USTAR mPOC Solutions

Presenter:

Date: December, 2025

Molecular Testing *Anywhere*

Contents

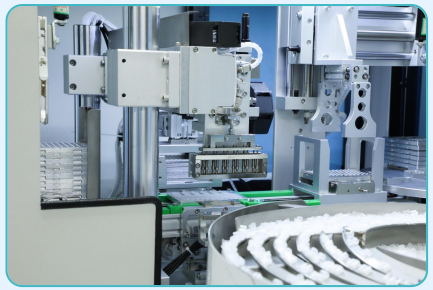
USTAR 20-year focus on Innovation of mPOC

Established in
2005

Ustar Biotechnologies (Hangzhou) Ltd.

Dedicated to develop, manufacture and distribute innovative molecular POCT solutions

Molecular Testing, Anywhere



- 5000m² GMP automated production system
- Certified with ISO13485:2016
- Acquired TÜV SÜD MDSAP

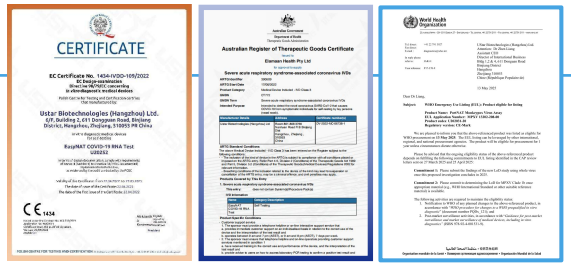
USTAR 20-year focus on Innovation of mPOC

World's first technology

- Cross Primer Amplification (CPA)
- Disposable nucleic acid testing device
- Nucleic acid immunochromatography technology
- Reagent Vitrification

Honors

- Second Prize of National Science and Technology Progress Award
- First Prize of Zhejiang Provincial Science and Technology Progress Award
- "Innovative Achievement Transformation Base" by Chinese Antituberculosis Association.....



Global Certifications

- Obtained the first EU CE certificate for nucleic acid self-test products
- Awarded China's first molecular diagnostic IVDR CE certificate
- Included in the World Health Organization (WHO) Emergency Use Listing (EUL)
- Received 15 NMPA Class III medical device licenses.....

90+
countries

5000+
Hospitals

20000+
Installations

1 Billion+
Tests

Intensive investments on molecular POC Technologies

150+
R&D Team

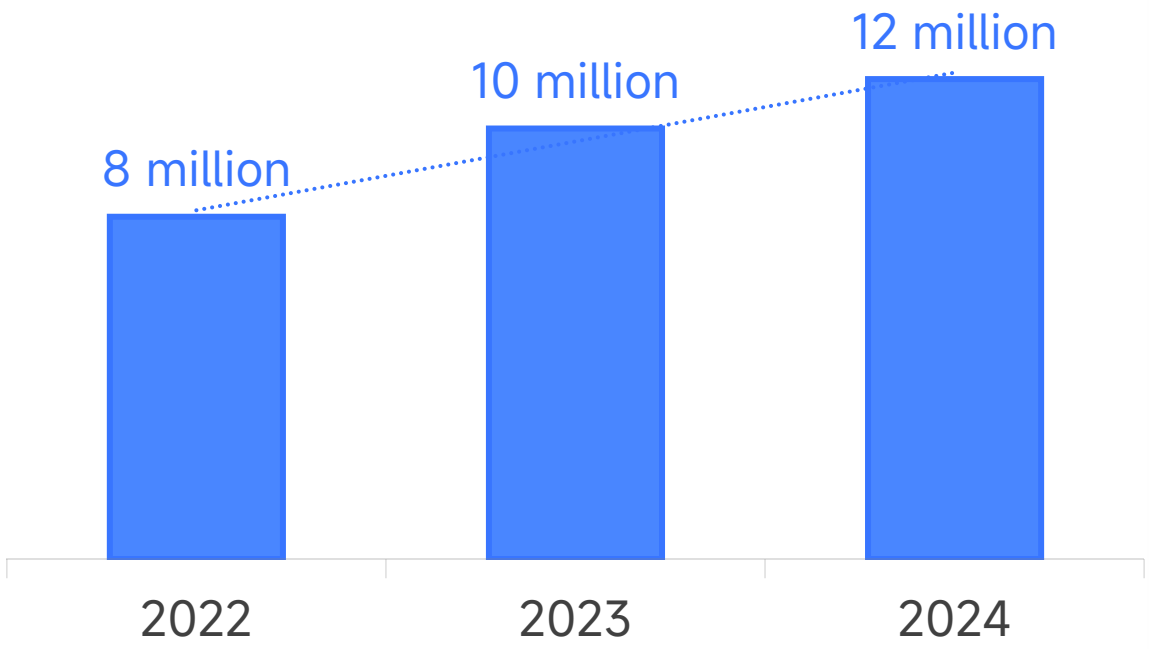
>32%
Ratio

>50%
Master Degree and Above

90+
Patents

62+
Authorized patent

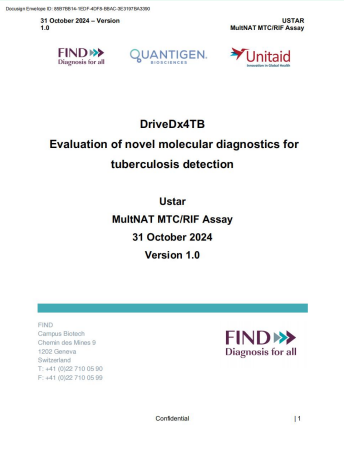
Investment on R&D in USD



R&D → Production → Promotion → Marketing

Progress of International Projects

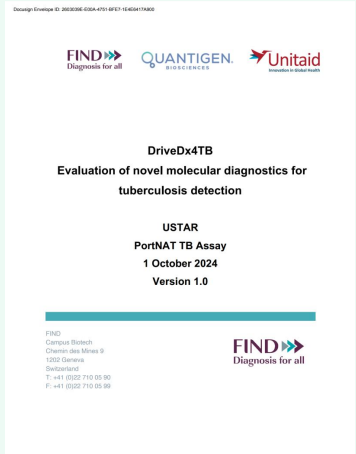
Passed the evaluations by FIND


31 October 2024 – Version 1.0

USTAR MultNAT MTC/RIF Assay

DriveDx4TB
Evaluation of novel molecular diagnostics for tuberculosis detection

Ustar
MultNAT MTC/RIF Assay
31 October 2024
Version 1.0

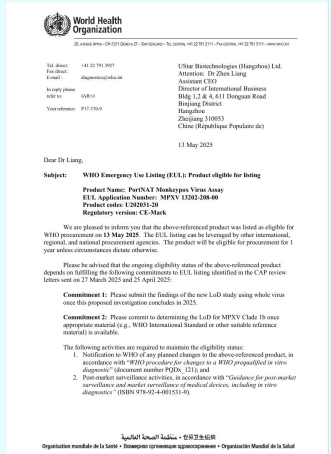

DriveDx4TB
Evaluation of novel molecular diagnostics for tuberculosis detection

USTAR
PortNAT TB Assay
1 October 2024
Version 1.0

- MultNAT MTC/RIF
- PortNAT TB (Tongue Swab)

Funded and evaluated by Foundation for Innovative New Diagnostics (FIND, collaborating center of WHO) and Unitaid.

Awarded with WHO EUL

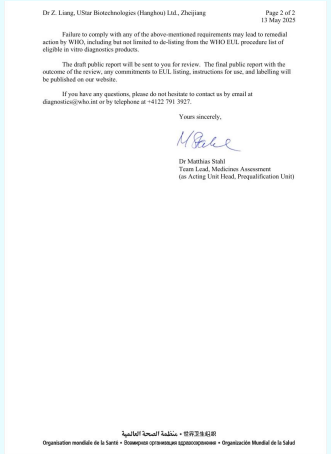

World Health Organization

13 May 2025

Dear Dr Liang,

Subject: WHO Emergency Use Listing (EUL): Product eligible for listing

Product Name: PortNAT Monkeypox Virus Assay
EUL Application Number: MPXV 13202-208-00
Product codes: U202031-20
Regulatory version: CE-Mark


Dr Z. Liang, UStar Biotechnologies (Hangzhou) Ltd., Zhejiang

Page 2 of 2
13 May 2025

Failure to comply with any of the above-mentioned requirements may lead to remedial action by WHO, including but not limited to de-listing from the WHO EUL procedure list of eligible in vitro diagnostics products.

The draft public report will be sent to you for review. The final public report with the outcome of the review, any commitments to EUL listing, instructions for use, and labelling will be published on our website.

If you have any questions, please do not hesitate to contact us by email at diagnostics@who.int or by telephone at +4122 791 3927.

Yours sincerely,

Dr Matthias Stahl
Team Lead, Medicines Assessment
(as Acting Unit Head, Prequalification Unit)

USTar Biotechnologies (Hangzhou) Ltd.
Attention: Dr Zhen Liang
Assistant CEO
Director of International Business
Bldg 1,2 & 4, 611 Dongsan Road
Binjiang District
Hangzhou
Zhejiang 310053
China (République Populaire de)

USTAR Monkeypox has been included in WHO EUL

UN's Sustainable Innovation Catalogue

The only medical company selected in the United Nations' "International Public Procurement Catalogue of China's Sustainable Innovative Products"

Progress of International Evaluations

Spain	RSP-24 compared with Fillmarry, sensitive with detecting 2 more Covid-19 samples SFR is largely consistent with GeneXpert GI 100% agreement with Culturing HP/DR 100% agreement with Culturing
France	GBS 100% agreement with Culturing
Sweden	GI 100% agreement with Culturing HP/DR 100% agreement with Culturing GBS is largely consistent with PCR
Italy	MPOX comparison study article publishment
Denmark	GBS is largely consistent with PCR
Greece	MPOX 100% agreement in the study
Germany	GI is largely consistent with PCR and Culturing Carba-R 100% agreement with PCR
Netherlands	Malaria is largely consistent with PCR

Contents

Infectious Diseases: Tuberculosis, Dengue and HIV

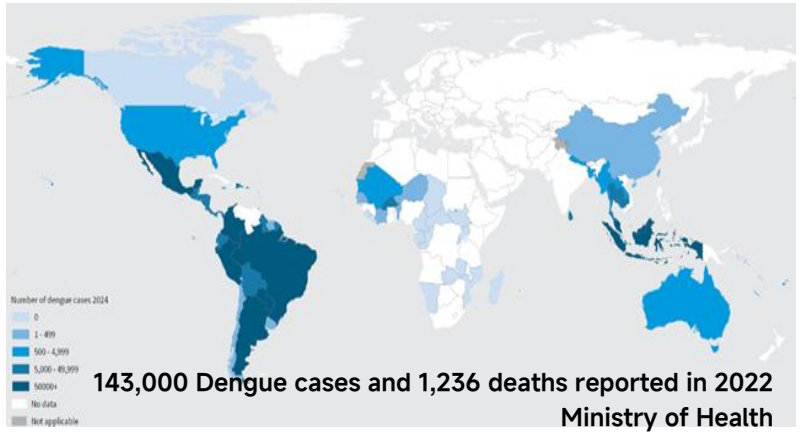
Indonesia continues to face challenges in its fight against tuberculosis (TB), particularly in identifying and reporting every case. Despite progress, at least one in four people with TB in total remains unreported or undiagnosed, leaving over 140 000 people undiagnosed in 2023.[1]

Strengthening TB surveillance to accelerate Indonesia's path to elimination

1 July 2025 | Highlights

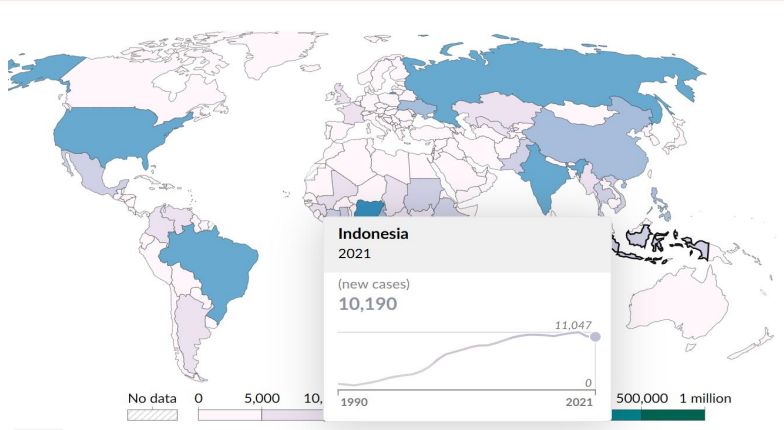
Indonesia continues to face challenges in its fight against tuberculosis (TB), particularly in identifying and reporting every case. Despite progress, at least one in four people with TB in total remains unreported or undiagnosed, leaving over 140 000 people undiagnosed in 2023. There are gaps in reporting from private sector facilities, inconsistent data submission from puskesmas, limited digital infrastructure integration and suboptimal surveillance among vulnerable groups such as children, people living with HIV and those in correctional facilities. Combined with limited human resources, decentralized health governance and the absence of a national vital registration system, these challenges could slow Indonesia's progress to eliminate TB by 2030.

By mid-2024, dengue had surged to nearly **150 000** cases and **884 deaths** across Indonesia. MoH selected Central Java in April 2024 to pilot MSCS, working with WHO and partners to map surveillance systems, identify gaps and define surveillance objectives, and align and implement priorities .[2]



143,000 Dengue cases and 1,236 deaths reported in 2022
Ministry of Health

The HIV epidemic in Indonesia is mostly concentrated among key populations (MSM, sex workers.There are an estimated 570,000 people living with HIV in Indonesia. Addressing the treatment gap is one of the country's biggest challenges. Only 31% of people living with HIV are accessing treatment and 14% are virally suppressed. [3]



[1] Strengthening TB surveillance to accelerate Indonesia's path to elimination — WHO
[2] Indonesia and WHO ramp up dengue fight with smarter surveillance — WHO
[3] Status of HIV Programmes in Indonesia — UNAIDS

Women and Children's Health Threats

GBS

- 25-30% Prevelance Rate
- 35-37 weeks are required to be screened (ACOG)

STI

- **Millions** cases of STIs (excluding HIV)
- The prevalence of **chlamydia** and **gonorrhea** is really high

Pneumonia

- **Leading cause** of death for children under five according to Unicef

Gastrointestinal (GI)

- **Diarrhea** is a major public health problem in children
- Cause of top 5 deadly disease for children under 5

Health System Gaps

Healthcare Inequality

Funding Shortfalls

Infrastructure Deficits

Key Transformation: From “Days Later” to “15-Minute Decisions

CASE STUDY

WellStreet Urgent Care (U.S.) has delivered rapid molecular respiratory testing to 200,000+ patients since February 2025 across Virginia, Texas, and North Carolina. Using the bioMérieux BioFire SpotFire platform, clinics obtain results in **~15 minutes for pathogens** including SARS-CoV-2, influenza, RSV, and rhinovirus, enabling same-visit diagnosis and treatment while improving workflow efficiency and reducing unnecessary prescriptions.

Unitaid: improve people-centered care through integrated diagnostic tools

Programmatic Priority: Accelerate access to integrated diagnostics and self-testing/self-care

Public Health Need	The "diagnostics gap" means that nearly 1 out of 2 people living in LMICs lacks access to essential, reliable diagnostic tests across multiple levels of the healthcare system – especially at the primary care level. The consequences are severe: delayed or missed diagnoses, inappropriate treatment, and preventable deaths from both infectious and noncommunicable diseases. This gap undermines health security, weakens pandemic preparedness and response (PPPR), and jeopardize progress towards the Sustainable Development Goals (SDGs) and universal health coverage (UHC). Increasing access to diagnostics requires innovative approaches to deliver equitable, high-quality care, supporting patient-centered, integrated services and stronger primary healthcare, and ultimately improving health outcomes for target populations.
Access Barriers	• **Demand & adoption**: lack of clarity on use cases, market size, awareness and demand; limited evidence on feasibility and cost-effectiveness of integrated diagnostic tools and services • **Innovation & availability:** lack of quality assured, fit-for-purpose integrated diagnostic tools (multi-plex(multi-disease/multi-modal) in LMICs at the primary and secondary healthcare levels • **Affordability:** current prices of diagnostic devices remain high and Integrated diagnostic tools are limited in LMIC markets • **Quality**: WHO prequalification and country regulatory systems currently have limited capacity for approving Integrated diagnostic tools • **Supply & delivery:** lack of concrete go-to market planning within LMICs and evidence on best use cases for integration of diagnostic tools and services within existing diagnostic systems and PPPR efforts
Pathway to impact	**Outputs** 1. **Evidence generated on the feasibility, viability, and scalability of integrated diagnostic tools and services, through implementation research, costing and modelling.** 2. **Demand for integrated diagnostic tools characterized to identify priority diseases and products, to inform country strategies, supplier engagement and resource allocation.** 3. **Country-specific diagnostic integration strategies and implementation plans are co-developed and endorsed, preparing countries for early introduction and scale-up of high-impact integrated diagnostic solutions and referral systems (at different levels of care).** 4. **Sustainable financing and transition supported through evidence dissemination, regional learning and advocacy.** **Expected Results (Outcomes)** **Primary outcome (SO1):** Accelerated availability and introduction of priority integrated diagnostic tools and services in LMICs. 1. **Patient-centered use-cases established to guide responsible uptake** of integrated diagnostic tools and services 2. **Pathways mapped and market-entry/commercialization strategies developed** to introduce integrated diagnostic tools and services in priority countries (including linkage to care) 3. **Evidence and learning generated on early introduction experience** in multiple countries across various use-cases to inform expansion 4. **Costing and cost-effectiveness established** for promising integrated diagnostic tools and services to facilitate demand and uptake 5. **Financing models identified** for introduction and sustainable roll-out **Supporting outcome (SO2):** Create systemic conditions for sustainable equitable access 1. **Integrated diagnostic** service delivery models/use cases defined for a range of LMIC settings 2. **Accessible demand established** for priority integrated diagnostic tools and services in context of national diagnostic lists 3. **Optimal positioning for integrated diagnostics identified** within health systems including PPPR frameworks **Supporting outcome (SO3):** Foster inclusive and demand-driven partnerships for innovation 1. **Integrated diagnostic strategies** and implementation plans co-designed in project countries with key stakeholders 2. **Continuous and meaningful engagement of key populations** in all aspects of product design, delivery, research and implementation of integrated diagnostic tools and services 3. **Donors and governments** engaged to **reach consensus** around the most **promising integrated diagnostic tools** **Impact** **Public health impact:** • Increased access to testing of priority diseases • Improved detection and linkage to care, contributing to improved health outcomes e.g. early diagnosis and treatment • Strengthened disease surveillance, including pandemic preparedness • Decentralisation of testing to PHC, communities and self care **Economic impact:** • Improved health system efficiencies & cost effectiveness
Key Risks	• **Strategic**: Integrated diagnostic tools development is not successful; sub-optimal alignment with other investments to strengthen diagnostic system capacity in LMICs • **Implementation**: Poor uptake and political willingness among countries to adopt newer integrated diagnostic tools, particularly in countries with a significant install base of existing technologies • **Scale-up**: Limited sources of sustainable funding for integrated diagnostic tools and services; delays in adoption into country policies and guidelines, supply side bottlenecks preventing access in targeted markets; emerging products are unaffordable

Call for proposals: Improving access to diagnostics through the adoption of tools and approaches that drive integration

A priority focus is on **molecular diagnostic tools**, which have demonstrated high performance and promise for TB detection, but also hold significant potential for additional diseases.

Technologies that support **multi-disease detection/diagnosis** rather than single-disease silos.

Enable testing at or **near point of care**, especially in lower levels of the health system.

Expand testing access within programmatic priorities (HIV, TB, cervical cancer, women's health, PPPR) and leverage it to health conditions or disease that are often deprioritized (e.g NCD, NTD, Outbreak, AMR)

source: https://unitaid.org/call-for-proposal/improving-access-to-diagnostics-through-the-adoption-of-tools-and-approaches-that-drive-integration/

Core Diagnostic needs

Accurate Results

Infectious diseases often manifest acutely and are highly dangerous. Empirical or traditional diagnostic approaches increase the risk of misdiagnosis, which make precise diagnosis essential.

Speed Medication

Samples sent to a central laboratory take several days. Rapid test results delivered within 60 minutes help seize the critical window for treatment and outbreak control.

Multiplex Detection

Diseases of same groups (like respiratory infecitons) tend to appear similar symptoms. Multiplex testing can significantly improve testing efficiency and the ability to identify co-infections.

Cost Effectiveness

Balancing reagent unit cost with comprehensive costs (labor, efficiency, ancillary requirements) and overall health economics (precision diagnostics reduce unnecessary medication and hospitalizations).

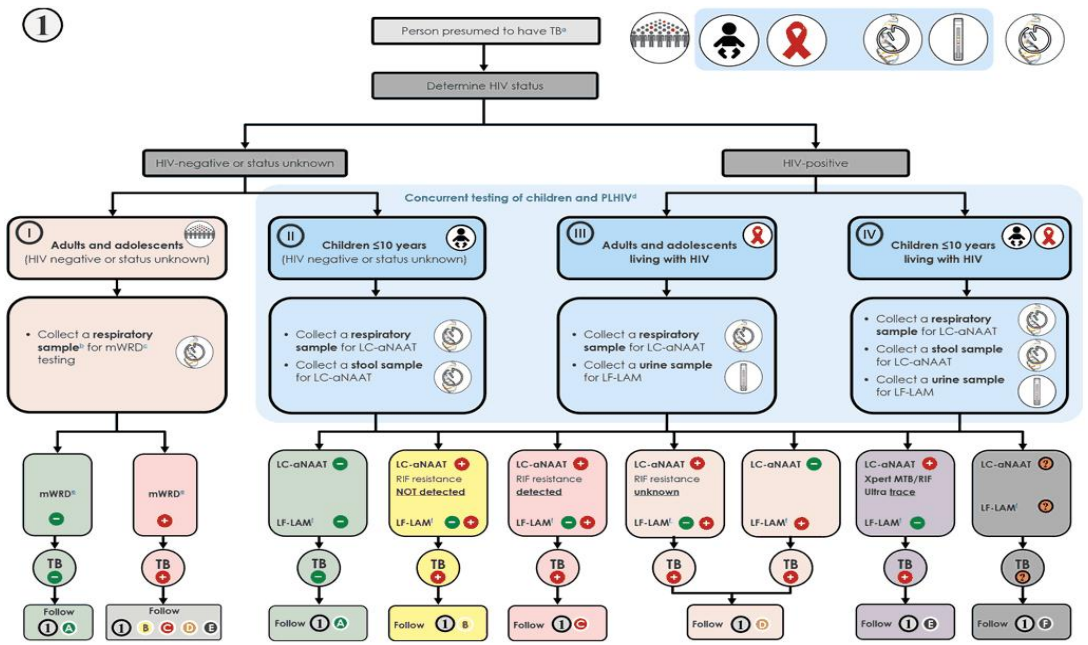
Multi Scenarios

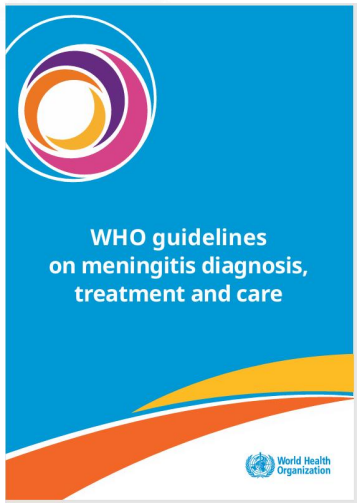
The equipment is portable and easy to operate, with minimal requirements for personnel, environment, and power supply, enabling truly decentralized deployment and resource allocation at the frontline.

Resilient Tests

The equipments can be flexibly configured with different test panels (e.g., respiratory, diarrheal, tuberculosis) according to epidemic needs, enabling multiple applications with a single device.

Core Requirements and Technical Orientation of WHO





- **WHO Recommend WRDs as initial diagnostic tests for TB**

  WRDs include molecular tests (LC-mNAAT, LC-aNAAT and MC-aNAAT) and a biomarker-based test (LF-LAM)

- **WHO Recommend TB diagnosis and detection of RIF resistance (simultaneously or as a two-step process) using an LC-aNAAT**

  Both GeneXpert and MultNAT are LC-aNAAT

- **WHO TPP call for Combined and single POCT assay for CT/NG/TV**
- **WHO guidelines on meningitis diagnosis：Multiplex PCR testing demonstrates an overall high diagnostic yield**

Strong recommendation for

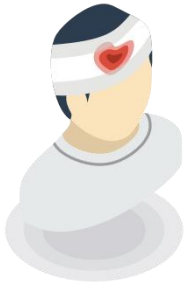
In individuals with suspected acute meningitis, PCR-based molecular tests for relevant pathogens should be performed on cerebrospinal fluid samples.

Three Principles for Innovative Medical Devices

01

Clinical Value

02

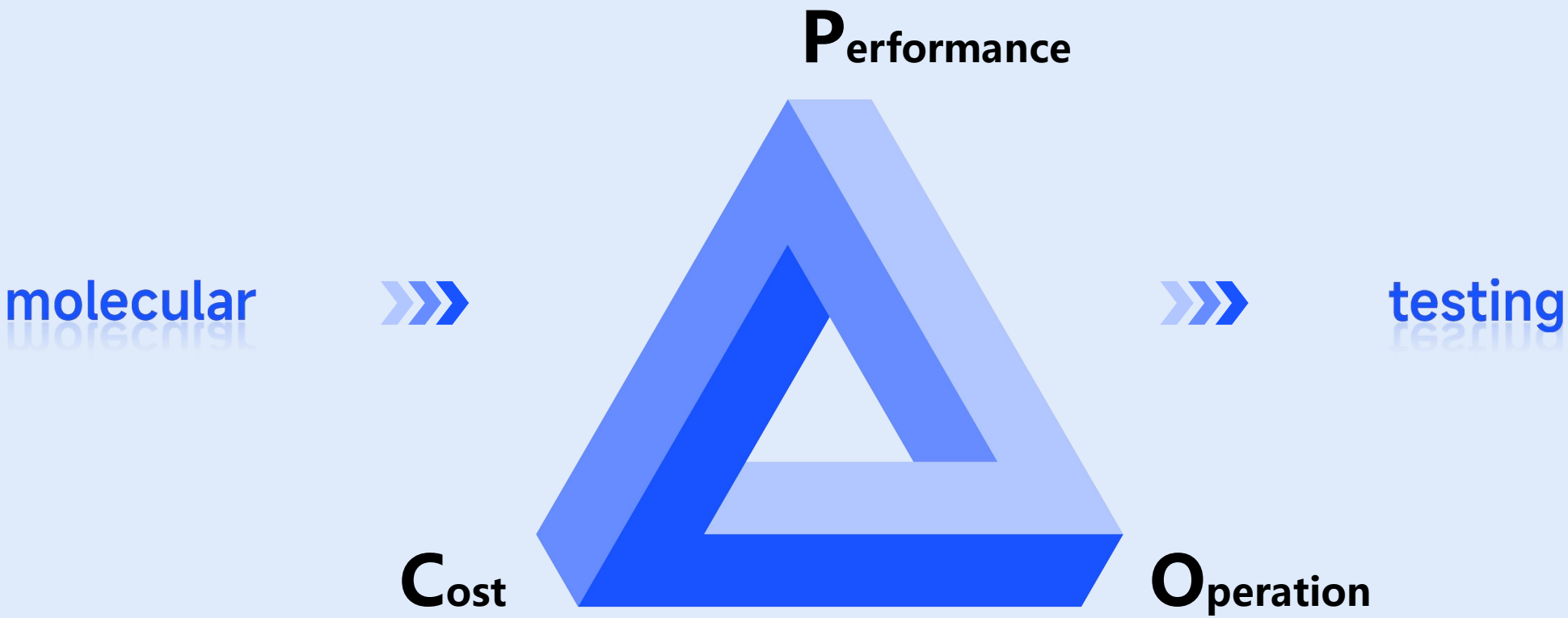


Patient Benefits

03

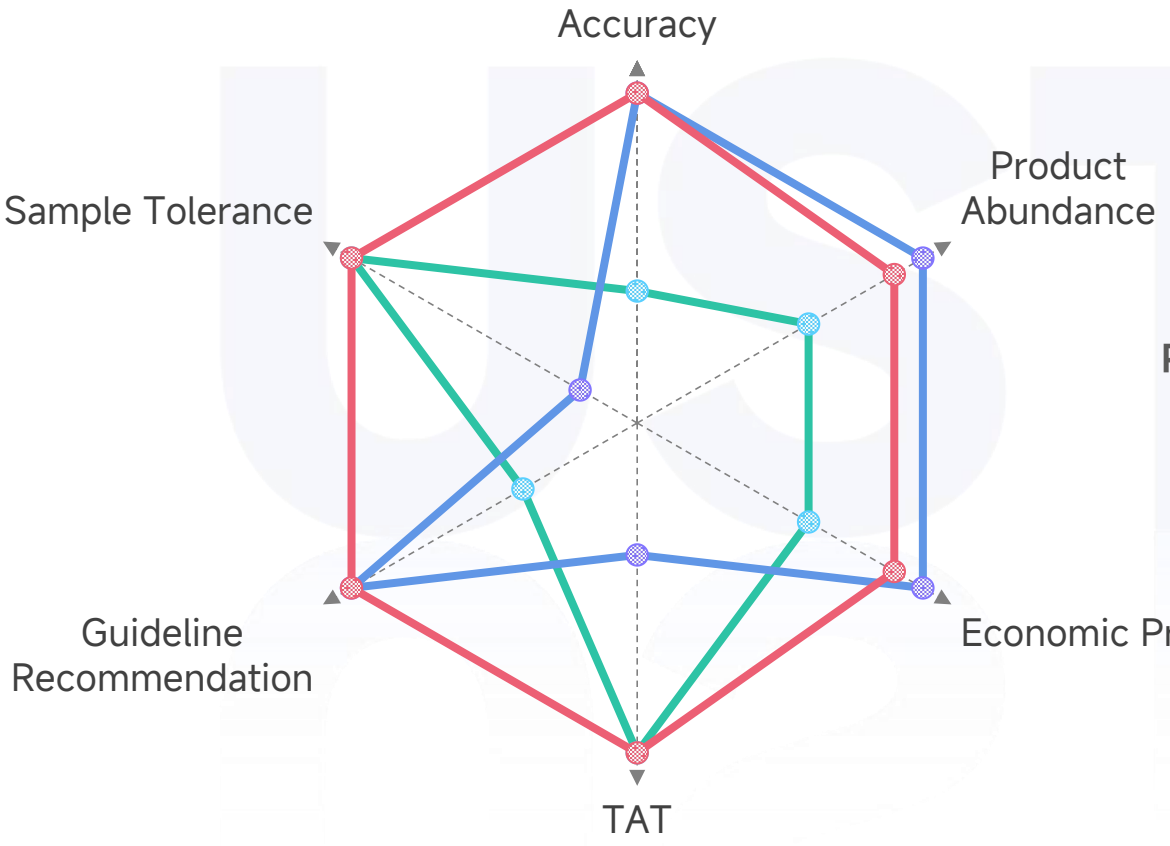
Medical Expense Optimization

mPOCT Triangular Principle



Molecular Testing *Anywhere* !

Comparistion Between RDT PCR and POCT



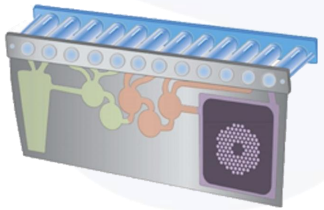
Molecular POCT combines the advantages of RDT and PCR

	RDT	POCT	PCR
Accuracy	★★	★★★★★	★★★★★
Product Abundance*	★★★	★★★★☆	★★★★★
Economic Profits	★★★	★★★★☆	★★★★★
TAT	★★★★★	★★★★★	★★
Guideline Recommendation	★★	★★★★★	★★★★★
Sample Tolerance	★★★★★	★★★★★	★

*BP、MP、MTC doesn't apply with RDT

Molecular POCT products and the technical features

- Mult-cell Catridge
  - 
    Cepheid Xpert
  - 

    SD M10
- Micro-fluidic chip
  - 
    BioFire FilmArray
  - 

    Qiagen QiaStat-Dx
- Separate Chamber
  - 
    Ustar MultNAT
  - 
    Roche Liat

MultNAT= GeneXpert + FilmArray

Separated Chambers

Ustar MultNAT

COMBO

- ✓ CoV2/Flu/RSV
- ✓ Strep A
- ✓ MTB/RIF
- ✓ MTB/XDR
- ✓ CT/NG
- ✓ MG
- ✓ GBS
- ✓ HPV
- ✓ MPOX
- ☐ MVP
- ☐ TV
- ✓ MRSA/SA
- ✓ Carba-R
- ✓ Norovirus
- ✓ C. difficile
- ✓ vanA/vanB
- ✓ Ebola
- ✓ HIV-1
- ✓ HIV-1-VL
- ✓HBV-VL
- ✓HCV-VL
- ☐BCR-ABL
- ☐Bladder Cancer Detection
- ☐Breast Cancer STRAT4
- ☐NMP1 Mutation
- ☐Bladder Cancer Monitor
- ☐FII & FV

Unique

- ✓ RSP-10
- ✓ MP/DR
- ✓ NTM/MTB
- ✓ MTC
- ✓ NTM Genotyping
- ✓ STI-10
- ✓ VC
- ✓ Malaria
- ✓ Dengue 1-4
- ✓ Dengue/Zika/Chikungunya
- ✓ JAK2-V617F
- ✓ SLE
- ✓ GI-5
- ✓ HP/DR
- ✓ HFM

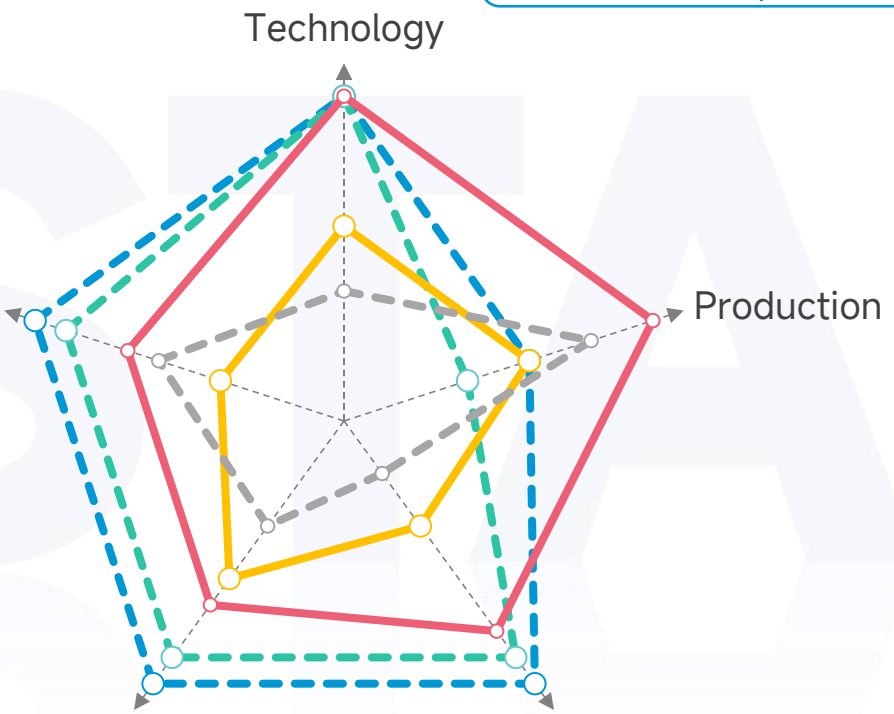
- ☐ Respiratory Mini-5
- ✓ Meningitis/Encephalitis-14
- ✓ Respiratory/Sore Throat-15
- ✓ Pneumonia Plus-14
- ✓ Respiratory 2.1 Plus-23
- ✓ Blood Culture Identification -43
- ✓ Gastrointestinal-22
- ☐Joint Infection-39
- ✓ Tropical Fever -6

- ✓ Fungal infection panel
- ✓ Drug-related gene Panel
- ✓ ASFV
- ✓ Bovine mastitis

Molecular POCT product Maturity model

Accuracy	Speed	Covenience
Through-put	Mult-targets	Portfolio

Coverage
Installation
Service



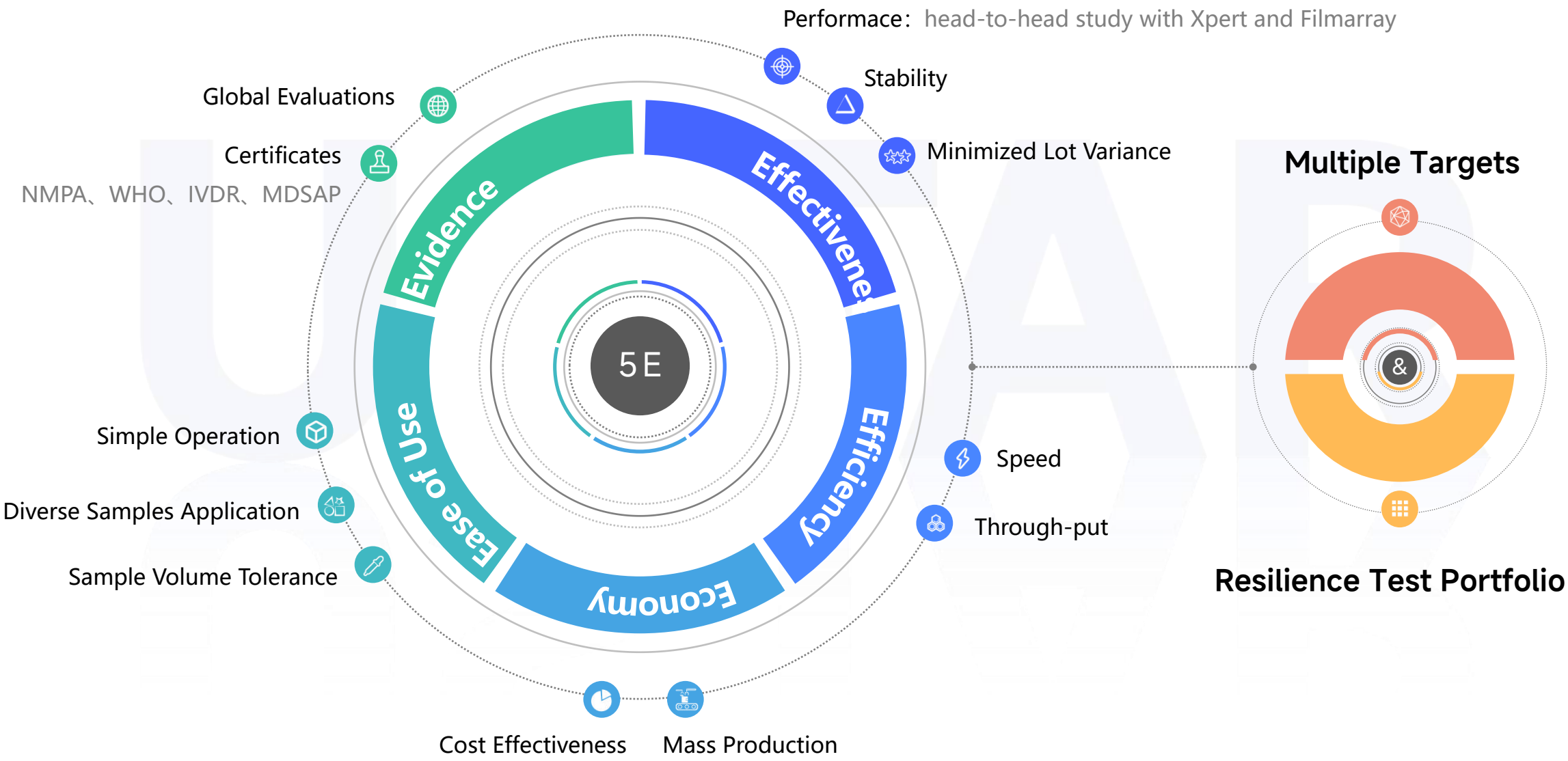
Unit Cost
Mass Production
Lot Variation

Differentiation	Insurance
Guidelines	Evaluation
High-end Market	

NMPA	WHO
FDA	TGA
IVDR	MDSAP

Xpert FlimArray A Company B Company Ustar

Significant Qulities of Excellent mPOCT



Contents

MultNAT Molecular Diagnostic Testing System

Fully Automated Medical PCR Analyzer

Accurate | Safe | Mult-targets | High Throughput

Proven Clinical Performance

Rapid detection ≤35min

Respiratory pathogens

> 30-plex molecular POCT

10 fluorescence system for broader target coverage

Customization

PCR →POCT Conversion

Technology Innovation Awards Achieved (Selected)

National Science and Technology Progress Award, Second Prize (2017)

Collaborating Institution: Nanjing Forestry University

Beijing Science and Technology Progress Award, Second Prize (2023)

Collaborating Institution: Beijing Chest Hospital

Zhejiang Provincial Science and Technology Progress Award, First Prize (2020)

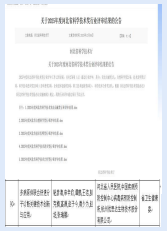
Collaborating Institution: Institute of Pathogen Biology, Chinese Academy of Sciences

Beijing Science and Technology Progress Award, Second Prize (2025)

Collaborating Institution: Peking Union Medical College Hospital

Guangdong Provincial Science and Technology Progress Award, First Prize (2024)

Collaborating Institutions: Beijing Chest Hospital and Southern Medical University



Hebei Provincial Science and Technology Progress Award, Second Prize (2025)

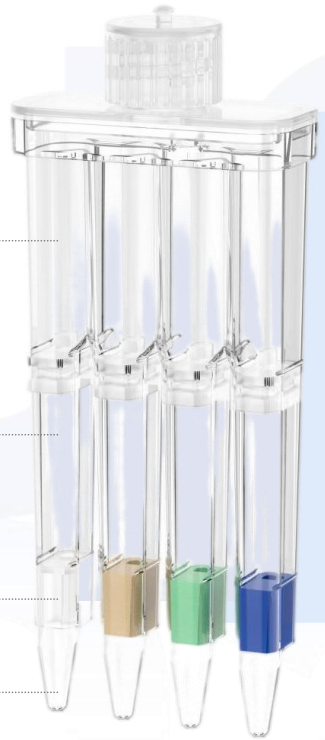
Collaborating Institutions: Hebei Provincial People's Hospital, China CDC

Cartridge Resilience Design Meet Capacity On-demand

4 Tubes

2 Tubes

1 Tube



Lysis

Purifications

Vetrification

PCR Amplification

Targets ↑

Tests ↑

10 Fluorescent Chanels

Classic 6: Atto425/FAM/HEX/ROX/Cy5/Cy5.5

Innovative 4: LS7/LS8/LS9/LS10

Abundant Test Menu

MultNAT Test Menu

Tuberculosis

	MTB/RIF	**CE-IVD**
⋆	INH/FLQ	CE-IVD
⋆	MTB	CE-IVD
⋆	NTM-Genotyping	CE-IVD
⋆	MTC/NTM	CE-IVD

Respiratory Pathogens

⋆	RSP-10 plex	CE-IVD
⋆	Pneumonia-14	CE-IVD
⋆	Fungal Panel-18	CE-IVD
⋆	EV/EV-71、CA-16/6/10	
	RSP-24 plex	CE-IVD

Sextually Transmitted Infections (STI)

⋆	STI-10 plex	CE-IVD
	HPV E6/E7 mRNA Genotyping	CE-IVD
	HIV/HBV/HCV	
⋆	HIV 1 -VL	

Gastrointestinal Infections

⋆	GI-5	CE-IVD
⋆	HP/DR	CE-IVD
	C. difficile	
	Norovirus	
	GI-24 plex	CE-IVD

Hospital Acquired Infections (HAI)

	Carba-R	CE-IVD
	MRSA/SA	CE-IVD
	VanA/vanB	CE-IVD

Tropical Diseases

	TF-11 plex	CE-IVD
⋆	Dengue, Zika, Chikungunya	CE-IVD
⋆	Dengue Genotyping	CE-IVD
⋆	Malaria	

Personalised Gene/Gene Mutation

⋆	BRAF V600E	CE-IVD
⋆	JAK2-V617F	CE-IVD
⋆	NSCLC、EGFR/ALK/ROS1/MET)	
⋆	Combined genetic testing for antiplatelet drugs (aspirin and clopidogrel)	
⋆	Stem cell quality control	

Veterinary

⋆	Africa Swine Fever
⋆	PRRSV
⋆	PEDV
⋆	Bovine Mastitis

⋆ Unique USTAR Product

TB Total Solution

- MTC
- NTM/MTB
- MTC/RIF
- INH/FLQ
- NTM Genotyping

NTM/MTB Differentiation

Fast TAT

POC Settings

Accuracy Improvement

Medication Guidance

Cost Reduction

MTC/RIF

World Health Organization

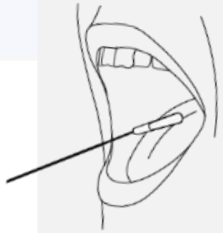
WHO recommended rapid diagnositc testing platforms to be used as initial tests for TB

Fig. 2. WHO-recommended rapid diagnostic testing platforms to be used as initial tests for TB, 2022

Xpert MTB/RIF & Ultra

FIND
Because diagnosis matters

Stop TB Partnership



Principle	RT-PCR Melting Curve
Sample	Sputum, **tongue swab**
Targets	IS6110、1081、rpoB

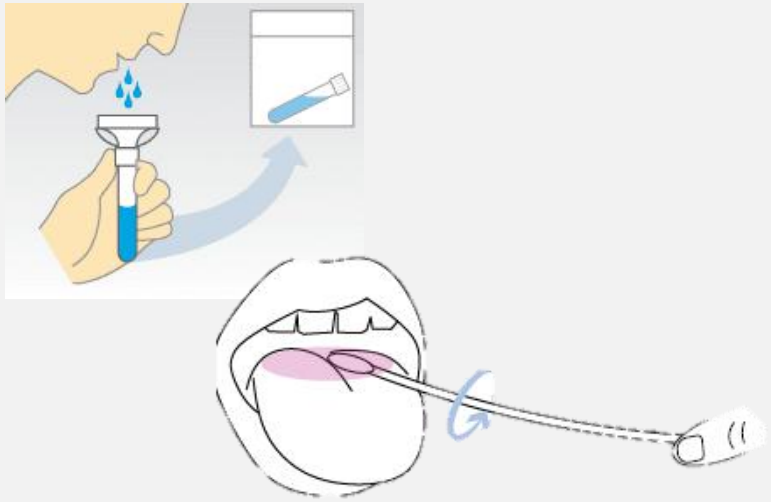
Comparative Study Initiated by Cepheid (Xpert TB/RIF Ultra)： Ustar TB solutions MultNAT MTB/RIF Assay、EasyNAT MTC Assay comparable to Xpert TB/Rif Ultra in a head-to-head evaluation

Conclusion: USTAR’ s assays demonstrate comparable performance to Xpert MTB/RIF Ultra.

INH/FLQ

Bacteriological confirmation of TB is necessary to test for resistance to first-line and second-line anti-TB drugs; such testing can be done using **rapid molecular tests,** phenotypic susceptibility testing or reference-level genetic sequencing.。

Method	RT PCR- Melting curve method
Sample	Sputum、Tongue Swab



WHO **US CDC**

The importance of monitoring tuberculosis resistance to isoniazid and fluoroquinolones is widely recognized internationally

Novel diagnostic test for the detection of *Mycobacterium tuberculosis* and its resistance to rifampicin, isoniazid, and fluoroquinolones directly in sputum samples

Rapid identification of tuberculosis (TB) and its drug resistance is crucial for starting effective treatment promptly and preventing the spread of resistant Mycobacterium tuberculosis (MTB) strains.

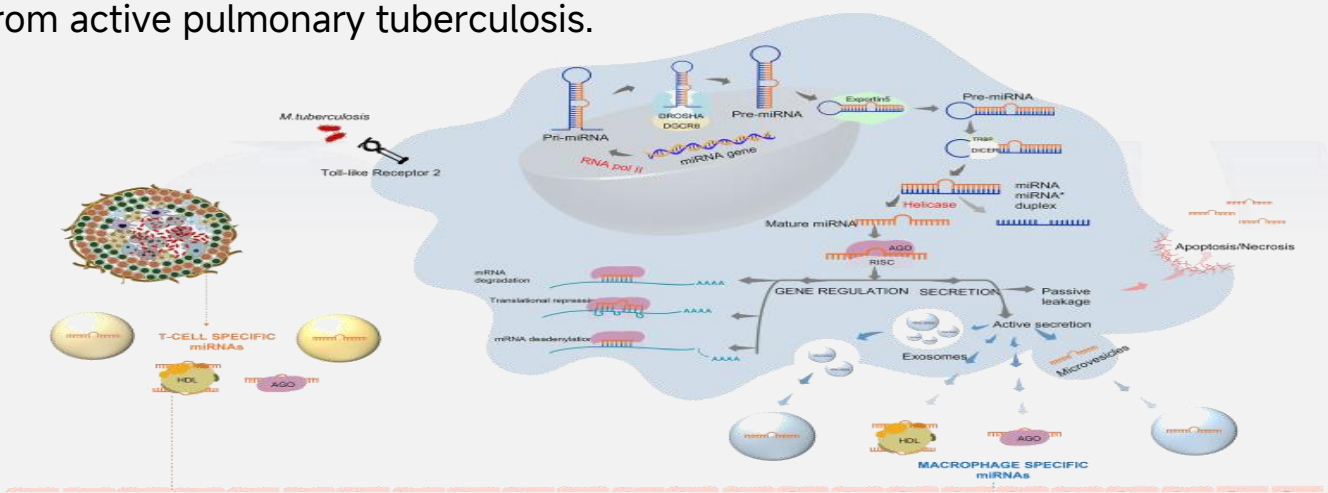
Targets

- ✓ inhA
- ✓ katG
- ✓ ahpC
- ✓ gyrA
- ✓ gyrB

Novel diagnostic test for the detection of Mycobacterium tuberculosis and its resistance to rifampicin, isoniazid, and fluoroquinolones directly in sputum samples

miRNA

MicroRNAs (miRNAs) are important regulatory factors in the pathogenesis of tuberculosis (TB). Recent studies have shown that distinct miRNA expression patterns among healthy individuals, patients with latent tuberculosis infection, and those with active tuberculosis highlight their potential as biomarkers. Research has demonstrated that multiple miRNAs undergo significant changes during pulmonary TB infection, making them promising early diagnostic biomarkers for TB and useful for distinguishing latent infection from active pulmonary tuberculosis.



Synthetic miRNAs during Mycobacterium tuberculosis infection

Turn-around-time：135 min

Sample Types：Serum、Plasma

LoD：10 copies/mL

Test Targets：

hsa-miR-143-3p	hsa-miR-193a-3p
hsa-miR-320d	hsa-miR-197-3p
hsa-miR-1290	hsa-miR-223-3p
hsa-let-7d-3p	hsa-miR-16-2-3p
hsa-miR-92b-3p	hsa-miR-151a-5p

Xin H, Cao X, Du Y, Yan J, He R, Liu Z, Zhang H, He Y, Zhang B, Wang D, Guan L, Shen F, Feng B, Quan Z, He Y, Liu J, Jin Q, Pan S, Gao L. The Association between Circulating microRNAs and the Risk of Active Disease Development from Latent Tuberculosis Infection: a Nested Case-Control Study. Microbiol Spectr. 2022 Jun 29;10(3):e0262521. doi: 10.1128/spectrum.02625-21. Epub 2022 Apr 18. PMID: 35435753; PMCID: PMC9241859.

Daniel EA, Sathiyamani B, Thiruvengadam K, Vivekanandan S, Vembuli H, Hanna LE. MicroRNAs as diagnostic biomarkers for Tuberculosis: A systematic review and meta- analysis. Front Immunol. 2022 Sep 27;13:954396. doi: 10.3389/fimmu.2022.954396. PMID: 36238288; PMCID: PMC9551313.

Performance Comparison with Xpert: High Consistency Achieved

MTC - Sputum Sample

Clinical Site: Beijing Chest Hospital, Capital Medical University (National Tuberculosis Clinical Laboratory)

Sample Size: 249 cases

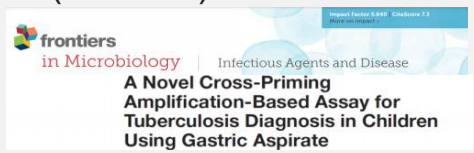
Conclusion: High concordance with GeneXpert.Among 169 confirmed pulmonary TB cases, EasyNAT demonstrated higher sensitivity than Xpert (72.19% vs. 61.54%).In 74 smear-negative and culture-negative TB cases, EasyNAT detected significantly more positives than Xpert (44.59% (33/74) vs. 22.97% (17/74)).

MTC - pediatric Gastric Aspirate sample

Clinical Site: Beijing Children's Hospital, Capital Medical University (National Center for Children's Health)

Sample Size: 249 cases

Conclusion: Comparable sensitivity to GeneXpert in active TB cases: EasyNAT: 22.6% (31/137) Xpert: 26.3% (36/137)Identical sensitivity (60%) in bacteriology-confirmed TB cases (9/15). Similar specificity: EasyNAT: 98.0% (100/102) Xpert: 99.0% (101/102)



MTC/RIF-Sputum Sample

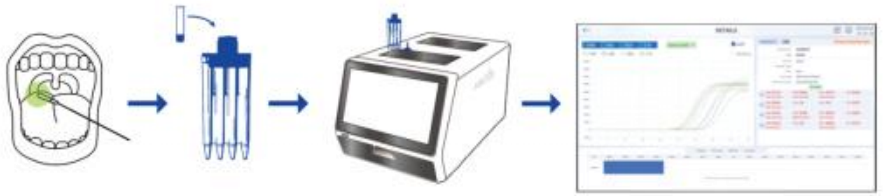
Clinical Site: Hunan Chest Hospital; Guangzhou Chest Hospital; Hangzhou Red Cross Hospital

Sample Size: 967 cases

Conclusion: Exceptional agreement with Xpert MTB/RIF Ultra: MTC Detection: Positive agreement: 99.51%; Negative agreement: 98.90%; Overall agreement: 99.32%; RIF Resistance Detection: 100% concordance (positive, negative, and overall agreement).

Respiratory Panel

~ 70 mins



Sampling → Loading → Barcode Scanning → Automated Result Reporting

Rapid identification of 24 Targets: **LoD 50-500 copies/mL**

- SARS-CoV-2
- Respiratory syncytial virus (RSV)
- Human metapneumovirus (hMPV)
- Influenza A virus (Flu A)
- Influenza A virus A/H1
- Influenza A virus A/H3
- Influenza A virus A/H1-2009
- Influenza B virus (Flu B)
- Parainfluenza Viruses (PIVs) type 1
- Parainfluenza Viruses (PIVs) type 2
- Parainfluenza Viruses (PIVs) type 3
- Parainfluenza Viruses (PIVs) type 4
- Human coronaviruses 229E
- Human coronaviruses NL63
- Human coronaviruses HKU1
- MERS-CoV
- Human coronaviruses OC43
- Adenovirus (AdV)
- Human Rhinovirus/Enterovirus
- *Mycoplasma pneumoniae*
- *Bordetella parapertussis (BPP)*
- *Legionella Pneumophila (LP)*
- *Bordetella pertussis (BP)*
- Chlamydia pneumoniae (CP)

Sample Types Sputum, oropharyngeal swab, nasal swab, nasopharyngeal swab, bronchoalveolar lavage fluid, pleural fluid

Targets Comparison

Catagory	Pathogens	USTAR Panel	QIAstat-Dx	Filmarray
Virus	Coronavirus OC43	✓	✓	✓
	Coronavirus 229E	✓	✓	✓
	Coronavirus NL63	✓	✓	✓
	Coronavirus HKU1	✓	✓	✓
	Parainfluenza Virus 1	✓	✓	✓
	Parainfluenza Virus 2	✓	✓	✓
	Parainfluenza Virus 3	✓	✓	✓
	Parainfluenza Virus 4	✓	✓	✓
	Respiratory syncytial virus A	✓	✓	✓
	Respiratory syncytial virus B	✓		
	Influenza A virus	✓	✓	✓
	Influenza A virus A/H3	✓	✓	✓
	Influenza A virus A/H1	✓	✓	✓
	Influenza A virus A/H1-2009	✓	✓	✗
	Influenza B virus	✓	✓	✓
	Enterovirus	✓	✓	✓
	Human Rhinovirus	✓		
	MERS-CoV	✓	✗	✗
	Human Metapneumovirus	✓	✓	✓
	Adenovirus	✓	✓	✓
	SARS-CoV-2	✓	✓	✓
Bacterial	Bordetella parapertussis	✓	✓	✗
	Bordetella pertussis	✓	✓	✓
	Legionella pneumophila	✓	✓	✗
	Mycoplasma pneumoniae	✓	✓	✓
	Chlamydia pneumoniae	✓	✓	✓

Respiratory 4-plex & 10-plex & Penumonia Panel 14-plex

Respiratory infectious diseases are extremely common in clinical practice, and rapid pathogen detection and accurate diagnosis are essential prerequisites for effective treatment.

Respiratory 10-plex

- SARS-CoV-2
- Influenza A virus
- Influenza B virus
- Mycoplasma
- Respiratory syncytial virus
- Adenovirus
- Human Rhinovirus
- Parainfluenza Virus
- Human metapneumovirus
- *Bordetella pertussis*

Acute Respiratory Infection（ARI）

Community-Acquired Pneumonia (CAP)

Rapid reporting within 30 minutes in emergency settings, nabling precise primary-care diagnosis

Respiratory 4-plex

SARS-CoV-2	Influenza A virus
Respiratory syncytial virus	Influenza B virus

TAT 34 minutes

Hospital-Acquired Pneumonia (HAP)

Ventilator-Associated Pneumonia (VAP)

For critically ill and severe patients, enables rapid identification of infectious pathogens

Penumonia Panel 14-plex

- Escherichia coli
- Klebsiella pneumoniae
- Streptococcus pneumoniae
- Pseudomonas aeruginosa
- Acinetobacter baumannii
- Haemophilus influenzae
- Moraxella catarrhalis
- Stenotrophomonas maltophilia
- Burkholderia cepacia
- Legionella pneumophila
- Pneumocystis jirovecii
- Aspergillus spp.
- Cryptococcus neoformans
- Staphylococcus aureus

Gastrointestinal Panel

World Health Organization

Diarrhoeal disease

Diarrhoeal disease is the **third leading cause** of death in children under 5 years old and is responsible for killing around **443 832 children** every year. Diarrhoea can last several days and can leave the body without the water and salts that are necessary for survival.

TAT	<1.5 hours
Targets	**24** per test
Sample Type	Stool

BACTERIA	Campylobacter (C,jejuni/C, coli/C,upsaliensis)
	Clostridium difficile (toxin A/B)
	Plesiomonas shigelloides
	Salmonella
	Vibrio spp.(Vibrio parahaemolyticus, Vibrio vulnificus, V. cholerae)
	Yersinia enterocolitica
	Yersinia pseudotuberculosis
	Enteroaggregative E. coli (EAEC)
	Enteropathogenic E. coli (EPEC)
	Enterotoxingenic E. coli (ETEC) lt/st
	Shiga toxin-producing Escherichia coli (STEC) stx1 stx2 (including stx2f)
	E. coli O157
	Shigella(combined with Enteroinvasive E. coli, EIEC)
VIRUSES	Adenoviruses F 40/41
	Norovirus GI/GII
	Rotavirus A
	Human Astrovirus
	Sapovirus(GI/GII/GIV/GV)
PARASITES	Cryptosporidium
	Cyclospora cayetanensis
	Entamoeba histolytica
	Giardia lamblia

Targets Comparison

Catogories	Pathogens	MultNAT GI Panel	QIAstat-Dx	Filmarray
Virus	Norovirus GI/GII	✓	✓	✓
	Rotavirus	✓	✓	✓
	Adenovirus	✓	✓	✓
	Sapovirus	✓	✓	✓
	Astrovirus	✓	✓	✓
Bacterial	Enteropathogenic E. coli (EPEC)	✓	✓	✓
	Shiga-like toxin-producing E. coli （STEC）	✓ (Differentiate stx1/stx2)	✓ (Differentiate stx1/stx2)	✓
	Enteroaggregative E. coli （EAEC）	✓	✓	✓
	Shigella/Enteroinvasive E. coli	✓	✓	✓
	Enterotoxigenic E. coli （ETEC）	✓	✓	✓
	Campylobacter (C. jejuni/C. coli/C. upsaliensis)	✓	✓	✓
	Campylobacter coli	✓	✓	✓
	V. vulnificus/Vibrio parahaemolyticus	✓	✓	✓
	V. cholerae	✓	✓	✓
	Plesiomonas shigelloides	✓	✓	✓
	Clostridium difficile (toxin A/B)	✓	✓	✓
	Yersinia enterocolitica	✓	✓	✓
	Salmonella	✓	✓	✓
	Yersinia pseudotuberculosis	✓	✗	✗
Parasites	Cryptosporidium	✓	✓	✓
	Cyclospora cayetanensis	✓	✓	✓
	Entamoeba histolytica	✓	✓	✓
	Giardia lamblia	✓	✓	✓

Gastrointestinal Panel 5-plex

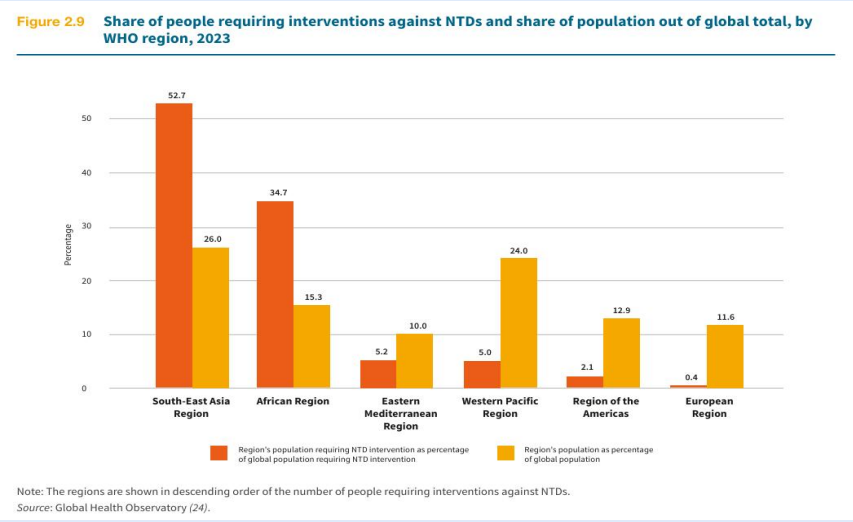
According to data from the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF), approximately 2 billion cases of diarrhea occur worldwide each year, and about 1.9 million children under the age of five die from diarrhea annually, most of whom are in developing countries.

Principle	RT PCR
Sample Type	Feces
Targets	fimY、ipaH、ORF、fiber、VP6

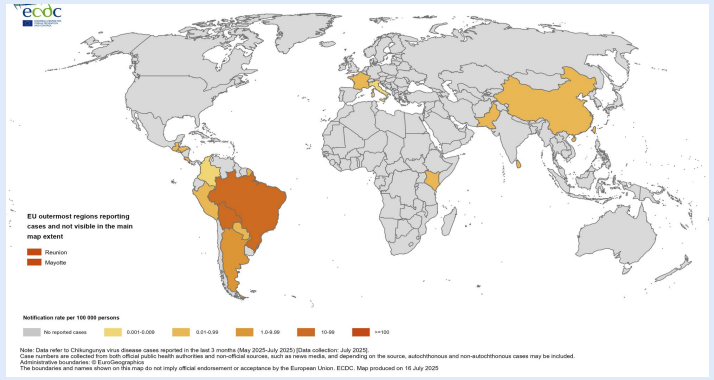
- **Pathogens**
- Salmonella
- Shigella
- Rotavirus A
- Norovirus GI/GII
- Adenovirus F40/41

Tropical Fever Panel

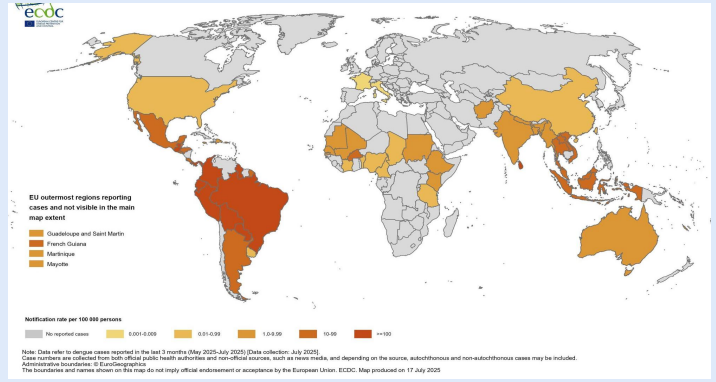
In 2023, 1.495 billion people globally required interventions for neglected tropical diseases (NTDs), marking a 32% decrease since 2010. However, this progress falls short of the global target of a 90% reduction by 2030. The highest NTD burden was concentrated in Southeast Asia and Africa, which together accounted for 87% of the global population requiring interventions in 2023 [1].



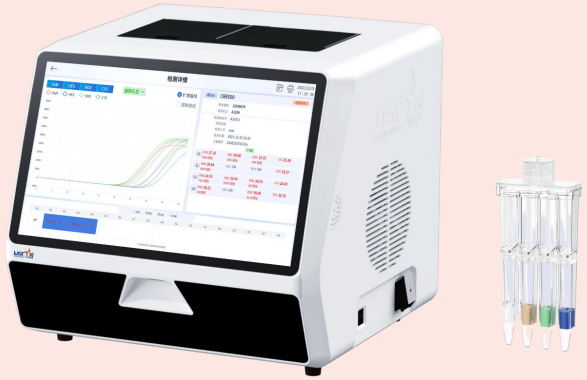
Global Incidence Rate Map of Chikungunya Virus, May-July 2025 [2]



Global Incidence Rate Map of Dengue Virus, May-July 2025 [3]



TAT:	Within 60 mins
Sample Types:	Plasma, Serum
Limit of Detection:	100-500 Copies/mL



1 Cartridge **11 Targets**

[1] 2025 World Health Statistics: Monitoring Health-related Sustainable Development Goals (SDGs)
[2] https://www.ecdc.europa.eu/en/chikungunya-monthly
[3] https://www.ecdc.europa.eu/en/dengue-monthly

Targets Comparison

Catogories	Pathogens	USTAR	Filmarray TF Panel	SD Biosensor Arbovirus Panel
Spirochete	Leptospira	✓	✓	✗
Viruses	★ Dengue virus Type I	✓	✓	✓
	★ Dengue virus Type II	✓		✓
	★ Dengue virus Type III	✓		✓
	★ Dengue virus Type IV	✓		✓
	Chikungunya	✓	✓	✓
	Zika	✓	✗	✓
	West Nile	✓	✗	✓
	Yellow Fever	✓	✗	✓
Parasites	Plasmodium	✓	✓	✗
	Leishmania	✓	✗	✗

Dengue/Zika/Chikungunya

World Health Organization

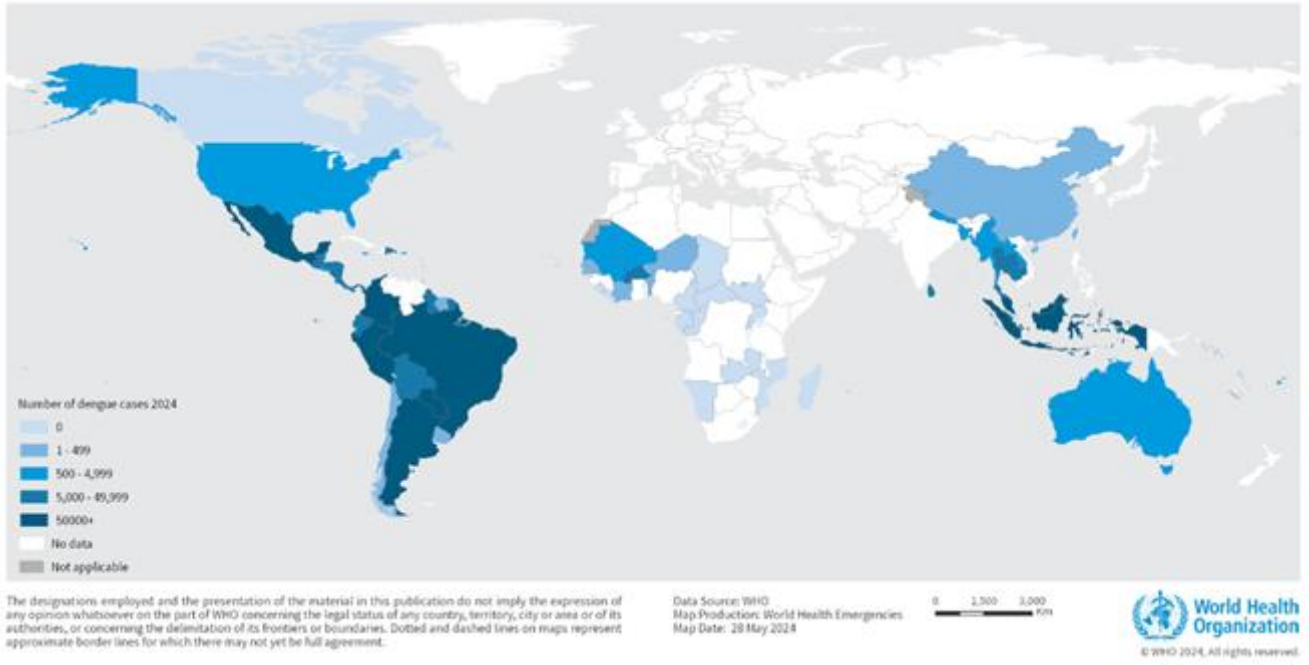
CDC
U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

Chikungunya and **Dengue** are viruses most commonly transmitted by Aedes aegypti and Aedes albopictus mosquitoes.

Zika infection is a cause of microcephaly and other congenital malformations and can cause neurological disease in children and adults.

Dengue and Zika have **similar symptoms** to chikungunya, making chikungunya easy to misdiagnose.

TAT	Around 1 hour
Sample Type	Serum、Plasma
LOD	500 copies/ml



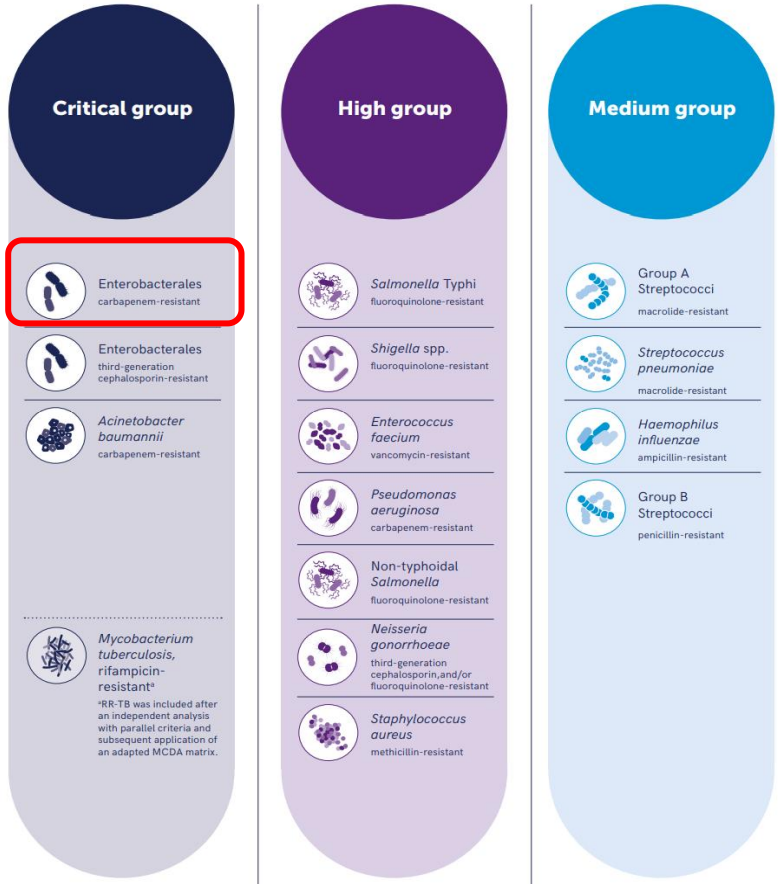
In 2024, more than **13 million cases** of dengue have been reported in North, Central, and South America and the Caribbean.

Carba-R

Enterobacterales **carbapenem-resistant** was listed on the top of **critical group** of Bacterial Priority Pathogens List by WHO

WHO | **US CDC** | **ECDC**

CRE Test is considered crucial by authorities.



ecdc EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

Increase in carbapenem-resistant Enterobacterales (CRE) poses a significant threat to patients and healthcare systems in the EU/EEA

ECDC recommends EU/EA countries to:

Provide adequate laboratory capacity for **rapid detection and characterisation** of CRE, including antimicrobial susceptibility testing and identification of carbapenemase genes for the targeted use of newly approved antimicrobials.

Strengthen innovation and access to antimicrobials indicated against CRE infections.

Targets

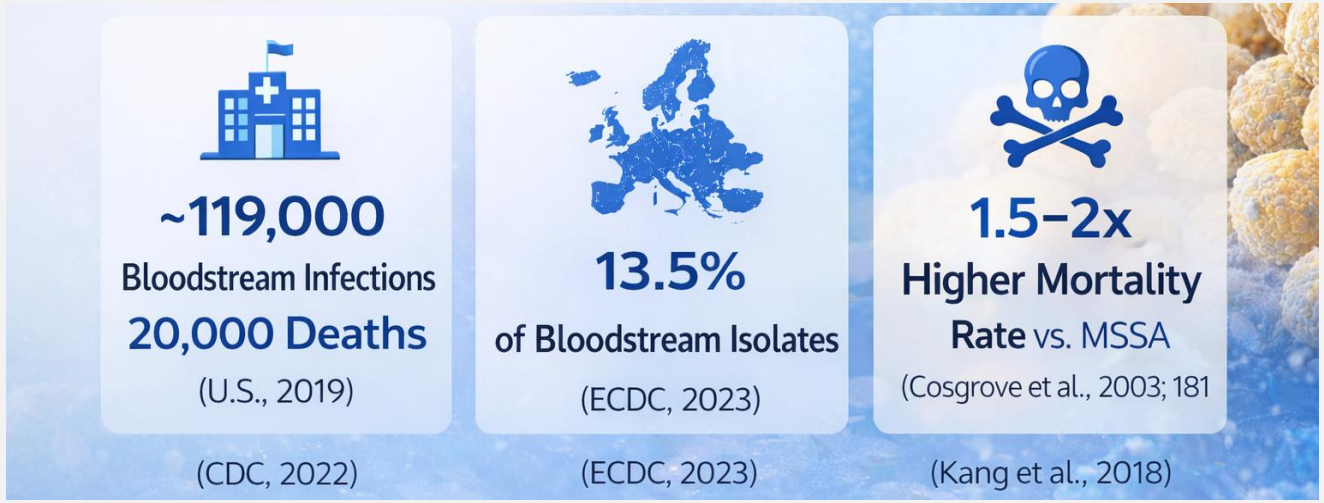
- ✓ KPC
- ✓ NDM
- ✓ VIM
- ✓ OXA-48
- ✓ OXA-23
- ✓ IMP

MRSA

Staphylococcus aureus is a major cause of severe community- and healthcare-associated infections worldwide.

- United States (2019): ~119,000 MRSA bloodstream infections and ~20,000 deaths
- Europe (2021): MRSA accounted for 13.5% of S. aureus bloodstream isolates, exceeding 25% in some countries
- MRSA bacteremia carries a 1.5–2× higher mortality than MSSA

Delays caused by culture-based diagnostics (24–72 h) significantly worsen outcomes, highlighting the urgent need for rapid MRSA/SA molecular testing.



Turn-around-time: 62 mins

Sample Types: Nasal swab

LoD: 100 CFU/Reaction

Test Targets:

- Spa
- SCC
- mec

Helicobacter Pylori

Antimicrobial susceptibility testing for Helicobacter pylori in times of increasing antibiotic resistance

Core tip: There has been a significant decrease in the success rate of empirical triple therapy to treat *Helicobacter pylori* (*H. pylori*) infection, largely due to a rapid increase in the prevalence of antibiotic resistant strains. Antibiotic resistance is a constantly evolving process and there are significant regional variations in *H. pylori* antibiotic resistance rates. As such, local surveillance of antibiotic resistance is warranted to guide clinicians in their therapeutic choice. Standard culture-based antimicrobial susceptibility testing and molecular methods provide key opportunities to tailor *H. pylori* treatment based on the detection of antibiotic resistant strains, thereby enhancing eradication rates and decreasing *H. pylori*-associated disease.

The **accurate diagnosis** of *H. pylori* infections and its **antibiotic resistance markers** is of great significance.

TAT	<1.5 hours
Sample Type	Mucosa
High Throughput	Up to 32 tests per time
LOD	1000 copies/ml
Targets	UreA、23S rRNA、gyrA

Antimicrobial susceptibility testing for Helicobacter pylori in times of increasing antibiotic resistance

STI Panel

All sexually active women younger than 25 years should be tested for **gonorrhea** and **chlamydia** every year.Sexually active men who are gay or bisexual and men who have sex with men should be tested: For **syphilis**, **chlamydia**, and **gonorrhea** at least once a year.

Recommendations of WHO

WHO, in Laboratory Diagnosis of Sexually Transmitted Infections and the Global Health Sector Strategies on HIV, Viral Hepatitis and Sexually Transmitted Infections 2022–2030, recommends the use of rapid, accurate, and highly automated molecular point-of-care testing (POCT) devices for the rapid screening, genotyping, and drug resistance detection of sexually transmitted pathogens, in order to achieve the goal of “diagnose and treat at the same visit.”

Test time： 79 minutes

Sample types： **Urine**、Genital swab

LoD： 500 copies/mL

Targets：

Chlamydia trachomatis (CT)	Herpes simplex virus type 1 (HSV1)
Neisseria gonorrhoeae (NG)	Herpes simplex virus type 1 (HSV2)
Mycoplasma genitalium (MG)	Trichomonas vaginalis (TV)
Ureaplasma urealyticum (UU)	Treponema pallidum (TP)
Mycoplasma hominis (MH)	Ureaplasma parvum (UP)

STI Target Comparison

Pathogens	MultNAT STI Panel	SeegeneAllplex™ STI Essential Assay Q
Chlamydia trachomatis (CT)	✓	✓
Mycoplasma hominis (Quantitative) (MH)	✓	✓
Trichomonas vaginalis (TV)	✓	✓
Ureaplasma urealyticum (UU)	✓	✓
Neisseria gonorrhoeae (NG)	✓	✓
Ureaplasma parvum (UP)	✓	✓
Herpes simplex virus type 1 (HSV1)	✓	✗
Herpes simplex virus type 1 (HSV2)	✓	✗
Treponema pallidum (TP)	✓	✗
Mycoplasma genitalium (MG)	✓	✓

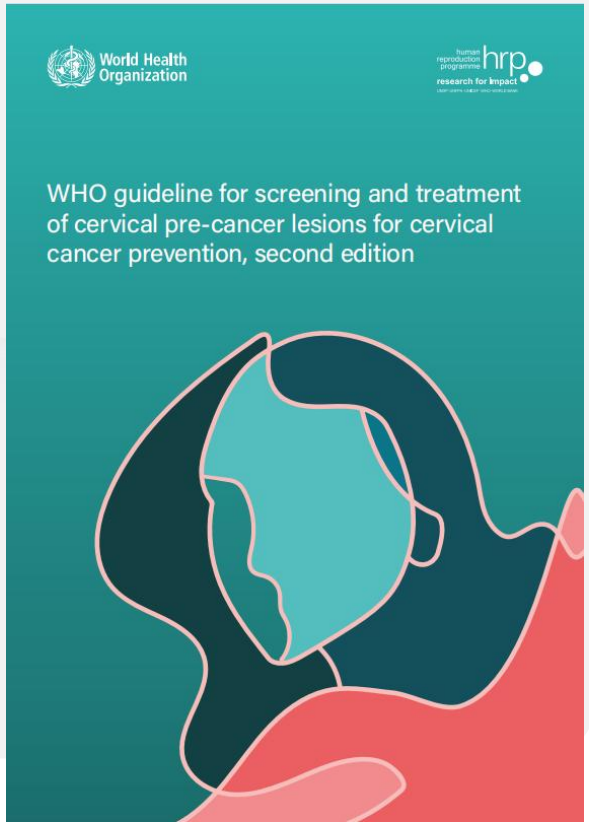
HPV E6/E7 mRNA 14 High Risk Types

In 2022, approximately 660,000 women worldwide were diagnosed with cervical cancer, and about 350,000 women died from the disease. The primary cause of cervical cancer is persistent infection with high-risk human papillomavirus (HPV).

The World Health Organization (WHO) recommends that, in screening and treatment strategies for the general female population, HPV DNA testing for 14 high-risk types (including HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, and 59) should be used, rather than visual inspection with acetic acid (VIA) or cytology-based screening.

The International Agency for Research on Cancer (IARC) and the Target Product Profile (TPP) development group classify 14 high-risk HPV types based on their prevalence and carcinogenicity in cervical cancer: Group 1a includes HPV 16; Group 1b includes HPV 18 and 45; Group 1c includes HPV 31, 33, 35, 52, and 58; Group 1d includes HPV 39, 51, 56, and 59; Group 2A includes HPV 66; and Group 2B includes HPV 68.

Group 1a:	HPV16 is singularly carcinogenic and causes about 60% of cases of squamous cell carcinoma (SCC).
Group 1b:	HPV18 and HPV45 cause 15% and 5% of SCC cases, respectively.
Group 1c:	Other closely related HPV types – HPV31, HPV33, HPV35, HPV52 and HPV58 – together account for 15% of SCC cases.
Group 1d:	The remaining carcinogenic types – HPV39, HPV51, HPV56 and HPV59 – are much less carcinogenic and together cause about 5% of SCC cases.



Turn around time：60min

Sample Type：Cervical swab

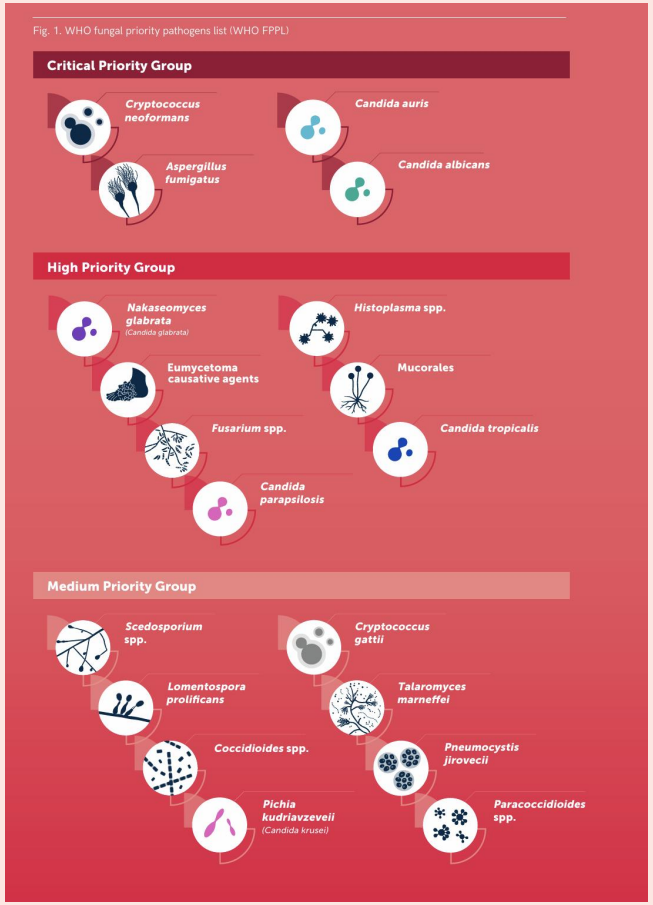
LoD： 10 IU/reaction

Test Targets： 14 HrHPV

- HPV 16
- HPV 18/45
- HPV 31/33/35/52/58
- HPV 39/51/56/59
- HPV 66/68

Fungal Panel

On April 1, 2025, the World Health Organization released its first report on the severe global shortage of medicines and diagnostic tools for invasive fungal diseases, highlighting the urgent need for innovative research and development to address these gaps.



Test time：79 minutes

Sample types：Sputum, lavage fluid, blood, and urine

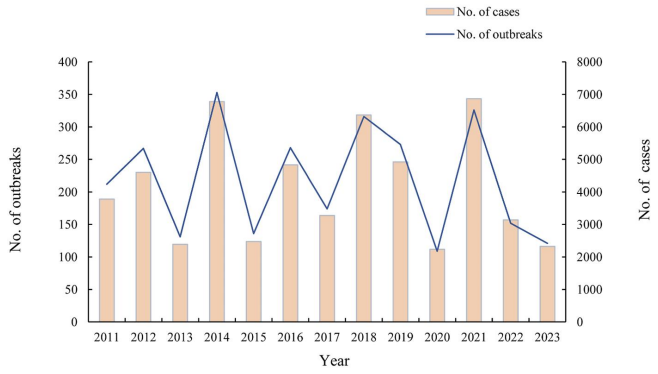
LoD：500 copies/mL

Targets：

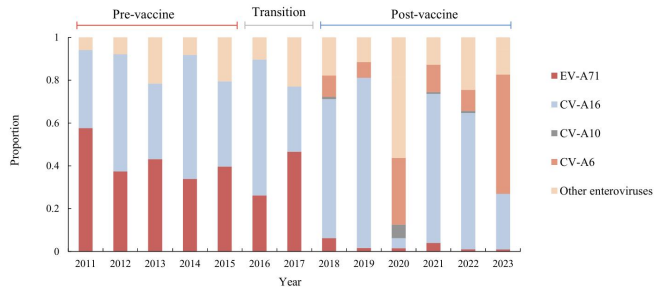
Aspergillus fumigatus	Candida albicans
Cryptococcus neoformans	Rhizomucor spp.
Aspergillus flavus	Candida tropicalis
Cryptococcus gattii	Cunninghamella spp.
Aspergillus niger	Candida glabrata
Pneumocystis jirovecii	Trichosporon spp.
Aspergillus terreus	Candida parapsilosis
Mucor spp.	Candida krusei
Candida auris	
Rhizopus spp.	

EV panel

According to data from the National Health Commission of China, the current incidence rate of hand, foot, and mouth disease (HFMD) in China ranges from 37.01 to 205.06 cases per 100,000 population, while the reported case-fatality rate in recent years has ranged from 6.46 to 51.00 per 100,000 cases.



Trend of Reported HFMD Cases in China from 2011 to 2023



Proportion of Enterovirus Types in HFMD Cases from 2011 to 2023 (China)

The enteroviruses that cause hand, foot, and mouth disease (HFMD) are most commonly Coxsackievirus A16 (CV-A16) and Enterovirus A71 (EV-A71). Severe and fatal cases are mainly attributed to EV-A71. Currently, only an inactivated vaccine against EV-A71 is available on the market. Since China introduced the EV-A71 vaccine in 2016, the proportion of HFMD cases caused by EV-A71 has decreased from 40.43% to 3.07%, while the proportions of infections due to CV-A16, CV-A6, CV-A10, and other enteroviruses have increased.

Test time: 79 minutes

Sample types: Throat swab, vesicle fluid, stool

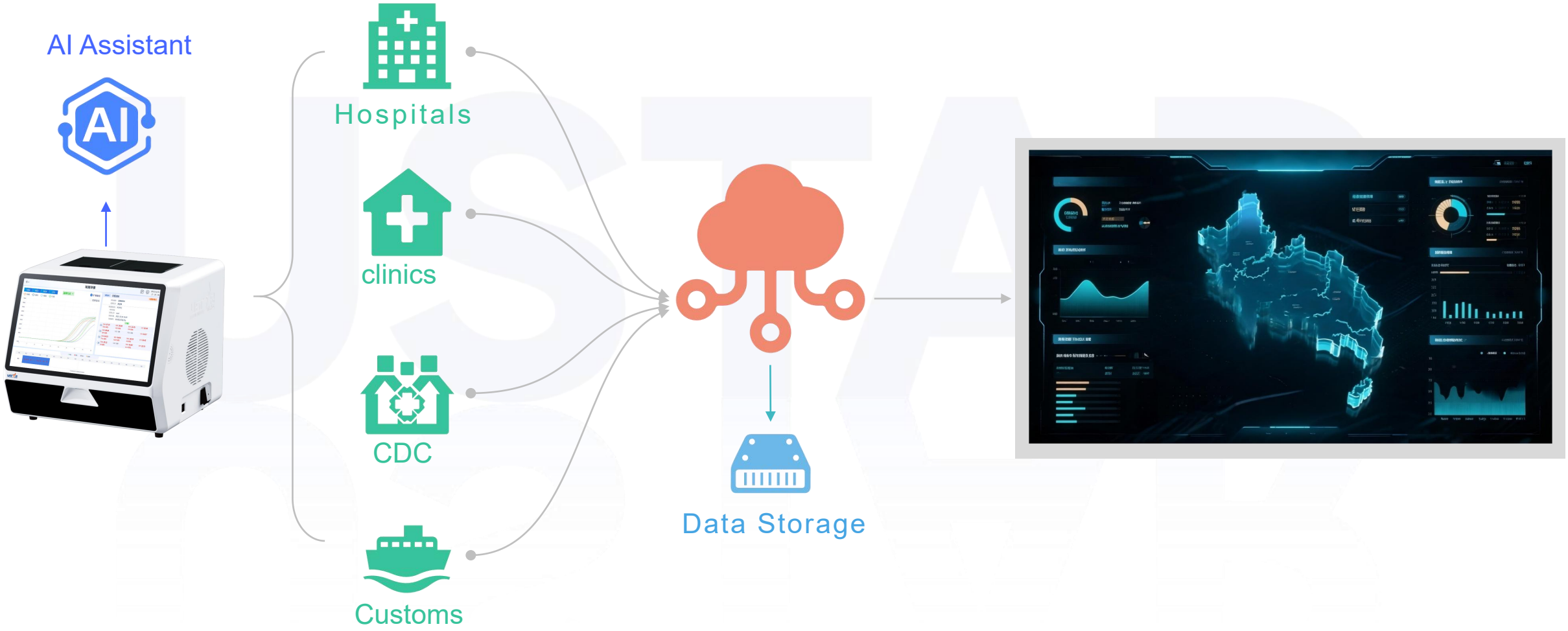
LoD: 500 copies/mL

Targets:

- EV
- EV71
- CA16
- CA6
- CA10

Epidemiology of hand, foot, and mouth disease outbreaks before and during availability of EV-A71 vaccine in China's mainland: analysis of outbreak surveillance data from 2011 to 2023 [J].The Lancet Regional Health - Western Pacific, 2025, June, 59.

Intelligent Data Management, AI decision-making



Used for infectious disease detection by CDC, and adapt to rapid monitoring during pandemics

Xiao U AI Assistant by Local Language

01

Digital Twins

- Live a Toy ,By your side.
- Support App,Web, wechat and So on
- Embedded in Ustar Instrament

02

Cabability of AI

- Top Large Language Model(GPT,Qwen)
- More than 20+ Languages
- ASR&TTS （RTF<0.5,MOS>4.2)
- NLP+NLU （Know What is “Next”）

03

Data Analysis

- Analyze and report test data
- Send alerts of infections diseases

AI Xiao U was training in Indonesian

Innovation Center

Innovation Center:

University Indonesia & Ustar Biotech

University of Indonesia (UI), abbreviated was founded in 1849. It is the oldest institution of higher education in Indonesia, a world-leading research university, and is widely recognized as the best university in the country.

- Talent Cultivation
- Technology Transfer
- Evaluation
- R&D Cooperation
- Early Warning

Core Advantages

Balance

A test that balances POCT performance, operational simplicity, and cost-effectiveness (including instrument and reagent expenses).

Customization

Supports rapid customized reagent development

Resilience

Supports flexible architecture with reagent panels ranging from single-plex to 20+ pathogens.

Migration

Third-party reagents can be rapidly migrated to the POCT platform.

High-Capacity

10-color fluorescence enabling 6-7 pathogen detection, supporting concurrent testing of 16 and 32 samples.

Integration

Supports OTA technology, integrates with NOC operations centers, and features an AI-powered dashboard for real-time epidemic monitoring, statistics, and early warning.

Values for MOH

Diagnostic Improvement

- Molecular POC Screening will cover 80% suspected cases
- Test Projects will be extended to more critial groups.

R&D Ability Development

- Boost talent cultivation and technology transfer
- Abundant Test Portfolio

Early Warning Capacity

- Improve CDC's surveillance and warning capacity
- Require minimum investment

Localized Production

- Facilitate large-scale Surveilance
- Reduced cost of tests
- Promote industrial development

THANKS

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