

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

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

IVD Devices:

AIMTB Rapid Test Assay

Classification: Others

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

The notification of abovementioned device has been completed by the European Authorized Representative in Spain. The Spain Competent Authority is notified of the manufacture's device and has allocated registration. The registration number is RPS/2617/2021

Executive Director

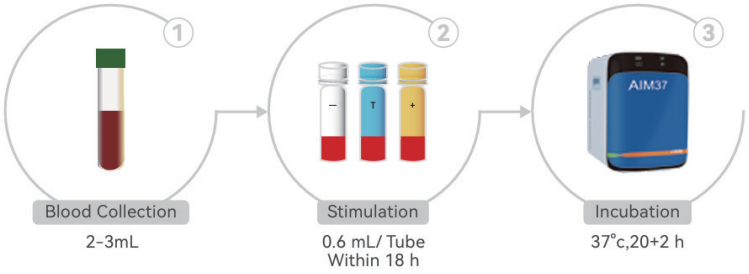
Issue date: 17/Dec/2021
Cert. No.: R20210202-3

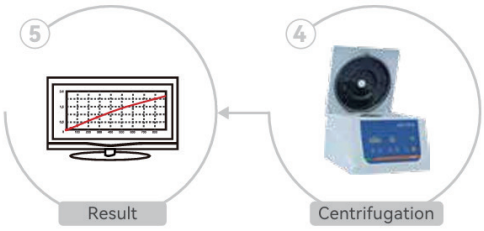
RIOMA

Riomavix S.L.
Calle de Almansa 55, 1D, Madrid 28039 Spain

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

1. Product appearance and operation flow chart



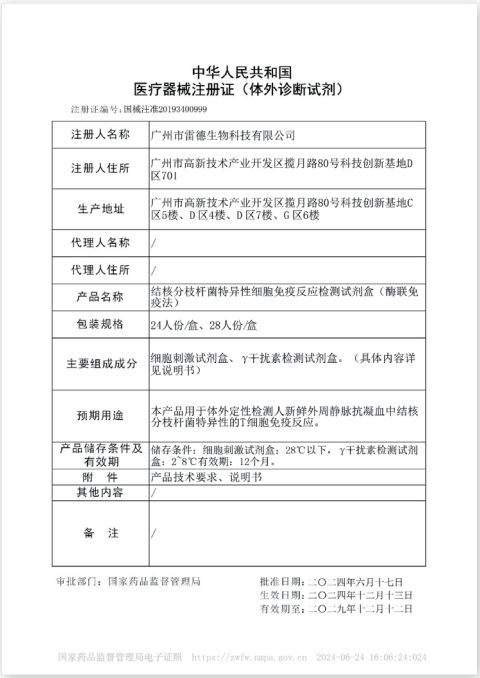


2. Detailed information

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

3. Description of characteristics and advantages

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



中华人民共和国
医疗器械注册证（体外诊断试剂）

注册证编号：国械注准20193400999

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

审批部门：国家药品监督管理局

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

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

RIOMAVIX

NOTIFICATION OF REGISTRATION

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

MANUFACTURER: Leide Biosciences Co., Ltd.

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

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

IVD Devices:

AIMTB Assay

Classification: Others

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

The notification of abovementioned device has been completed by the European Authorized Representative in Spain. The Spain Competent Authority is notifed of the manufacture's device and has allocated registration. The registration number is RPS/2616/2021

Executive Director

Issue date: 17/Dec/2021
Cert. No.: R20210202-2

RIOMA

Riomavix S.L.
Calle de Almansa 55, 1D, Madrid 28039 Spain

Epilogue

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

In the past 20 years, technological breakthroughs have been achieved in the field of artificial intelligence (AI), microfluidics and point-of-care testing (POCT) in China. In turn, these innovations have translated to benefit the field of TB diagnostics R&D. Many novel TB diagnostic solutions that are efficacious, peripheral level deployable and with cost-effectiveness have been successfully hatched. A number of these solutions have been validated and studied under trial or programmatic conditions across vast regions of China to probe their potential in optimizing the existing cascade of TB care or creating novel strategies and models of case detection.

In light of the limitations inherent in the currently available TB screening and diagnosing tools, following areas of R&D should be prioritized. First, to address the challenges posed by the inability to collect appropriate sputum sample from certain patient groups, discovery and validation of non-sputum sample types, such as urine, blood, nasopharyngeal aspirate and expiration samples, is pivotal for early TB case detection among asymptomatic TB patients and general population. Second, to address the challenges posed by a lack of ideal biomarker-based treatment response evaluation tool, R&D of novel culture-free solutions of treatment response evaluation should be prioritized. Third, to overcome the challenges posed by the inability to differentiate latent TB infection and active TB disease by the currently available tools, R&D of novel TB testing methods that are capable of distinguishing LTBI and active TB should be prioritized.

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 the above-mentioned areas, and in turn, making China's contribution to the 2035 END-TB targets.

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