USTAR WHOLE-PROCESS SOLUTIONS FOR POINT-OF-CARE DIAGNOSTIC TESTING

Ustar Biotechnologies (Hangzhou) Ltd.

Molecular Testing *Anywhere*

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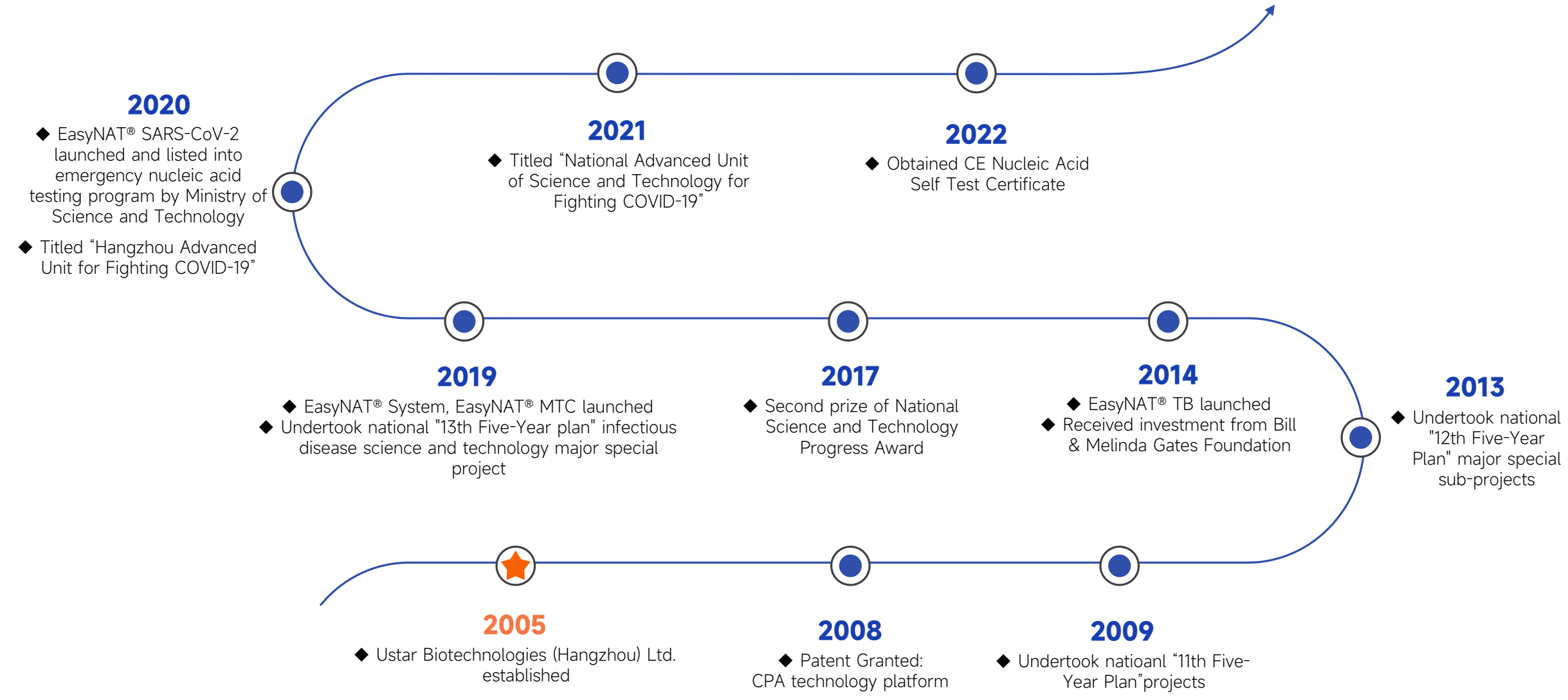
About Ustar

USTAR, founded in 2005, is a leading point-of-care molecular diagnosis provider for tuberculosis, COVID-19, malaria and other major communicable diseases.

Our vision and mission is:

Molecular Testing, Anywhere!

Milestone


2020
◆ EasyNAT® SARS-CoV-2 launched and listed into emergency nucleic acid testing program by Ministry of Science and Technology
◆ Titled “Hangzhou Advanced Unit for Fighting COVID-19”
2021
◆ Titled “National Advanced Unit of Science and Technology for Fighting COVID-19”
2022
◆ Obtained CE Nucleic Acid Self Test Certificate
2013
◆ Undertook national "12th Five-Year Plan" major special sub-projects
2014
◆ EasyNAT® TB launched
◆ Received investment from Bill & Melinda Gates Foundation
2017
◆ Second prize of National Science and Technology Progress Award
2019
◆ EasyNAT® System, EasyNAT® MTC launched
◆ Undertook national "13th Five-Year plan" infectious disease science and technology major special project
2005
◆ Ustar Biotechnologies (Hangzhou) Ltd. established
2008
◆ Patent Granted: CPA technology platform
2009
◆ Undertook natioanl “11th Five-Year Plan”projects

Our Team

600+
Employees

200+
Employees in R&D team

Good Manufacturing Practice

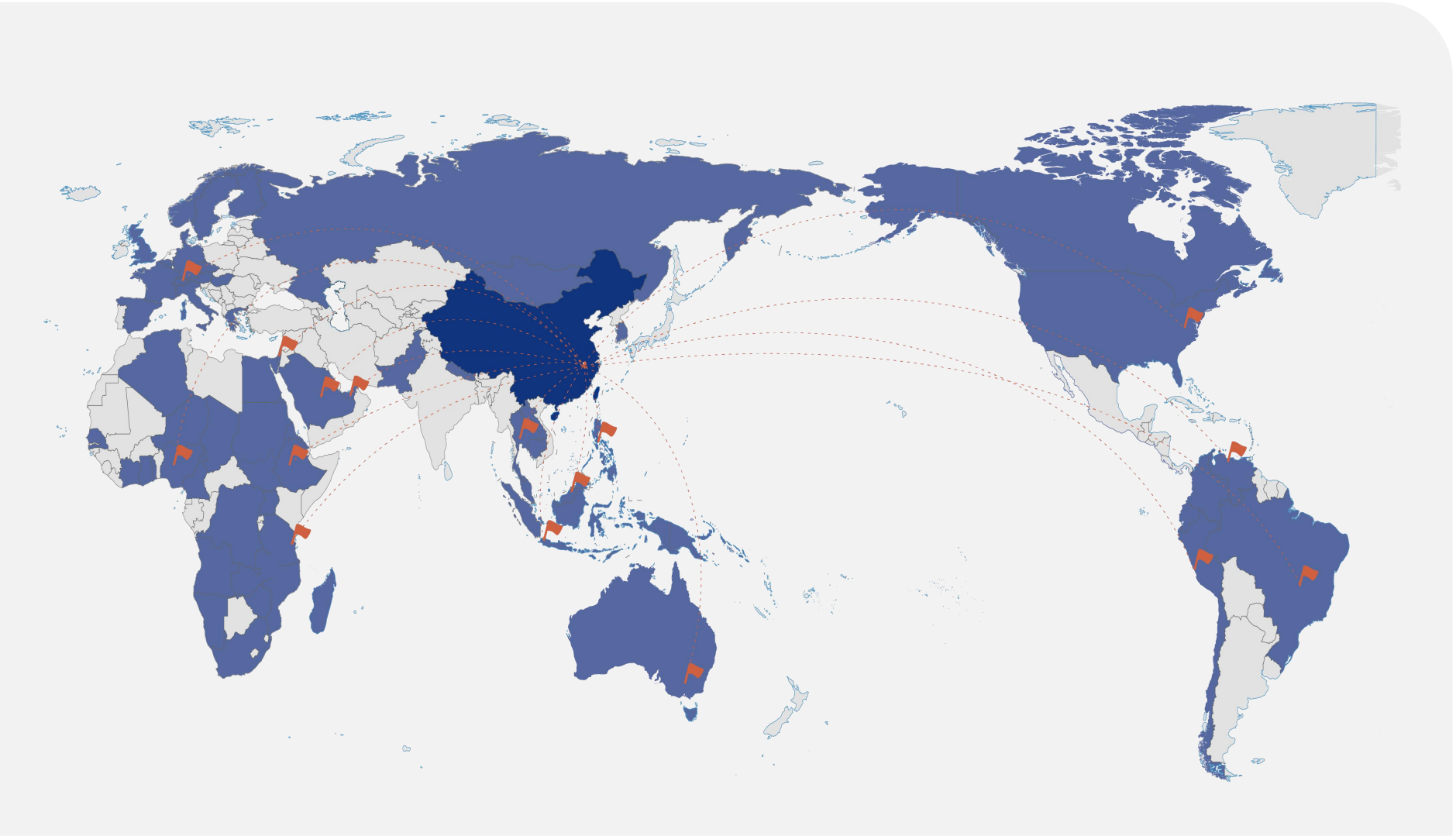
20,000+ m²

GMP workshop

In compliance with

ISO13485:2016

Global Presence



Distributors
500+

Installations
30,000+

Hospitals
3,000+

Countries
70+

International clients & partners
100+

Key Accounts

Patents

Domestic and International Patents

90+

Granted Patents

45+

Key Products

PortNAT® System

At-Home Self Testing

EasyNAT® System

Fast Screening, Primary Diagnosis

MultNAT® System

Therapy-Oriented Diagnosis

CONTENTS

PortNAT® System

Nucleic Acid Self-Testing

Result in 15 min

Simplified testing steps

Accurate

Nucleic acid Testing

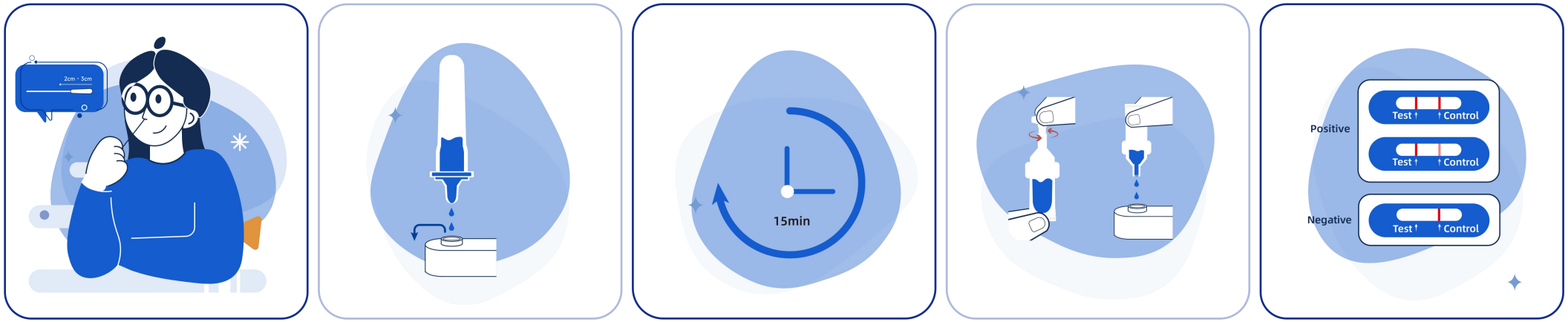
Environmentally-friendly

Independent test cassette & reusable incubator

PortNAT® System

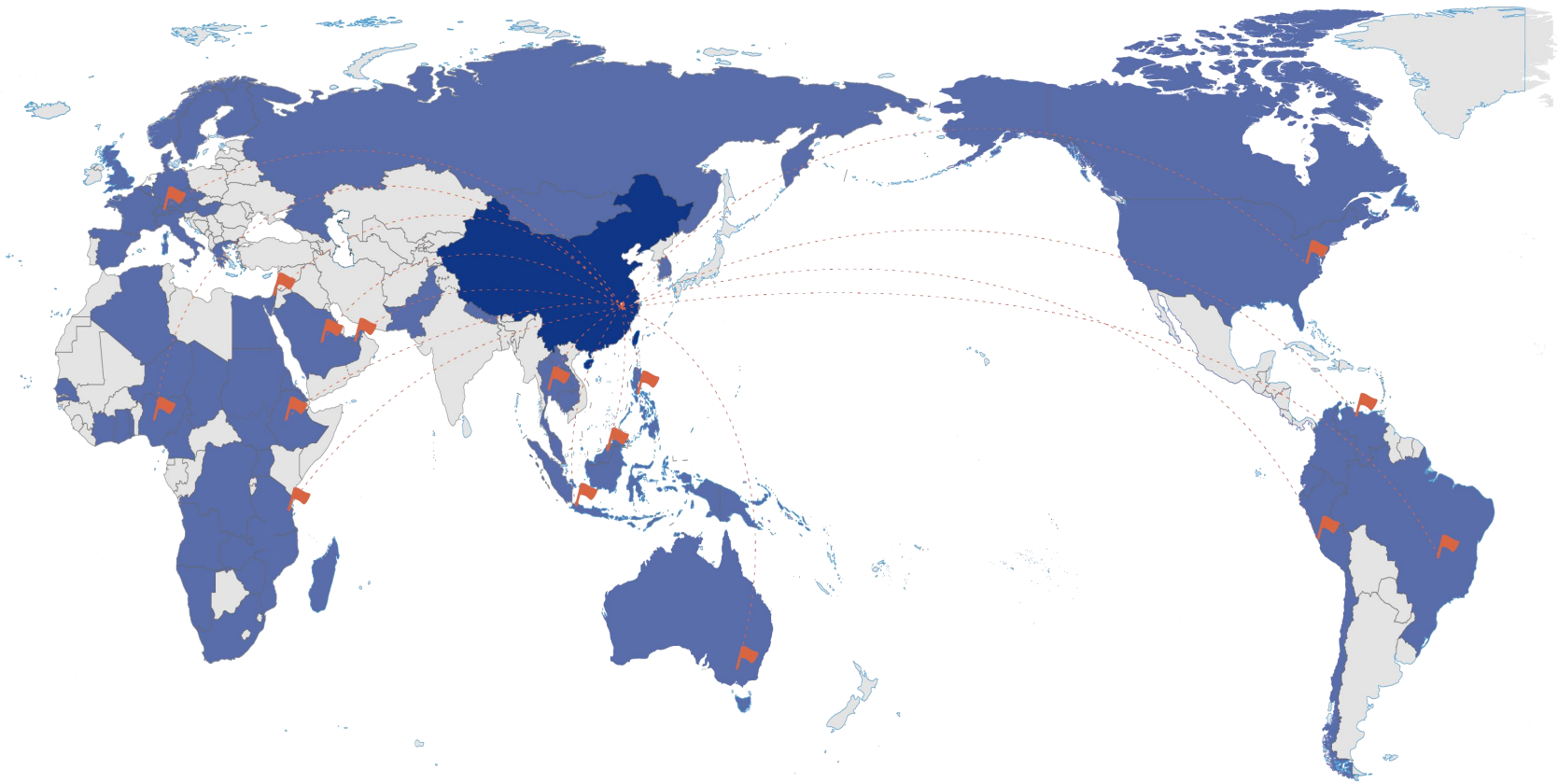
Combine the speed of antigen test and the accuracy of PCR test

Workflow



Collect sample → Add sample → Amplification → Add buffer → Read result

Global Presence



Exported to 30+

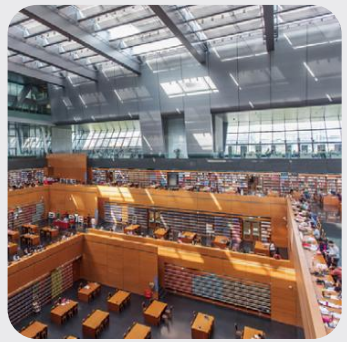
countries and regions, including

Germany,Netherlands, Italy, Spain, Sweden,Israel, HongKong,Japan, Australia,Singapore, Malaysia, Brazil, Peru.

Application Scenarios

Business

Healthcare

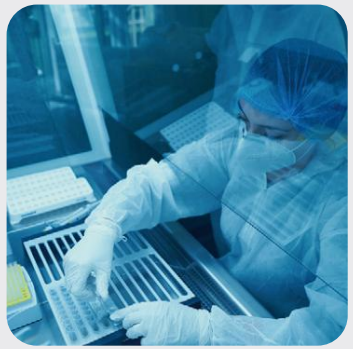


Public Sector

Pet Clinic

Education

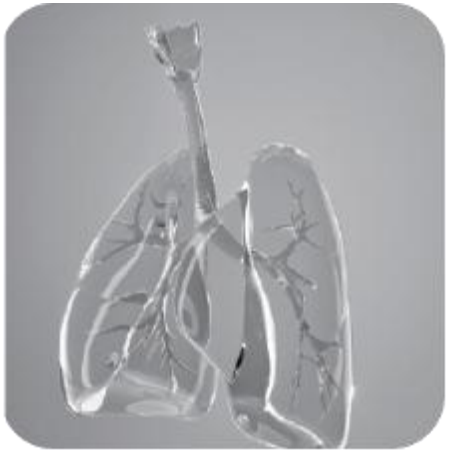
Airports & Customs



Testing Lab

Home Detection

Extensive Testing



- COVID-19
- MTC/NTM
- Flu A/B
- RSV
- LP
- Parainfluenza virus

- *Helicobacter pylori*
- *Feline herpes virus*
- *Feline calicivirus*
- *Feline mycoplasma*

- HIV
- TP
- CT/NG
- GBS
- Mycoplasma /Chlamydia

- *Salmonella*
- *L. monocytogenes*
- *S.aureus*
- STEC
- *Vibrio cholerae*

COVID-19 RNA Test

All-In-One Testing

Compact&Portable

Easy to Use

Test Anywhere, Anytime

LOD: 3,000 copies/mL

Result in 35 min

PCR Quality

Variants Detected

Alpha/Beta/Delta/Omicron variants

COVID-19 RNA Test

First Nucleic Acid Self Test for COVID-19

Approved by:

- **EU (CE)**
- **Australia (TGA)**

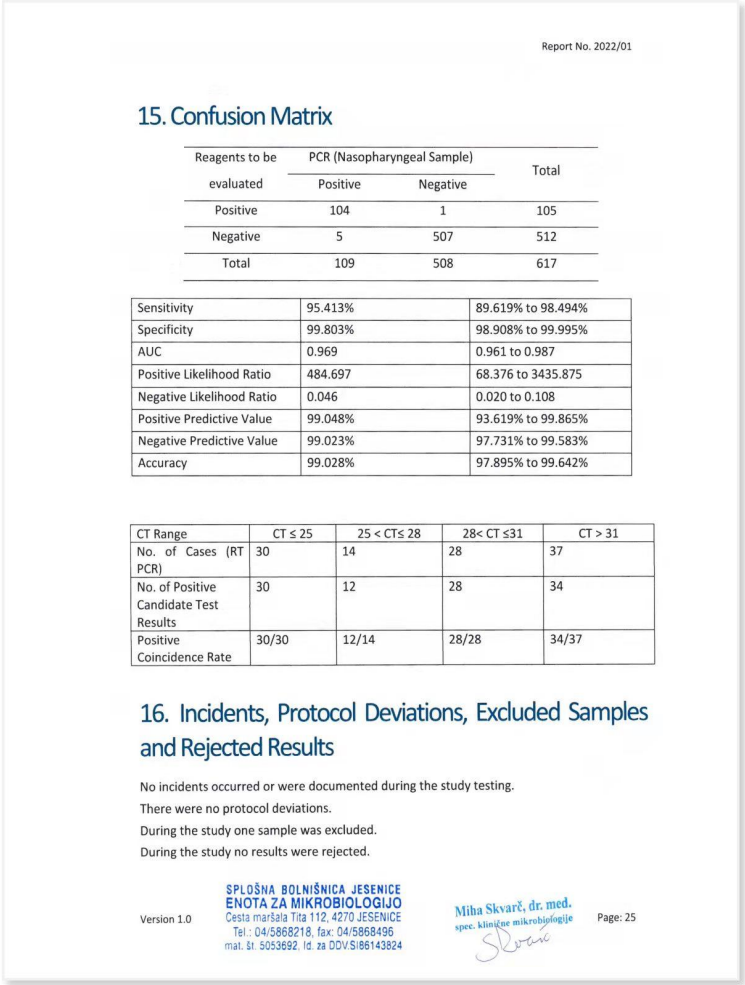
Clinical Performance-Europe

Comparing with RT-PCR : Sensitivity ≥ 95.4%

Specificity ≥ 99.8%

Sensitivity	95.413%
Specificity	99.803%
Positive Likelihood Ratio	484.697
Negative Likelihood Ratio	0.046
Positive Predictive Value	99.048%
Negative Predictive Value	99.023%
Accuracy	99.028%

Study timeline: 2021.9-2022.1
General Hospital Jesenice (Slovenia)
Clinical Hospital Rijeka (Croatia)



Report No. 2022/01

15. Confusion Matrix

Reagents to be evaluated	PCR (Nasopharyngeal Sample)		Total
	Positive	Negative	
Positive	104	1	105
Negative	5	507	512
Total	109	508	617

Sensitivity	95.413%	89.619% to 98.494%
Specificity	99.803%	98.908% to 99.995%
AUC	0.969	0.961 to 0.987
Positive Likelihood Ratio	484.697	68.376 to 3435.875
Negative Likelihood Ratio	0.046	0.020 to 0.108
Positive Predictive Value	99.048%	93.619% to 99.865%
Negative Predictive Value	99.023%	97.731% to 99.583%
Accuracy	99.028%	97.895% to 99.642%

CT Range	CT ≤ 25	25 < CT≤ 28	28< CT ≤31	CT > 31
No. of Cases (RT PCR)	30	14	28	37
No. of Positive Candidate Test Results	30	12	28	34
Positive Coincidence Rate	30/30	12/14	28/28	34/37

16. Incidents, Protocol Deviations, Excluded Samples and Rejected Results

No incidents occurred or were documented during the study testing.
There were no protocol deviations.
During the study one sample was excluded.
During the study no results were rejected.

Version 1.0

SPLOŠNA BOLNIŠNICA JESENICE
ENOTA ZA MIKROBIOLOGIJO
Cesta maršala Tita 112, 4270 JESENICE
Tel.: 04/5868218, fax: 04/5868496
mat. št. 5053692, Id. za DDV SI86143824

Miha Skvarč, dr. med.
spec. klinične mikrobiologije

Page: 25

Clinical Performance-China

Tested by national reference:

Results of positive, negative, sensitivity, and repeatability reference panels all **met the requirements.**

中国食品药品检定研究院

检验报告

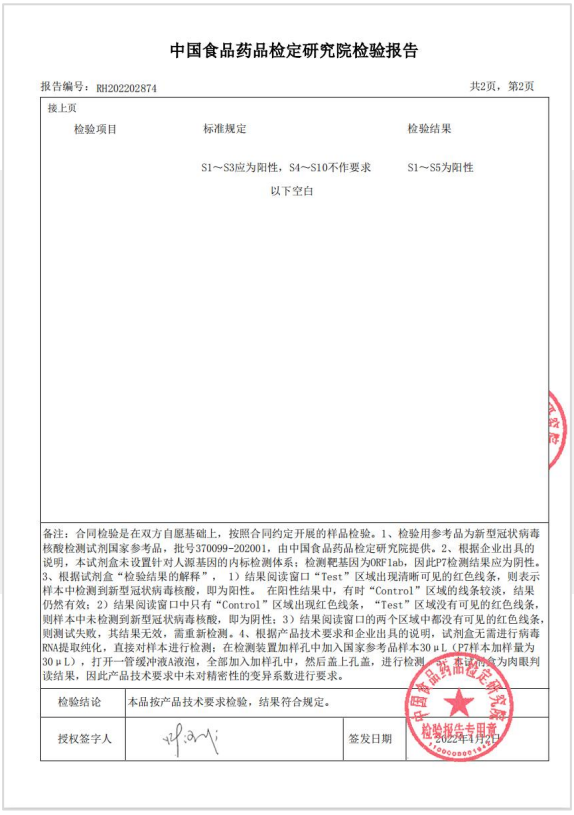
报告编号：RH202202873

检品名称：新型冠状病毒(2019-nCoV)核酸检测试剂盒（自驱动微流控
恒温扩增-试纸条法）

生产单位/产地：杭州优思达生物技术有限公司

检验目的：合同检验

检验依据：产品技术要求



中国食品药品检定研究院检验报告

报告编号：RH202202874　　共2页，第2页

接上页

检验项目	标准规定	检验结果
	S1～S3应为阳性，S4～S10不作要求	S1～S5为阳性
	以下空白	

备注：合同检验是在双方自愿基础上，按照合同约定开展的样品检验。1、检验用参考品为新型冠状病毒核酸检测试剂国家参考品，批号370099-202001，由中国食品药品检定研究院提供。2、根据企业出具的说明，本试剂盒未设置针对人源基因的内标检测体系；检测靶基因为ORF1ab，因此P7检测结果应为阴性。3、根据试剂盒“检验结果的解释”，1）结果阅读窗口“Test”区域出现清晰可见的红色线条，则表示样本中检测到新型冠状病毒核酸，即为阳性。在阳性结果中，有时“Control”区域的线条较淡，结果仍然有效；2）结果阅读窗口中只有“Control”区域出现红色线条，“Test”区域没有可见的红色线条，则样本中未检测到新型冠状病毒核酸，即为阴性；3）结果阅读窗口的两个区域中都没有可见的红色线条，则测试失败，其结果无效，需重新检测。4、根据产品技术要求和企业出具的说明，试剂盒无需进行病毒RNA提取纯化，直接对样本进行检测；在检测装置加样孔中加入国家参考品样本30μL（P7样本加样量为30μL），打开一管缓冲液A液泡，全部加入加样孔中，然后盖上孔盖，进行检测。本试剂盒为肉眼判读结果，因此产品技术要求中未对精密性的变异系数进行要求。

检验结论	本品按产品技术要求检验，结果符合规定。		
授权签字人		签发日期	2022年1月21日

Study unit: National Institutes for Food and Drug Control

Clinical Performance-China

1. Clinical trial in Disease Control and Prevention Center, Hubei, China:

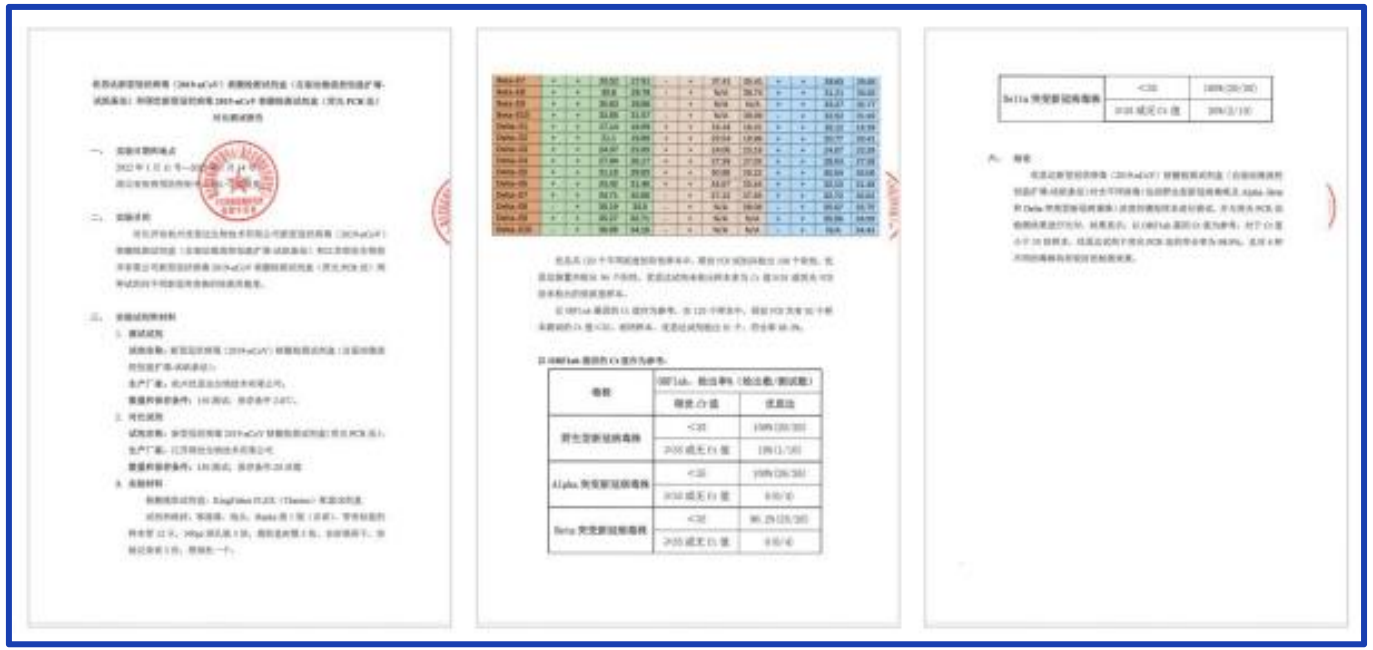
✓ **98.9% agreement rate with PCR assay (Ct < 35)**

✓ Four types of SARS-CoV-2 strains (wild type, Alpha, Beta, Delta) were detected successfully

2. Clinical trial in State Key Laboratory for Diagnosis and Treatment of Infectious Diseases, The First Affiliated Hospital, Zhejiang University:

✓ **98.5% agreement rate with comparison assay (ORF1ab Ct ≤ 35)**

✓ Two SARS-CoV-2 strains from different sources were detected successfully.



CONTENTS

EasyNAT® System

4/8/16

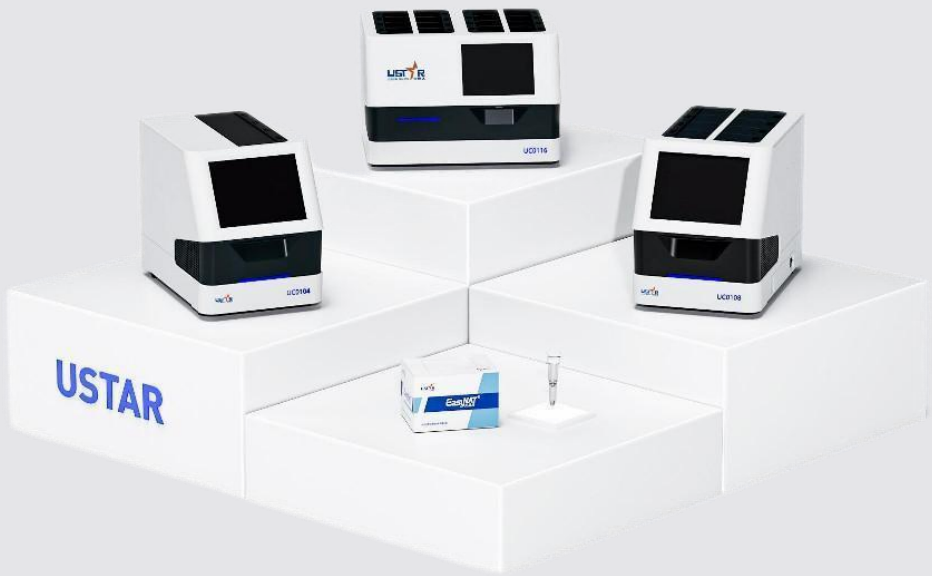
EasyNAT®
Nucleic Acid Amplification and Detection Analyzer

Highlights

Fast

Accurate

Simple



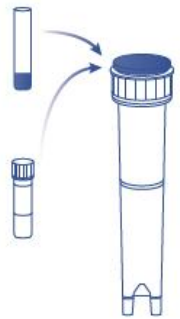
High Throughput

Cost effective

Safe

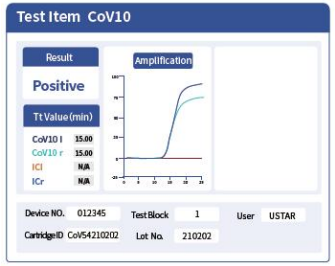
Mechanism & Workflow

Extract, purify, amplify and detect nucleic acid (NA) in a sealed cartridge



① Add sample

② Automated

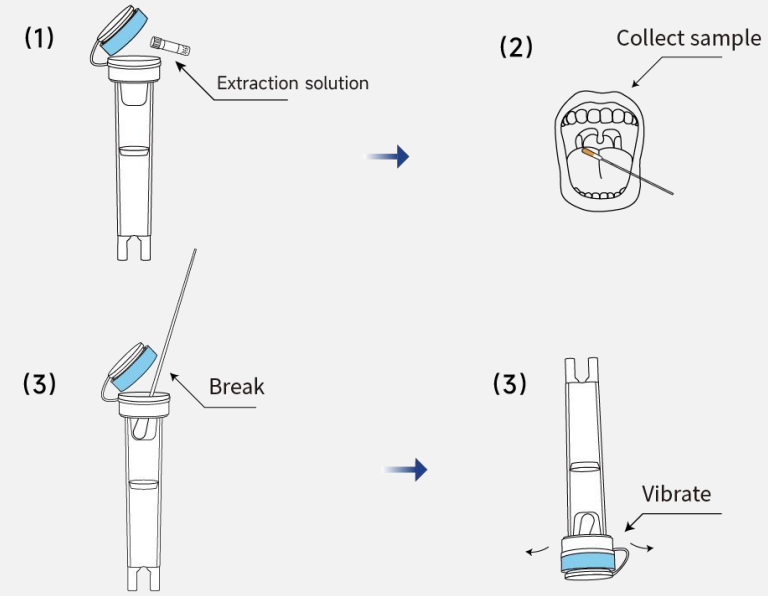


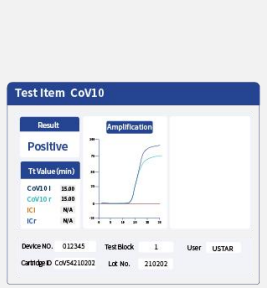
③ Read result

Swab in, Result out

DO NOT NEED

VTM & BSC





- **Viral transport medium (VTM)**
- **Biological safety cabinet (BSC)**

Simplifed Workflow Collect and handle sample in **ONE** step

Biological Safty Nucleic acid lysis, amplification, purification and detection in **ONE** enclosed cartridge

Application Scenarios

Hospitals & Clinics

CDC

Customs

Mobile testing

Pet clinic

Testing Lab

Extensive Testing

Respiratory Tract

- SARS-CoV-2
- MTC
- MTC/NTM
- Influenza A/B Virus
- MP
- RSV
- BP
- LP

Reproductive Health

- CT/NG
- MG
- UU
- HSV 1/2
- GBS
- Syphilis
- TV
- HPV
- Monkeypox

Pet

- FCV
- FHV
- CF
- TOX
- CPV
- CDV
- CHV

Vet

- ASF
- TGEV
- M. bovis
- Rinderpest virus

Food Safety

- Alicyclobacillus acidoterrestris
- Staphylococcus aureus
- Salmonella

Plant

- BX
- HLB

EasyNAT® Certificate & Registration

China NMPA	European Union CE
U.S. FDA	Australia TGA
Brazil ANVISA	Singapore HSA
Philippines FDA	Malaysia MDA
Nigeria NAFDAC	Thailand
Peru	Israel

U.S. FOOD & DRUG ADMINISTRATION | Establishment Registration Device Listing

New Search — Back To Search Results

Proprietary Name:	Nucleic Acid Amplification and Detection Analyzer
Classification Name:	REAL TIME NUCLEIC ACID AMPLIFICATION SYSTEM
Product Code:	OOI
Device Class:	2
Regulation Number:	862.2570
Medical Specialty:	Clinical Chemistry
Registered Establishment Name:	USTAR BIOTECHNOLOGIES (HANGZHOU) LTD.
Registered Establishment Number:	3009312616
Owner/Operator:	Ustar Biotechnologies (Hangzhou) Ltd.
Owner/Operator Number:	10077585
Establishment Operations:	Manufacturer

EasyNAT® COVID-19

- **Targets:** ORF1ab, N gene
- **Sample type:** swab, sputum
- **LOD≤200 copies/mL**
- **Sensitivity ≥ 98.0%, specificity ≥ 99.6%**
- **All in one cartridge:** sample-in, result-out, within 20 min
- **Ambient transportation:** -25~30°C

EasyNAT® Clinical Evaluation

1

Israel MOH

Comparable with Thermo kit and GeneXpert

MINISTRY OF HEALTH
For a healthier life

PUBLIC HEALTH SERVICES | Public Health Laboratories
Department of Laboratories

www.health.gov.il

July 28, 2021
18 Tammuz 5781
Reference: 515939921

To
Dr. Adina Bar Haim
Director, Department of Laboratories
Shamir Medical Center
Tzrifin

Dear Sir,

re: Authorization to perform PCR tests to identify SARS-CoV-2 virus by the Sample-Result – EasyNAT rapid device

Reference: Device Validation Tests Report, accompanying documents for the device

On the basis of the good results of the validation tests performed by the laboratory under your responsibility, including the test results by the EasyNAT device compared with the PCR test results on the basis of nucleic acids and running in the PCR device (using the Thermo kit), and, in addition, performance test results comparison by the EasyNAT device with the test results of the Genexpert – sample-to-result rapid device, we approve use of the EasyNAT device to undertake the tests.

The approval is valid from the date of this letter.

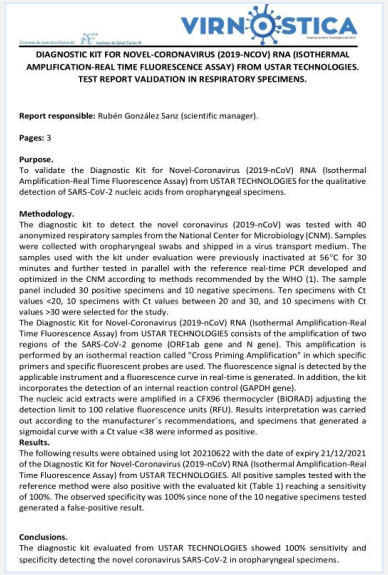
Make sure to undertake outside quality tests as part of the routine.

Sincerely,
[signature]
Dr. Ruthie Yishai
Director, Department of Laboratories

2

Spain MOH Lab

100% sensitivity and specificity



VIRNOSTICA

DIAGNOSTIC KIT FOR NOVEL-CORONAVIRUS (2019-NCOV) RNA (ISOTHERMAL AMPLIFICATION-REAL TIME FLUORESCENCE ASSAY) FROM USTAR TECHNOLOGIES. TEST REPORT VALIDATION IN RESPIRATORY SPECIMENS.

Report responsible: Rubén González Sanz (scientific manager).

Pages: 3

Purpose.
To validate the Diagnostic Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay) from USTAR TECHNOLOGIES for the qualitative detection of SARS-CoV-2 nucleic acids from oropharyngeal specimens.

Methodology.
The diagnostic kit to detect the novel coronavirus (2019-nCoV) was tested with 40 anonymized respiratory samples from the National Center for Microbiology (CNM). Samples were collected with oropharyngeal swabs and shipped in a virus transport medium. The samples used with the kit under evaluation were previously inactivated at 56°C for 30 minutes and further tested in parallel with the reference real-time PCR developed and optimized in the CNM according to methods recommended by the WHO (1). The sample panel included 30 positive specimens and 10 negative specimens. Ten specimens with Ct values <20, 10 specimens with Ct values between 20 and 30, and 10 specimens with Ct values >30 were selected for the study.
The Diagnostic Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay) from USTAR TECHNOLOGIES consists of the amplification of two regions of the SARS-CoV-2 genome (ORF1ab gene and N gene). This amplification is performed by an isothermal reaction called "Cross Priming Amplification" in which specific primers and specific fluorescent probes are used. The fluorescence signal is detected by the applicable instrument and a fluorescence curve in real-time is generated. In addition, the kit incorporates the detection of an internal reaction control (GAPDH gene).
The nucleic acid extracts were amplified in a CFX96 thermocycler (BIORAD) adjusting the detection limit to 100 relative fluorescence units (RFU). Results interpretation was carried out according to the manufacturer´s recommendations, and specimens that generated a sigmoidal curve with a Ct value <38 were informed as positive.
Results.
The following results were obtained using lot 20210622 with the date of expiry 21/12/2021 of the Diagnostic Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay) from USTAR TECHNOLOGIES. All positive samples tested with the reference method were also positive with the evaluated kit (Table 1) reaching a sensitivity of 100%. The observed specificity was 100% since none of the 10 negative specimens tested generated a false-positive result.

Conclusions.
The diagnostic kit evaluated from USTAR TECHNOLOGIES showed 100% sensitivity and specificity detecting the novel coronavirus SARS-CoV-2 in oropharyngeal specimens.

3

US Cabell Huntington Hospital

Accuracy - 100%

Cabell Huntington Hospital Laboratory

1340 Hal Greer Blvd. Huntington, WV 25701

Date: 04/21/2020

Purpose: Addition of Ustar Biotechnologies' 2019-nCoV RNA Assay.

Testing: Multiple technologists ran our validation during the day. The same COVID order will be used in the LIS as is currently being used for other covid testing.

Technologists ran 20 positive and 20 negative controls for the 2019-nCoV assay for nine consecutive days. The technologists also repeated 10 previous positive specimens that were provided by WV State Laboratory and 10 previous negative patients that were tested on the other in-house test or by one of the reference laboratory test sites. These results were compared to results on the Ustar instrument and all results proved accurate to the originals. This was repeated for nine days.

A second Ustar instrument was validated as well. The same technologists ran validations for this instrument. A total of 10 positive and 10 negative controls were run on this analyzer as well as 5 previous positive specimens that were provided by WV State Laboratory and 5 previous negative patients that were tested on the other in-house test or by one of the reference laboratory test sites.

Results: All testing went as expected. The Ustar instruments accurately detected all 2019-nCoV RNA in QC samples as well as expected results from patient samples. There are no expected issues in going live with this new test and instrument.

Conclusion: The Ustar Biotechnologies' instrument has been fully validated for RUO purposes with plans to immediately submit for EUA approval by the FDA. We feel confident that this system is working correctly and are ready to go live with this instrument 4/21/2020.

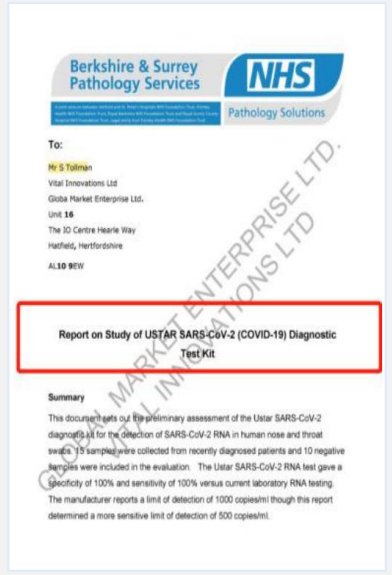
Traci Schauer
Section Chief Microbiology
04/21/2020

Reviewed by: _____ Date: 4/21/2020
Kristin Lynn Denning, MD

4

UK NHS

Sensitivity - 100 %
Specificity - 100 %



Berkshire & Surrey Pathology Services
NHS
Pathology Solutions

To:
Mr S Tollman
Vital Innovations Ltd
Globa Market Enterprise Ltd.
Unit 16
The IO Centre Hearle Way
Hatfield, Hertfordshire
AL10 9EW

Report on Study of USTAR SARS-CoV-2 (COVID-19) Diagnostic Test Kit

Summary

This document sets out the preliminary assessment of the Ustar SARS-CoV-2 diagnostic kit for the detection of SARS-CoV-2 RNA in human nose and throat swabs. 15 samples were collected from recently diagnosed patients and 10 negative samples were included in the evaluation. The Ustar SARS-CoV-2 RNA test gave a specificity of 100% and sensitivity of 100% versus current laboratory RNA testing. The manufacturer reports a limit of detection of 1000 copies/ml though this report determined a more sensitive limit of detection of 500 copies/ml.

EasyNAT® COVID-19 in Healthcare Units

EasyNAT® COVID-19 in Mobile Detection Vehicle

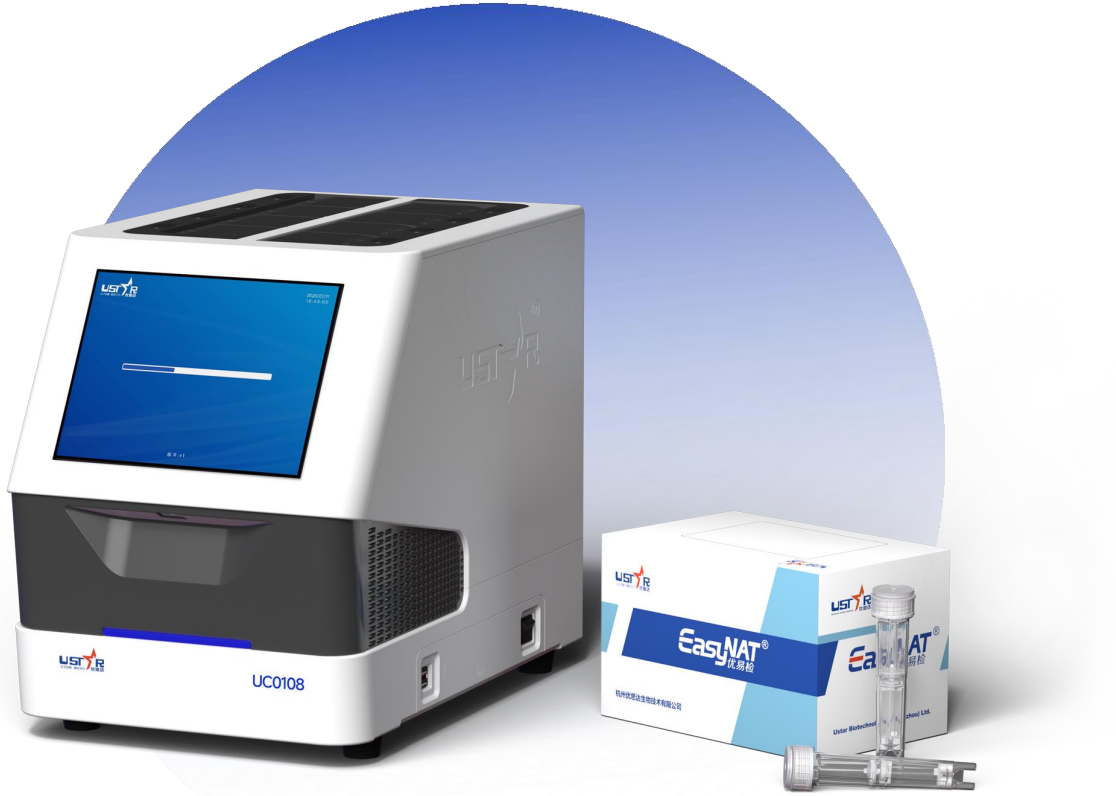
Shanghai-based China International Import Expo

Running at full capacity:25,000 tests/day/vehicle

Shangyi Health Bureau, Zhangjiakou, Hebei

Shenzhenbei Railway Station

EasyNAT® MTC

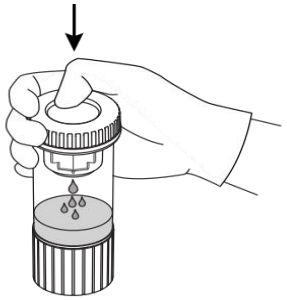


- **Target:** IS6110
- **Sample type:** sputum, BALF, urine, paraffin-embedded tissue sample, pus, CSF, gastric aspirate, ascites with hydrothorax
- **LOD ≤100 CFU/mL**
- **Sensitivity ≥ 96.6%, specificity ≥ 98.6%**
- **Integrated testing:** sample-in, result-out, result in 65 min
- **Ambient transportation:** -25~30°C

EasyNAT® MTC: Workflow

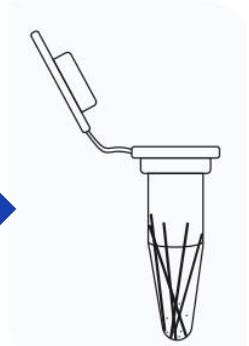
Sputum

① Collect in a sputum container

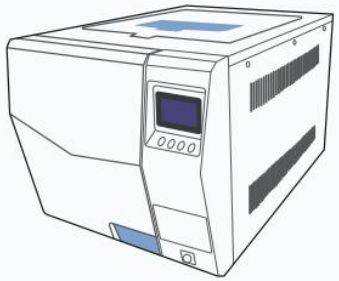


② Liquefy without opening lid

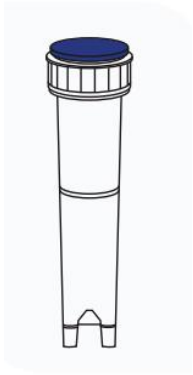
Paraffin section



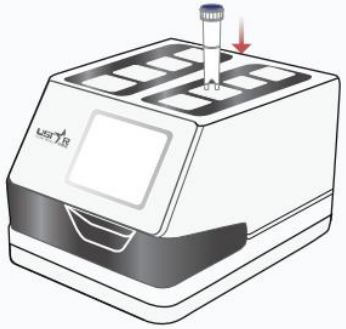
① Add lysis buffer



② Autoclave 10 min



③ Add into cartridge



④ Detection

⑤ Report result

EasyNAT® MTC: Highlights

Fast testing — Optimized sample pre-treatment, shortened turnaround time (TAT)

Point-of-care testing — Applicable for tent hospital, airport, and mobile van (lab)

Test anytime — Independent modules, providing instant testing for every single sample

Biologically safe

- All-in-one sealed cartridge
- Self-contained sputum container
- Free-of-xylene paraffin section pretreatment process

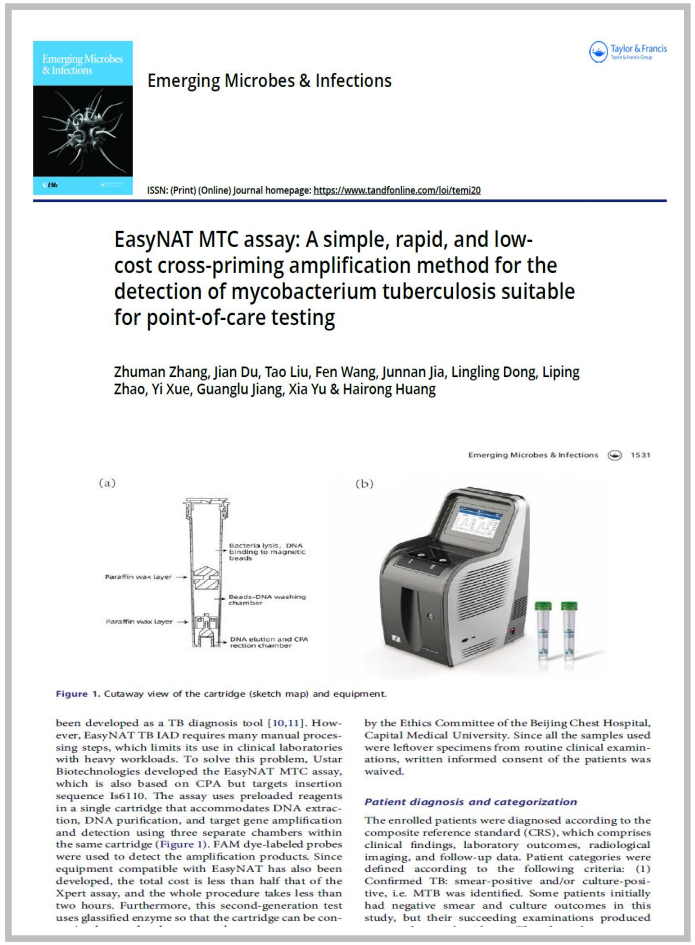
Clinical Evaluation: Sputum

"EasyNAT could be used as an initial test for PTB diagnosis due to its simplicity, rapid turnaround time, high sensitivity, and low cost."

Of the 169 PTB patients				
Methodology	EasyNAT	Smear	Culture	Xpert
Sensitivity	72.19%	32.54%	53.85%	61.54%

Of the 91 patients with culture-positive outcomes			
Methodology	EasyNAT	Smear	Xpert
Sensitivity	93.40%	56.04%	91.21%

Emerg Microbes Infect. 2021; 10(1): 1530–1535.Published online 2021 Aug 1. doi: 10.1080/22221751.2021.1959271



Emerging Microbes & Infections

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/temi20

EasyNAT MTC assay: A simple, rapid, and low-cost cross-priming amplification method for the detection of mycobacterium tuberculosis suitable for point-of-care testing

Zhuman Zhang, Jian Du, Tao Liu, Fen Wang, Junnan Jia, Lingling Dong, Liping Zhao, Yi Xue, Guanglu Jiang, Xia Yu & Hairong Huang

Figure 1. Cutaway view of the cartridge (sketch map) and equipment.

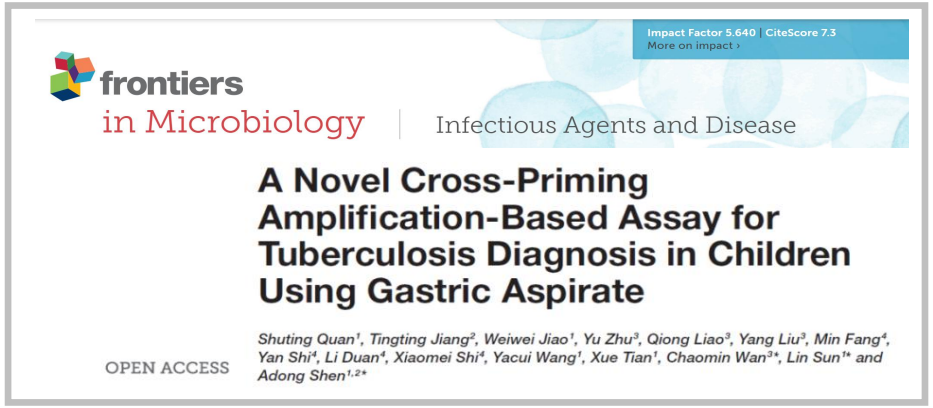
been developed as a TB diagnosis tool [10,11]. However, EasyNAT TB IAD requires many manual processing steps, which limits its use in clinical laboratories with heavy workloads. To solve this problem, Ustar Biotechnologies developed the EasyNAT MTC assay, which is also based on CPA but targets insertion sequence Is6110. The assay uses preloaded reagents in a single cartridge that accommodates DNA extraction, DNA purification, and target gene amplification and detection using three separate chambers within the same cartridge (Figure 1). FAM dye-labeled probes were used to detect the amplification products. Since equipment compatible with EasyNAT has also been developed, the total cost is less than half that of the Xpert assay, and the whole procedure takes less than two hours. Furthermore, this second-generation test uses glassified enzyme so that the cartridge can be con-

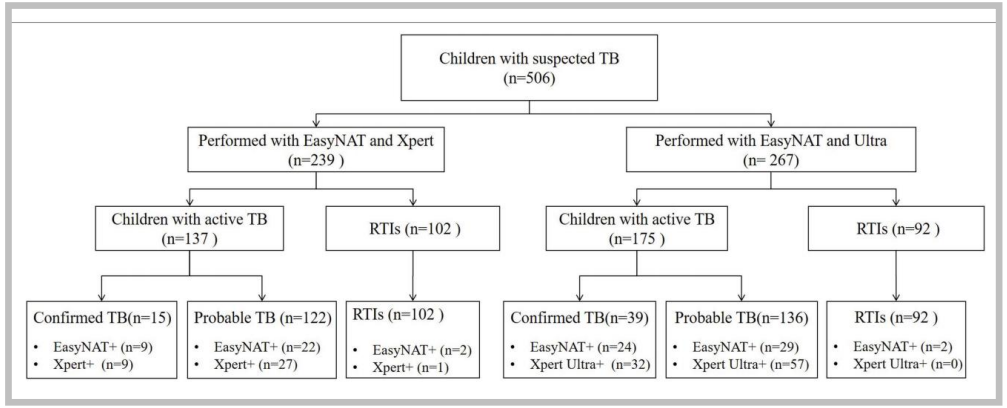
by the Ethics Committee of the Beijing Chest Hospital, Capital Medical University. Since all the samples used were leftover specimens from routine clinical examinations, written informed consent of the patients was waived.

Patient diagnosis and categorization

The enrolled patients were diagnosed according to the composite reference standard (CRS), which comprises clinical findings, laboratory outcomes, radiological imaging, and follow-up data. Patient categories were defined according to the following criteria: (1) Confirmed TB: smear-positive and/or culture-positive, i.e. MTB was identified. Some patients initially had negative smear and culture outcomes in this study, but their succeeding examinations produced

Clinical Evaluation: Children Gastric Aspirate





	Sensitivity, % (n/N)		Specificity, % (n/N)	
	EasyNAT	Xpert	EasyNAT	Xpert
All enrolled children	22.6 (31/137)	26.3 (36/137)	98.0 (100/102)	99.0 (101/102)
Bacteriologically confirmed	60.0 (9/15)	60.0 (9/15)		
Probable TB	18.0 (22/122)	22.1 (27/122)		

“EasyNAT may therefore be useful as a suitable alternative method of childhood TB diagnosis based on its cost-effectiveness, speed, and accuracy.”

Clinical Evaluation: Pathological Tissue

Clinical site: Beijing Chest Hospital, Capital Medical University

Sample enrolled: 103

Compare with RT-PCR:

Positive agreement rate: 97.01%

Negative agreement rate: 97%

Overall agreement rate: 97.09%

		RT-PCR		
EasyNAT® MTC		Positive（CT≤36）	Negative	Total
	Positive	65	1	66
	Negative	2	35	37
	Total	67	36	103

EasyNAT® MTC/NTM

- **Targets:** IS6110 (MTC), 16s rDNA (NTM)
- **Sample type:** sputum， BALF, urine, paraffin-embedded tissue sample, pus, CSF, gastric aspirate, ascites with hydrothorax
- **LOD ≤100 CFU/mL**
- **Integrated testing:** sample-in, result-out, result in 65 min
- **NTM:**
  - *M. Kansas, M. Avium, M. intracellular, M. chelonae*
  - *M. Abscess, M. Fortuitans, M. Smegmatis, M. Marseillae*
  - *M. scrofula, M. Gordon, M. toad, M. ulcerate*
  - *M. mariae, M. haemophilus, M. apes, M. gastroticus*

EasyNAT® CT/NG

- **Safe:** CT+NG detection in an enclosed cartridge
- **Sample type:** urethral swab, endocervical swab
- **LOD≤ 400 copies/mL**
- **Integrated testing:** sample-in, result-out, result in 30 min
- **Ambient transportation:** -25~30°C

EasyNAT® CT/NG Clinical Evaluation

Clinical sites (856 included samples):

- Zhejiang Provincial People's Hospital
- Dermatology Hospital of Southern Medical University
- Beijing Ditan Hospital, Capital Medical University

	Positive Agreement (%)	Negative Agreement (%)	Total Agreement(%)	Kappa
CT	99.57% 95% CI (97.61%, 99.92%)	99.36% 95% CI (98.36%, 99.75%)	**99.42%** 95% CI (98.64%, 99.75%)	**0.985** 95% CI (0.973-0.998) , P < 0.001
NG	96.20% 95% CI (91.96%, 98.25%)	99.71% 95% CI (98.96%, 99.92%)	**99.07%** 95% CI (98.17%, 99.53%)	**0.969** 95% CI (0.947-0.990) , P < 0.001

EasyNAT® MG Clinical Evaluation

Clinical sites （787 included samples）

- Dermatology Hospital of Southern Medical University
- Dermatology Hospital of Jiangxi Hospital
- Tianjin Academy of Traditional Chinese Medicine Affiliated Hospital

Compared with PCR kit

		PCR kit		Total
		Positive	Negative	
EasyNAT®	Positive	156	0	156
	Negative	3	628	631
Total		159	628	787

Positive percent agreement=98.11%, 95% CI (94.58%~99.61%);

Negative percent agreement=100%, 95% CI (99.41%~100%);

Overall percent agreement=99.62%, 95% CI (98.89%~99.92%);

Kappa=0.9881, 95% CI (0.9746~1.0015); P < 0.001

EasyNAT® MP Clinical Evaluation

Clinical sites（665 included samples）

- The Affiliated Hospital of Hangzhou Normal University
- Children’ s Hospital of Hebei Province
- The Second Xiangya Hospital of Central South Hospital
- Jinan Children's Hospital

Compared with PCR kit

		PCR kit		Total
		Positive	Negative	
EasyNAT®	Positive	223	2	225
	Negative	2	438	440
	Total	225	440	665

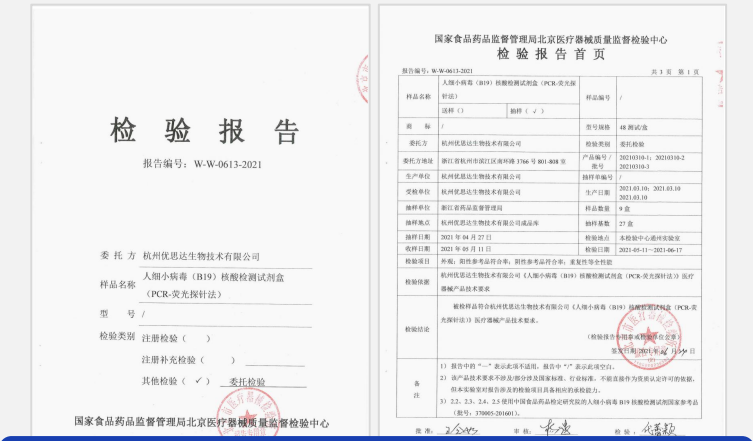
Positve percent agreement=99.11%, 95% CI (96.83%~99.89%);

Negative percent agreement=99.55%, 95% CI (98.37%~99.94%);

Overall percent agreement=99.40%, 95% CI (98.47%~99.84%);

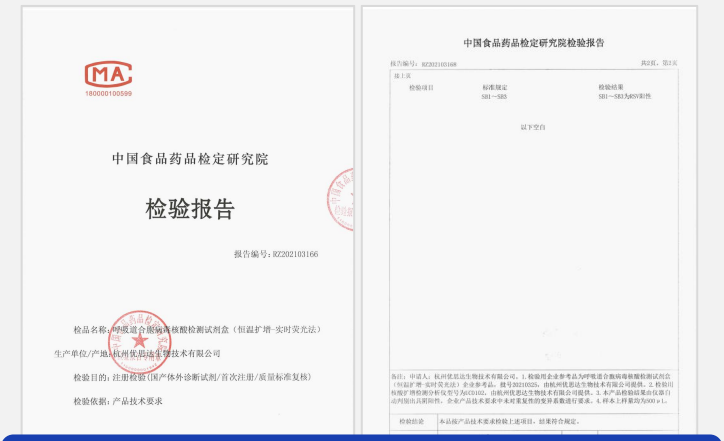
Kappa=0.9866，95% CI (0.9734~0.9997)；P＜0.001

EasyNAT® Flu A/B, B19, RSV Perfrmance Evaluation



EasyNAT Human Parvovirus B19 Assay

Test by: National Medical Products Administration, Beijing Institute of Medical Device Testing



EasyNAT Rapid RSV Assay

Test by National Institutes for Food and Drug Control

EasyNAT Rapid Flu Assay

Test by National Institutes for Food and Drug Control

Thenational reference materials were used for registration and testing, and the results of positive, negative and sensitivity reference panels **all met the requirements.**

CONTENTS

MultNAT® System

MultNAT®

MOLECULAR DIAGNOSTIC PCR SYSTEM

FDA-Listed

Multiplex

High-thoroughput

Bio-safe

Test to Treat

Diagnosis provides guidance on medication and therapy

① Diagnosis of infection of unknown origin（Respiratory, reproductive tract, Gastrointestinal, CNS, Blood）

② Individual medication differences（Warfarin , Clopidogrel）

③ Quantitative testing（HIV, HBV）

④ Antimicrobial resistance（MTC, CRE）

MultNAT® System: Highlights

※ Extensive panels

Test for virus, bacteria, parasites, genotyping, and antimicrobial resistance

※ Multiplex

1 sample, up to 24 targets per round

※ High-throughput

1 test, up to 32 samples per round

※ Safe

All in one enclosed cartridge

※ User-friendly

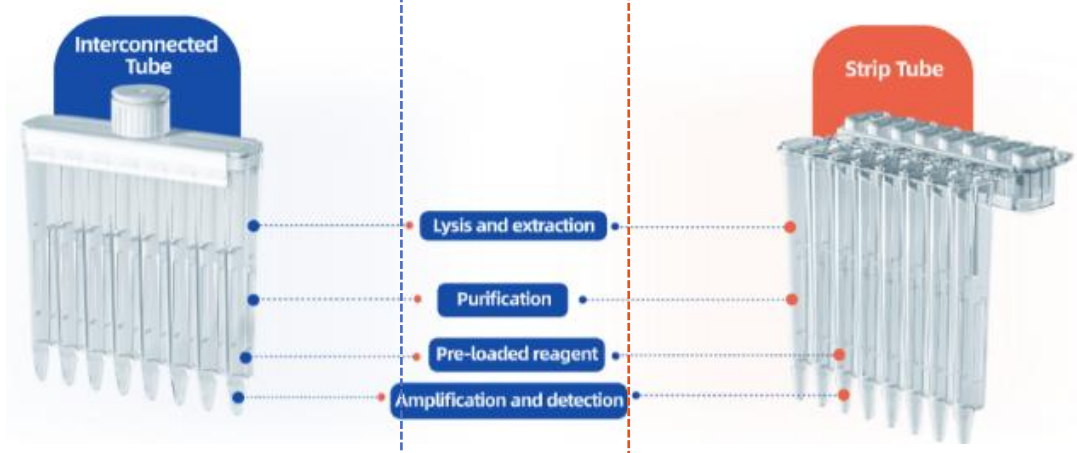
13.3 inches touch screen & QR code access

MultNAT® Certificate & Registration

U.S. FOOD & DRUG ADMINISTRATION | Establishment Registration Device Listing

Proprietary Name:	MultNAT Molecular Diagnostic Testing System; Nucleic Acid Amplification and Detection Analyzer
Classification Name:	REAL TIME NUCLEIC ACID AMPLIFICATION SYSTEM
Product Code:	OOI
Device Class:	2
Regulation Number:	862.2570
Medical Specialty:	Clinical Chemistry
Registered Establishment Name:	USTAR BIOTECHNOLOGIES (HANGZHOU) LTD.
Registered Establishment Number:	3009312616
Owner/Operator:	Ustar Biotechnologies (Hangzhou) Ltd.
Owner/Operator Number:	10077585
Establishment Operations:	Manufacturer

MultNAT® System: Consumables



Multiplex

1 sample

Up to 24 targets

High-throughput

1 test

Up to 32 samples

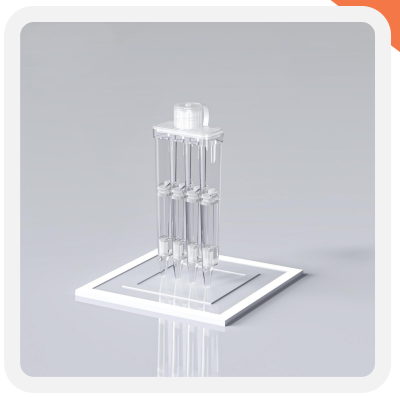
1. Sample in, result out
2. High specificity
3. Extract, purify, amplify and detect nucleic acid in a sealed tube
4. Pre-filled reagent
5. Glassified reagent enables ambient transport
6. No cross contamination

MultNAT® System: Consumables

1-Strip Tube

8-Strip Tubes

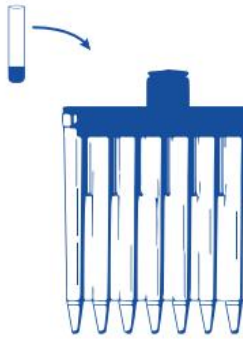
2-Interconnected tube



4-Interconnected Tube

8-Interconnected Tube

MultNAT® System: Workflow



① Add sample

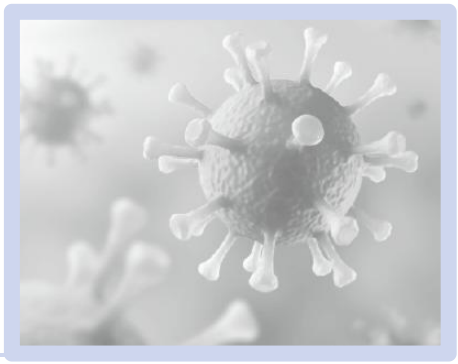
② Automated testing

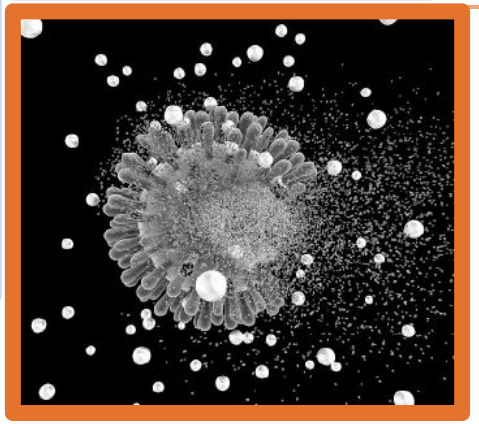
③ Read result

MultNAT® System: Test Menu

Pathogen Infection

- RTI panel
- STI panel
- Meningitis panel
- Gastrointestinal panel
- BCID panel





Medication Guidance

- MTC/MDR
- MTC/XDR
- Carba-R
- MRSA/SA
- Warfarin Gene Polymorphism
- *H. pylori* resistance

Genotyping

- NTM
- HPV
- HIV

Viral Load Testing

- *Epstein-Barr virus*
- HIV
- HBV
- HCV

MultNAT® Carba-R and Four Pathogens PCR Assay (RUO)

Mod	Target	Fluorescent channel	Sensitivity			
A	OXA	FAM	OXA-48 (*K.pneumoniae*)	100 CFU/mL	OXA-48 (*E.Coli*)	50CFU/mL
	KPC	HEX	KPC-3 (*K.pneumoniae*)	50CFU/mL	KPC-4 (*K.pneumoniae*)	100CFU/mL
	VIM	ROX	VIM-4 (*E.Coli*)	50CFU/mL	VIM-1 (*K.pneumoniae*)	50CFU/mL
B	IMP	FAM	IMP-1 (*E.Coli*)	50CFU/mL	IMP-2 (*P.aeruginosa*)	100CFU/mL
C	NDM	FAM	NDM-1 (*K.pneumoniae*)	200CFU/mL	NDM-2 (*A.baumannii*)	50 CFU/mL
	K.pneumoniae	HEX	400 CFU/mL		/	
	A.baumannii	ROX	400 CFU/mL		/	
D	*P.aeruginosa*	FAM	400 CFU/mL		/	
	E.Coli	ROX	400 CFU/mL		/	

MultNAT® Carba-R and Four Pathogens PCR Assay (RUO)

Cpmpare with PCR (Xpert)

Target	Template	Test concentration CFU/mL	MultNAT/Ct	Xpert/Ct
OXA	**OXA-48 (*K.pneumoniae*)**	1	N/A	N/A
		10	N/A	N/A
		100	37.7	37.6
IMP	**IMP-1 (*E.Coli*)**	10	N/A	N/A
		100	33.9	39.0
		1000	30.8	33.3
KPC	**KPC-4 (*K.pneumoniae*)**	10	N/A	N/A
		100	35.9	36.7
		1000	30.8	29.6
VIM	**VIM-1 (*K.pneumoniae*)**	10	36.0	N/A
		100	36.5	37.6
		1000	31.9	30.4
NDM	**NDM-2 (*A.baumannii*)**	10	N/A	N/A
		100	36.0	37.0
		1000	34.6	37.7

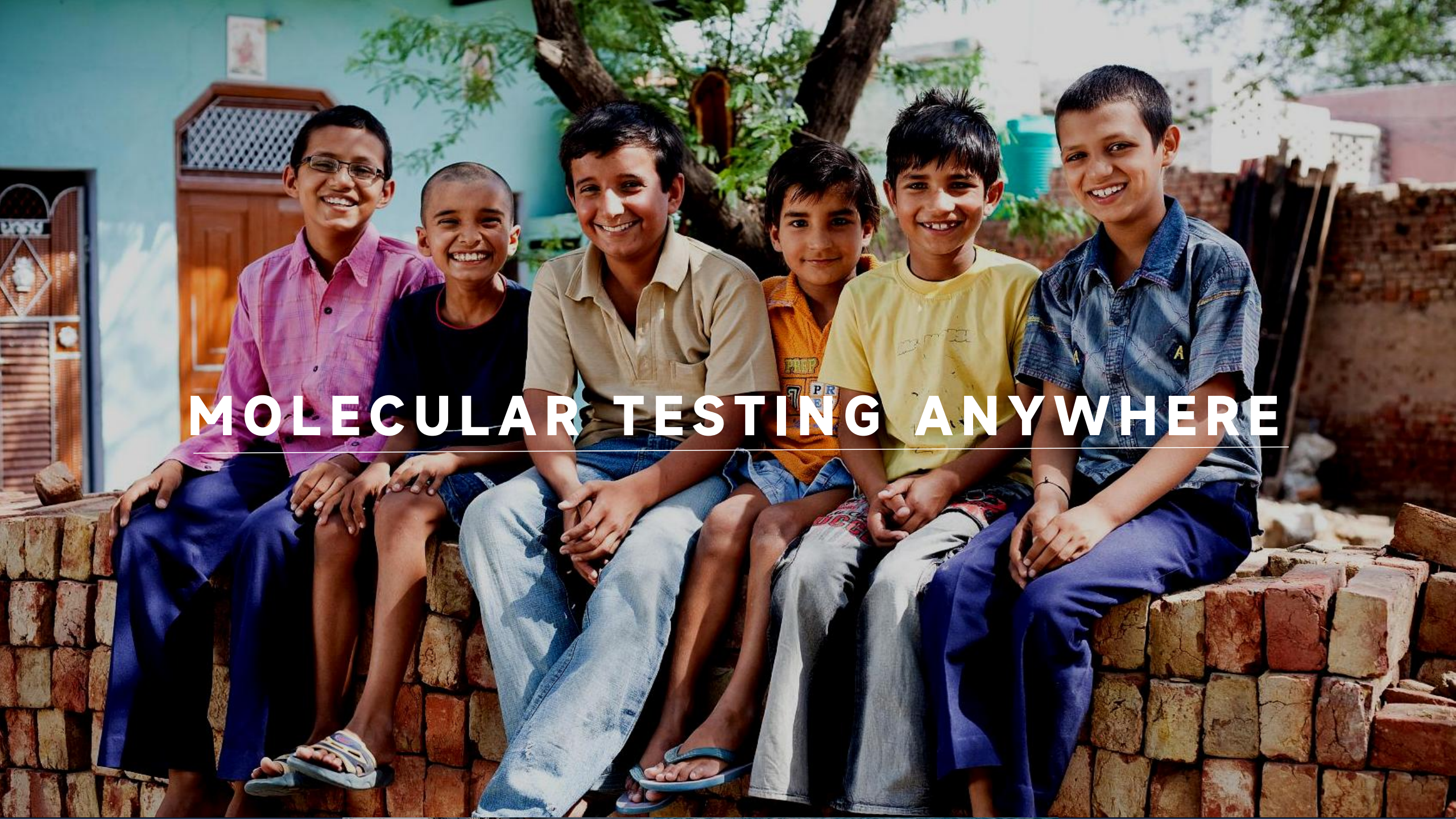
MultNAT® Gastrointestinal Panel (RUO)

Mod	Pathogens	Fluorescent channel	Sensitivity (cps/mL)
A	Salmonella	HEX	100
	Campylobacter	CY5	1000
	E.Coli O157	FAM	1000
B	*Y. enterocolitica*	HEX	30
	C. difficile (Toxins A/B)	CY5	1000
	Enterotoxigenic E. coli (ETEC)	FAM	5000
C	Shiga Toxin-Producing Escherichia coli (STEC)	HEX	300
	Shigella Castellani (plus EIEC)	CY5	100
	Vibrio (*V.cholerae*, *V.parahaemolyticus*, *V.vulnificus*)	FAM	100
D (Virus)	Adenovirus 40/41	HEX	1000
	Rotavirus	CY5	100
	Norovirus GI/GII	FAM	1000

Internal control is at β-actin, ROX channel

Highlights

- **12 pathogens tested in ONE cartridge**
- **Less interference**
- **Higher specificity & sensitivity**


MOLECULAR TESTING ANYWHERE

THANKS

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