

PORTABLE REAL-TIME PCR FOR RAPID SCREENING

SHINEWAY TECHNOLOGY CORPORATE



Shineway

The Company



Shineway Technology Corporate

was founded by a team of researchers at Hong Kong University of Science and Technology in September 2016.

The company is a national high-tech enterprise specializing in the development of **rapid nucleic acid molecular in vitro diagnostic technology**, which is committed to research and development, production and sales of world-class on-site rapid molecular in vitro diagnostic medical device products.



COVID-19

CORONAVIRUS



Coronavirus cases soar to > 70,000.

China reported that 1,716 medical workers were infected. (1,502 of those cases in Hubei Province), and six of these workers have died, the Times reports.

Hubei Province, where the outbreak started, has changed how it diagnoses the virus, causing the number of cases to skyrocket in the area.

About 74,456 confirmed coronavirus cases (primarily in mainland China), according to the Johns Hopkins virus dashboard.

2,800 deaths due to the infection. Number of deaths worldwide is leading over SARS.

The coronavirus cruise ship quarantine is a scary public health experiment

The second-largest outbreak outside China is floating at sea — and health experts are increasingly worried.

By Julia Belluz | @juliaoftoronto | julia.belluz@voxmedia.com | Updated Feb 12, 2020, 8:33am EST

f   SHARE



Their concern is driven by the details emerging from the ship, which paint an alarming portrait. According to a **must-read New York Times** report, as of February 10, Japanese officials had only tested 439 of the 3,700 passengers onboard for the coronavirus, citing shortages of testing supplies. This means that at least a fraction of the remaining thousands onboard may have the virus and not know it.

There has also been criticism of the slow pace of testing, although officials have said they hope to increase the number of daily tests from 300 to 1,000.

“On the ship, infections are getting very dense... it now provides a

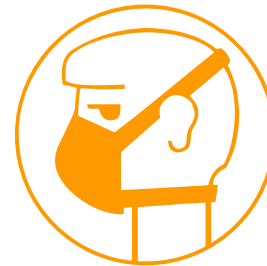
CASE STUDY



Shineway

NEWS :

About 3,700 people are being quarantined on the Diamond Princess cruise ship off Japan due to COVID-19. 213 were tested positive (as of 16th of Feb 2020), including a onboard Japanese health official.



Problems Statement:

- Epidemic outbreak
- Samples-in queue for testing
- Lacking of portable laboratory
- Complicated sample handling
- Long testing time
- Long quarantine time





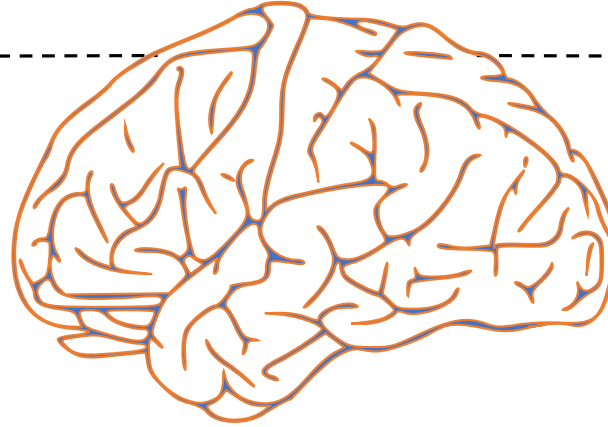
Shineway

VISION

Remote Laboratory

MISSION

To provide testing solution
without boundaries

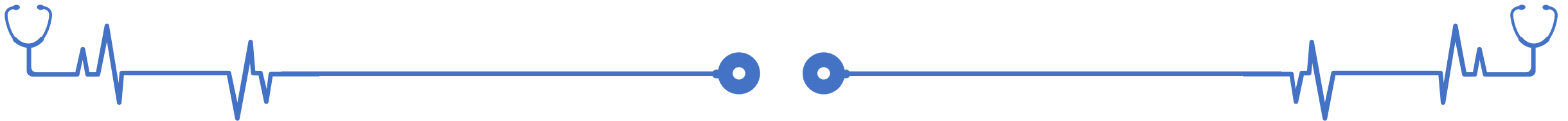


VALUE

MOBILITY

PRECISION

EFFICIENCY

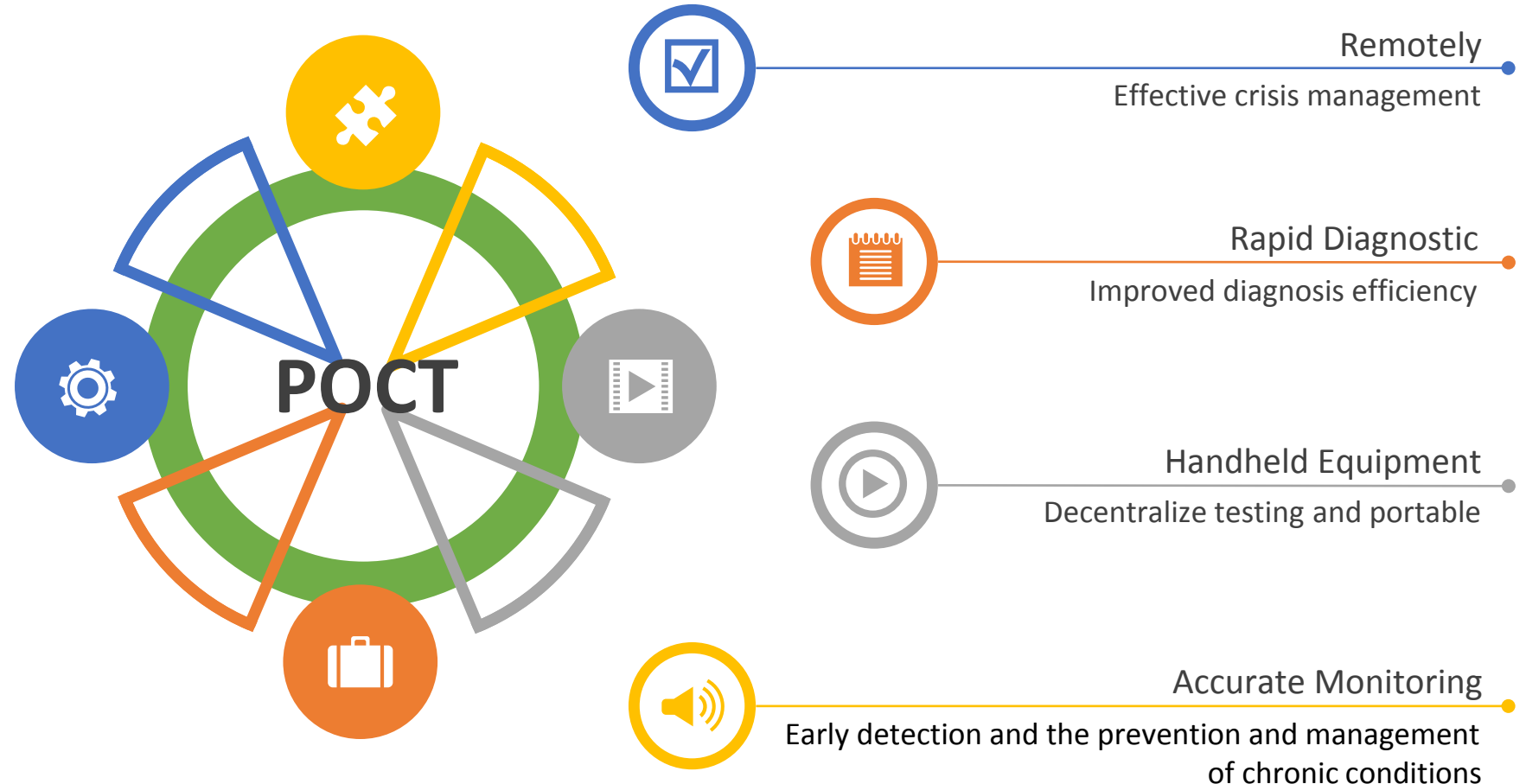


Point of Care Testing (POCT) Solution

DEFINITION:

POCT is defined as an investigation taken at the time of the consultation with instant availability of results to make immediate and informed decisions about patient care...”

Kamlesh Khunti, a Professor of Primary Care Diabetes and Vascular Medicine at the University of Leicester





POCT Type Difference

Molecular Test

- Test based on DNA or RNA.
High technological barriers
- ✓ High specificity and sensitivity
- ✓ Short window period



Immunoassays

VS

Molecular Test

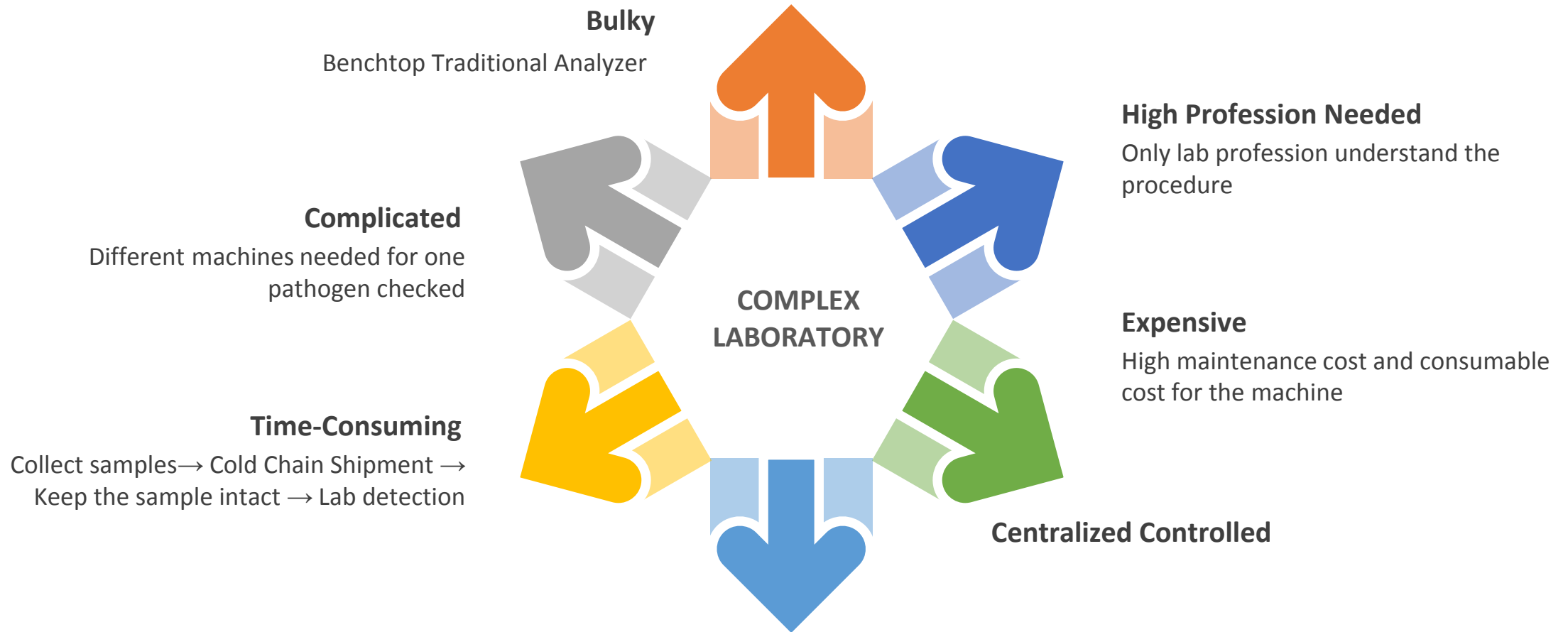


Immunoassays

- Test based on protein, metabolites, carbohydrate, lipids, Inorganic ion, etc.
- ✓ Mature and prevalent
- Low sensitivity and limited range
- Long window period

Viruses can be tested at the primary stage by Molecular Test, which can effectively block the spread of the virus.

Challenges in Diagnosis Industry





Key Product

Microfluidic PCR Reagents

- Nucleic Acid amplification Reaction Components
- Specification: 24T/kit



**Portable
Real-time PCR**

Microfluidic PCR Chip

- PCR reaction chamber
- Chamber Volume 2-18microlitre

PCR Nucleic Acid Analyzer

- consist of temperature control systems, electro-optical system, microfluidic chip, data processing and overall control chip, and etc.

On-site Rapid PCR Diagnostic System

PCR Nucleic Acid Analyzer

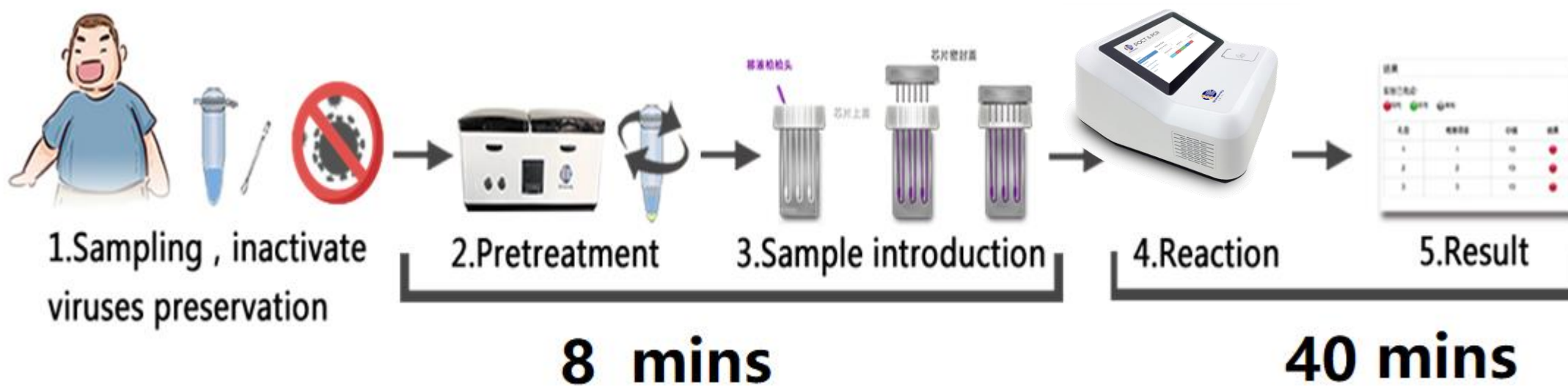


Pre-processing Centrifuge



On-site rapid PCR diagnostic system
consist of PCR Nucleic Acid Analyzer,
Preprocessing Centrifuge, Test Kits, Pipettes,
Supporting jig and fixture

Rapid Detection Process



Test Samples:

Throat Swabs, Nasal Swabs, Deep cough sputum, blood specimens, fecal specimens, conjunctival swab specimens

Scenario Application:

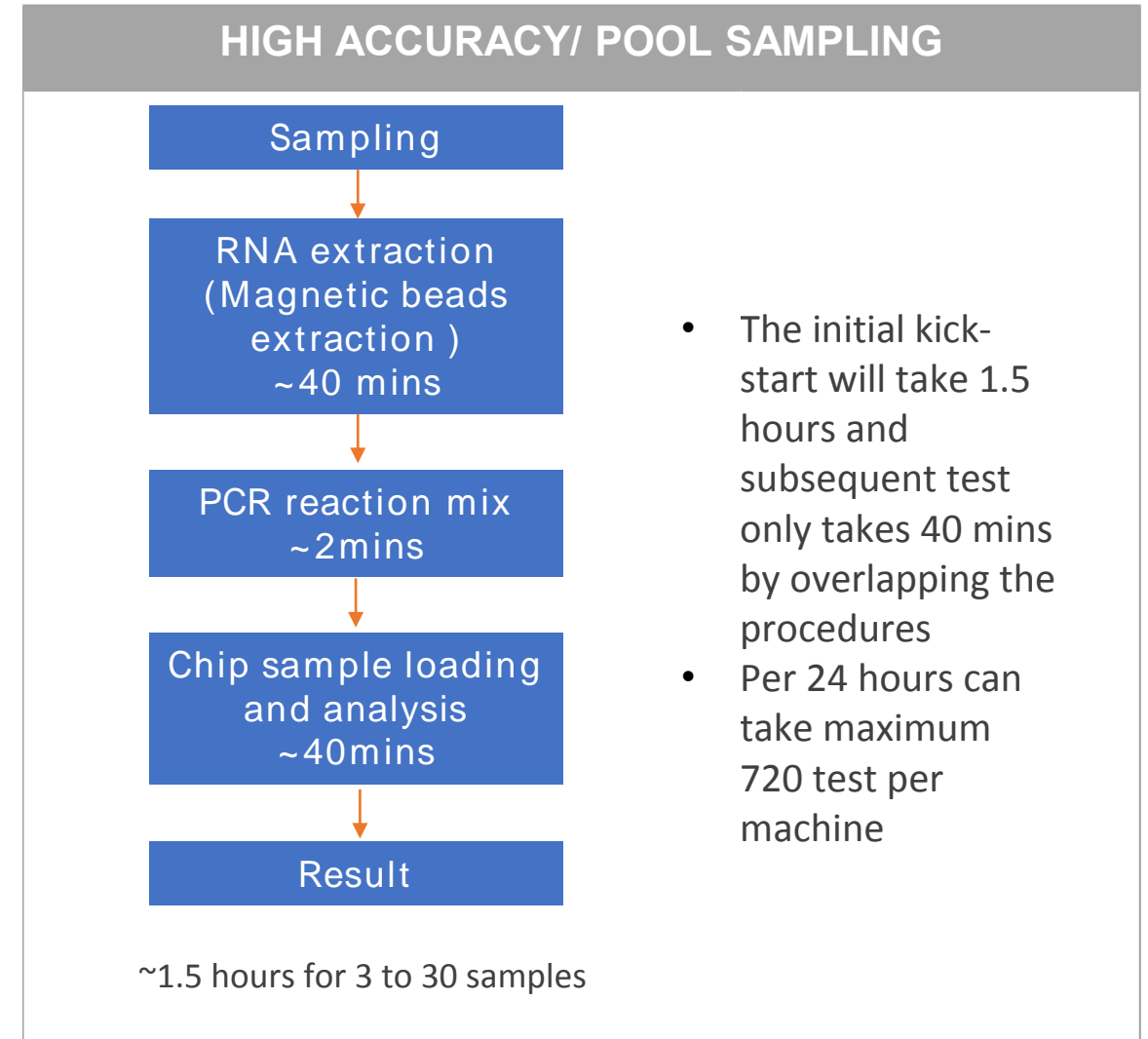
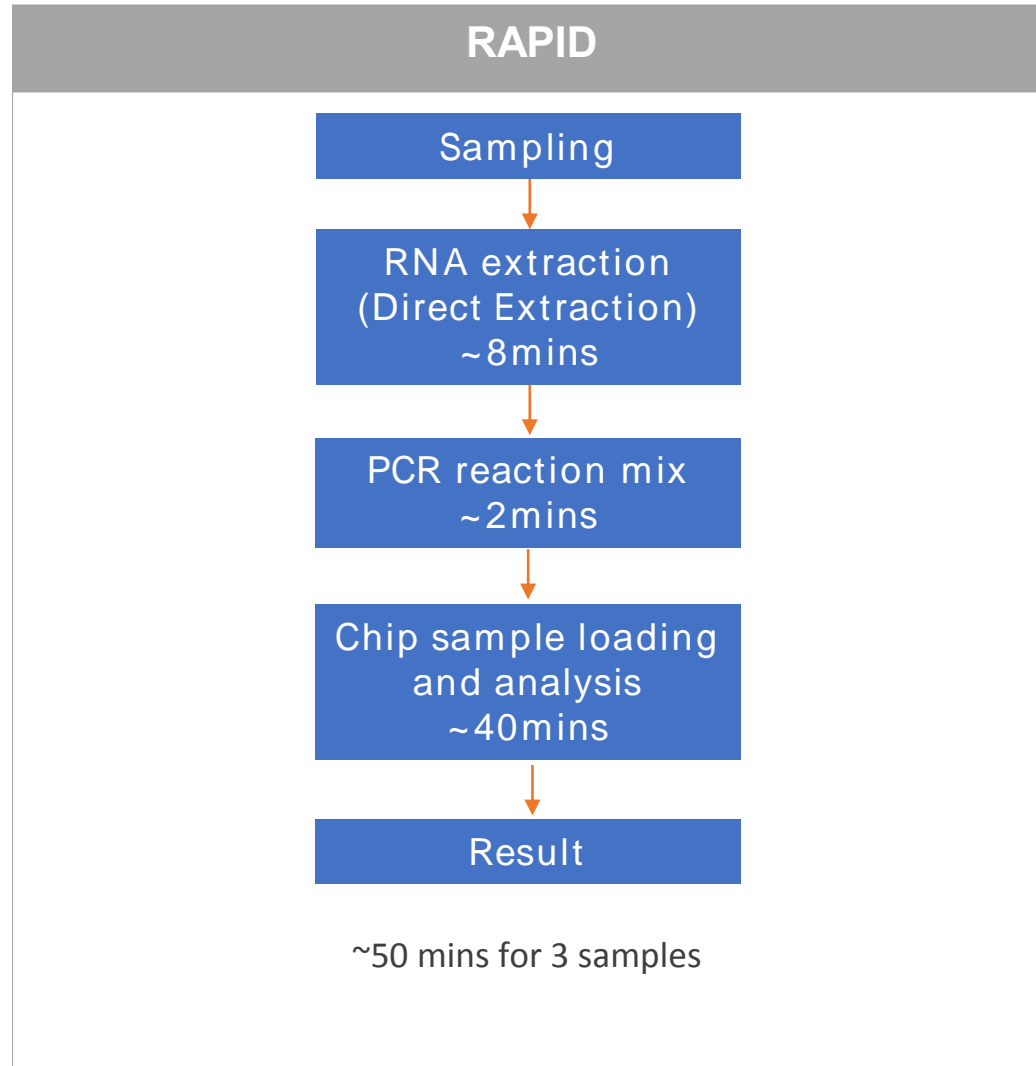
E.g.: Test Kit for COVID-19:

Rapid Screening, total estimated time: **50 mins**

Pool test or accuracy check with 3rd parties' solution, total estimated time: **1.5 hours**

** Note: Total estimated times varies for different test kits with different protocol*

Different Protocol for COVID-19



** Note: Total estimated times varies according to the third parties suggested procedure*



Shineway

Portable Real-time PCR

Affordable, Convenient and Precise.

<1 hour



Efficiency

Conventional analyzer take 3 hours to analyze.

<3 kg



Portability

Move the central laboratory to the front line of the epidemic

**1
—
2**



Affordable

Half the price of the conventional analyzer.

On-site Rapid PCR Diagnostic System

Move the central laboratory to the front line of the epidemic

- User friendly interface
- Portable for outdoor testing, zero delivery time
- High reaction efficiency, rapid screening
- Less reagent consumption, lower testing cost
- High detection sensitivity
- New light path and image segmentation algorithm design with 99% accuracy
- Support wireless network for easy data storage and transmission

On-site Rapid PCR Diagnostic System

Broad Application Range

Pathogen in Epidemic Area (COVID-19)

Flu Virus

Enterovirus

Respiratory Virus

Blood Infectious disease (Hep-B, HIV, HPV, etc)

As reference by **Nature Biotechnology** (February 19, 2020) to be the reliable diagnostic

<https://www.nature.com/articles/d41587-020-00002-2>

Hong Kong
University of
Science and
Technology

On-site rapid
molecular
diagnostic
system based
on Shenzhen
Shineway
Technology

Integrated microfluidic PCR
test employing silicon-based
micro-heater module for rapid
heating and processing of test
samples; delivers test results in
40 minutes

Platform has
European Union
CE approval



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Application Area



Non-Clinical

- CDC
 - Custom
 - Entry-Exit Inspection and Quarantine Bureaus
 - Inspection and Quarantine
 - Animal Clinic
 - Public Safety
- (Airport, Train Station)



Clinical

- Emergency Unit
- Hospital
- Blood Centre
- Clinic

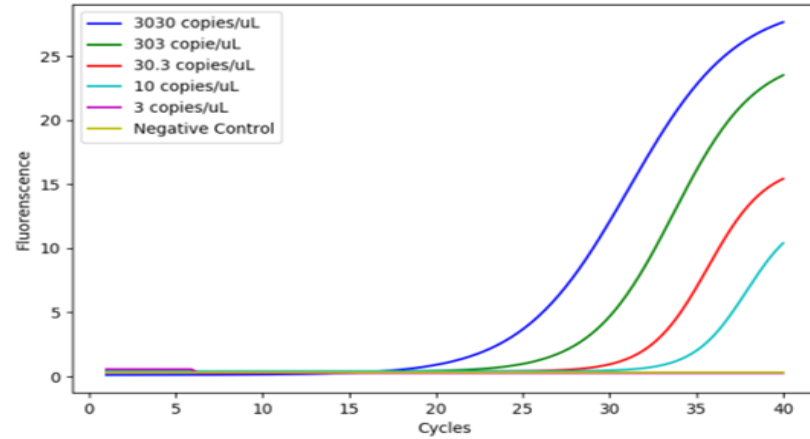


Domestic

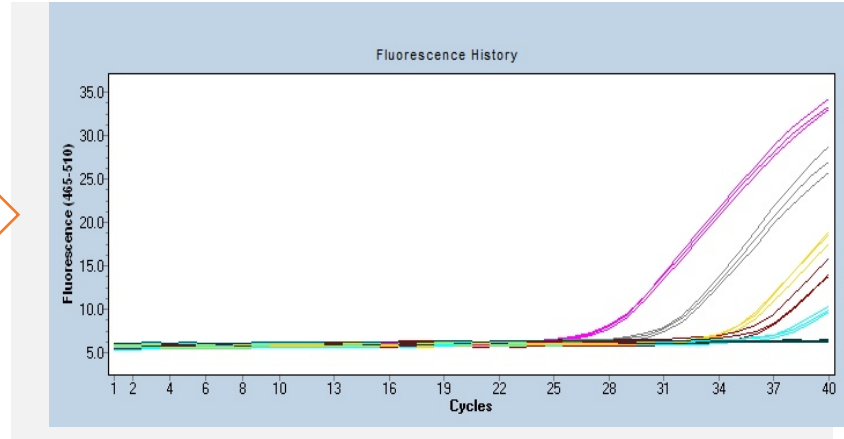
- Self Health Check
- Enterprise
- School
- Construction Units
- Industrial Park



Product Performance

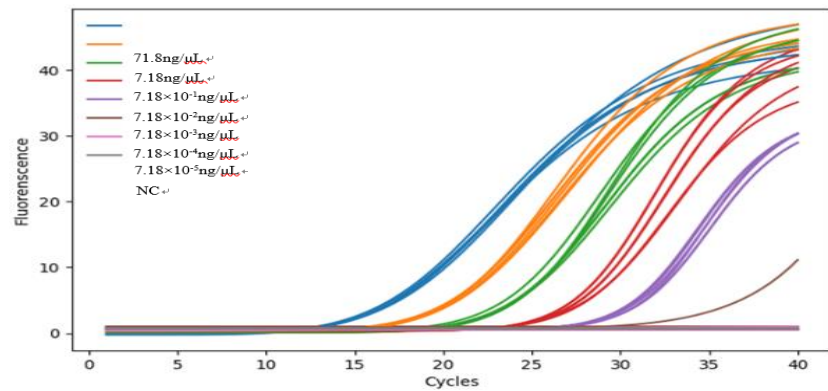


Salmonella test result by Shineway SWM-01

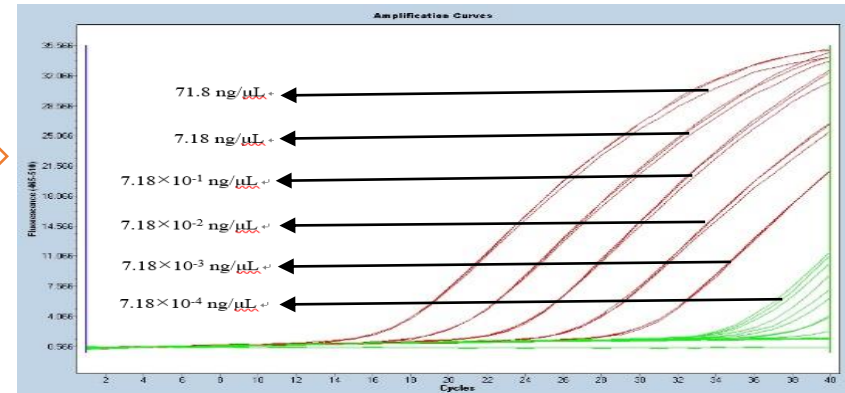


Salmonella test result by LightCycler® 480

99% Accuracy



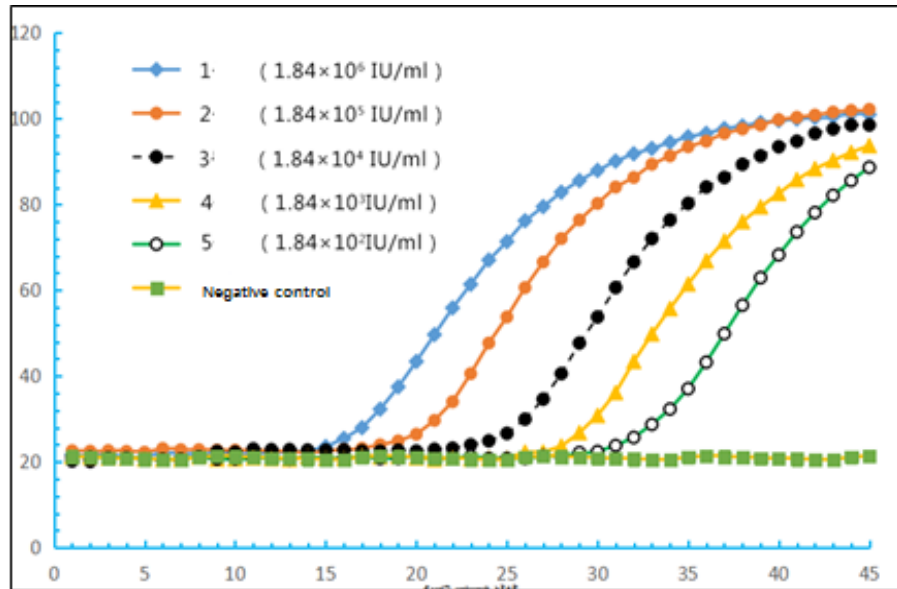
E. coli test result by Shineway SWM-01



E. coli test result by LightCycler® 480

Product Performance-COVID-19

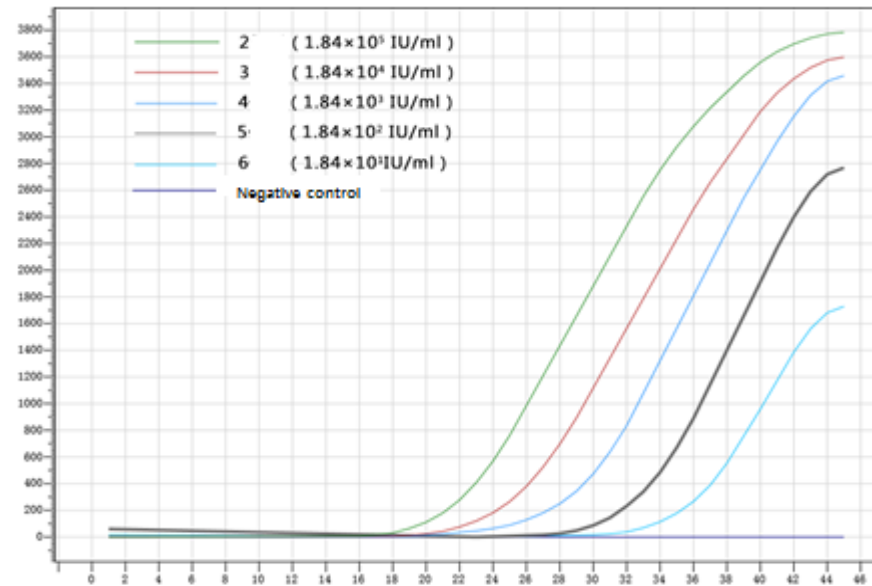
Fluorescence vs Cycle Graph



COVID-19 test result by Shineway SWM-01

Sample Amount in the chip well of SWM-01: 20microl

Fluorescence vs Cycle Graph



COVID-19 test result by LightCycler® 480

Sample Amount in the tube-based by LightCycler® 480: 200microl



99% Accuracy

Certification and Qualification



ISO 9001



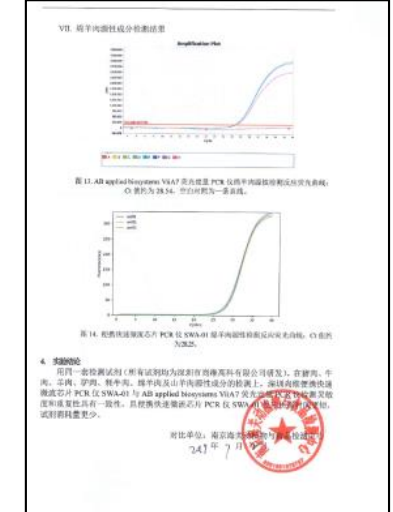
ISO13485



CE



CAIQ



GDMDT



National High-Tech Enterprise



Shenzhen City Academician Workstation



Guangdong Province Academician Workstation



Shenzhen Enterprise Science Association



2019 Outstanding Academician Workstation Construction Unit

Our Team Leader



DR. WEIJIA WEN

Main Research Interest:

Soft condensed matter physics, electrorheological (ER) and magnetorheological (MR) fluids, field-induced pattern and structure transitions, micro- and nano-fluidic controlling, microsphere and nanoparticle fabrications, thin film physics, band gap materials, metamaterials and nonlinear optical materials.

- ✓ Published more than 300 SCI papers, others cited more than 10,000
- ✓ Obtained 18 US patents, more than 40 Chinese patents
- ✓ Hosted more than 40 national, provincial and ministerial levels, innovation funds and other research projects, with a total research funding of more than 80 million yuan

<http://www.phys.ust.hk/phwen/>

PhD in Applied Physics
Chinese Academy of Sciences, 1995.

Professor
Department of Physics, HKUST

Director of Shenzhen Shineway Technology
Corporation

- 2000 National Outstanding Youth Fund (Class B)
- 2013 Chief scientist of scientific research in the non-profit industry (agriculture)
- 2014 National Natural Science Second Prize
- 2016 Shenzhen Peacock Venture Team Leader

Clients and Collaborations

CHINA



NOTE: Due to privacy and confidentiality, we are not allowed to share some of our client's information.

01 Guizhou Province

-District Health Bureau

02 Hainan Province

People's Hospital

03 Hubei Province

-District Health Bureau, CDC, People's Hospital

04 Guangdong Province

-CDC, First Affiliated Hospital, People's Hospital
-Walmart, Livzon

05 Zhejiang Province

Zhejiang University Hospital

06 Jiangsu Province

Second People's Hospital

07 Liaoning Province

-CDC

Clients and Collaboration

WORLD WIDE



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01 Democratic Republic of the Congo

02 Malaysia

03 Hong Kong

04 Kuwait

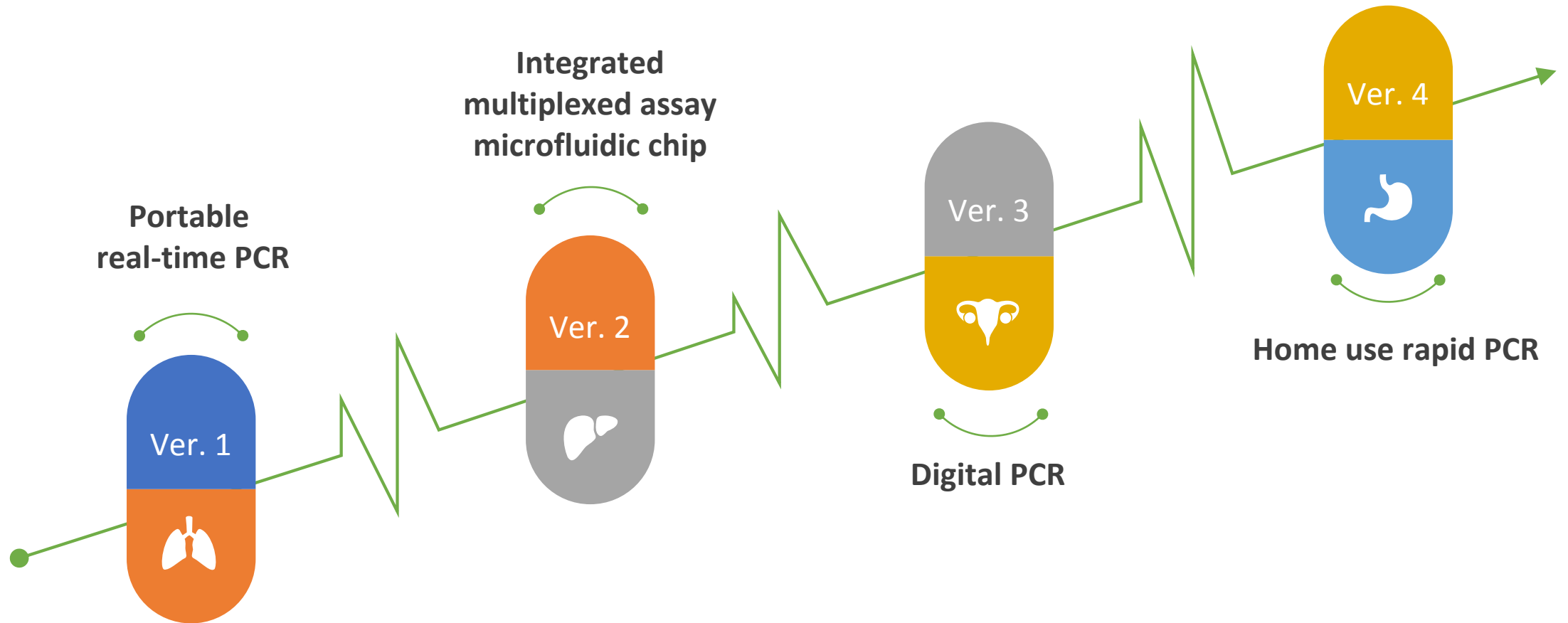
05 United Arab Emirates

06 Italy

Product Comparison with Competitors

	Accuracy	Portability	Fastest Diagnostic Time	Product on Market	Technology Used and Future Potential
Shineway Hong Kong	>99%	<ul style="list-style-type: none"> • 2kg, on-site embedded system • no PC required 	40 minutes	<ul style="list-style-type: none"> • IVD CE was obtained in 2019 • Product currently on sale 	<ul style="list-style-type: none"> • Microfluidic chip PCR technology • Thin film micro heater • Great future potential
Novacyt UK	99%	<ul style="list-style-type: none"> • 4kg, on-site • PC required 	<2 hour	<ul style="list-style-type: none"> • CE was obtained in 2020 • For research use only • Product launch estimated last quarter of 2020 	<ul style="list-style-type: none"> • Tube based PCR, • Traditional electronic heater • Saturated technology
Biomeme USA	70%	<ul style="list-style-type: none"> • 1kg, hand-held • Mobile phone/PC required 	1 hour	<ul style="list-style-type: none"> • Currently prototype build, no further progress 	<ul style="list-style-type: none"> • Traditional PCR technology • Traditional electronic heater • More on software development

Roadmap



NEWS UPDATE

China Daily - HKUST's invention to speed up diagnoses of novel coronavirus

<http://www.chinadailyhk.com/article/120331#HKUST%E2%80%99s-invention-to-speed-up-diagnoses-of-novel-coronavirus>

Shenzhen Daily - Coronavirus fast-detection device developed

http://www.szdaily.com/content/2020-02/07/content_22836688.htm

Dimsum Daily - Research team from HKUST launches world's fastest portable detector for novel coronavirus

<https://www.dimsumdaily.hk/research-team-from-hkust-launches-worlds-fastest-portable-detector-for-novel-coronavirus/>

Mirage News - HKUST Research Team Invents World's Fastest Coronavirus Detection Device Offering Diagnostic Results

<https://www.miragenews.com/hkust-research-team-invents-world-s-fastest-coronavirus-detection-device-offering-diagnostic-results/>

Unwire.HK: 科大全球最快40分鐘肺炎病毒檢測機 溫維佳教授：售價平一半 + 政府正商討引入

https://unwire.hk/2020/02/07/cornoavirusdetection/life-tech/health/?fbclid=IwAR3cutVuTmQJuCBVSoile41bHLZebtm_PiIOpdSXJJ_dOguNfXTTNoAoSAQ

文匯報- 抗擊新型肺炎：科大手提箱測冠毒快絕全球

<http://paper.wenweipo.com/2020/02/07/HS2002070035.htm>



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THANK YOU



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