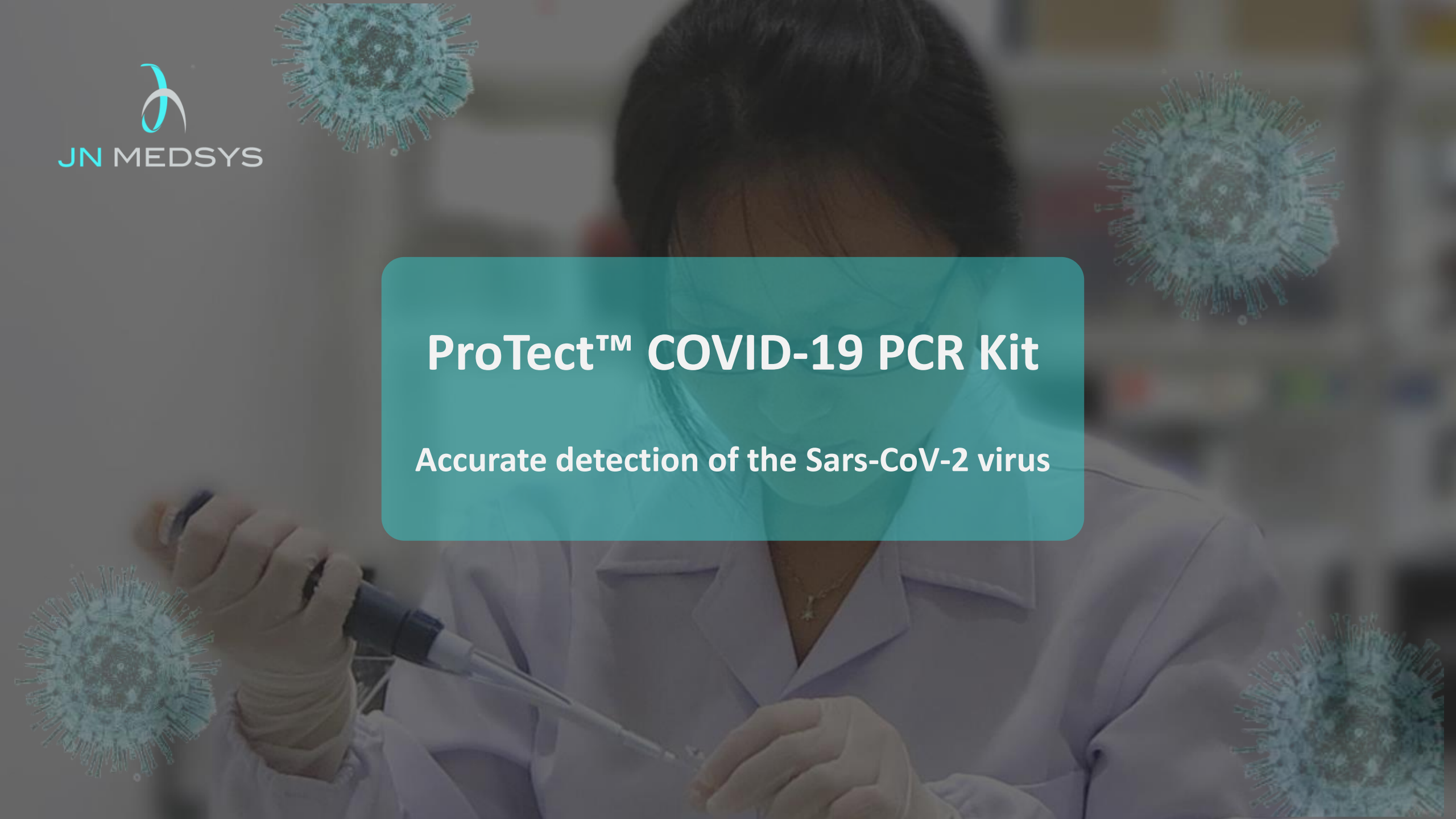
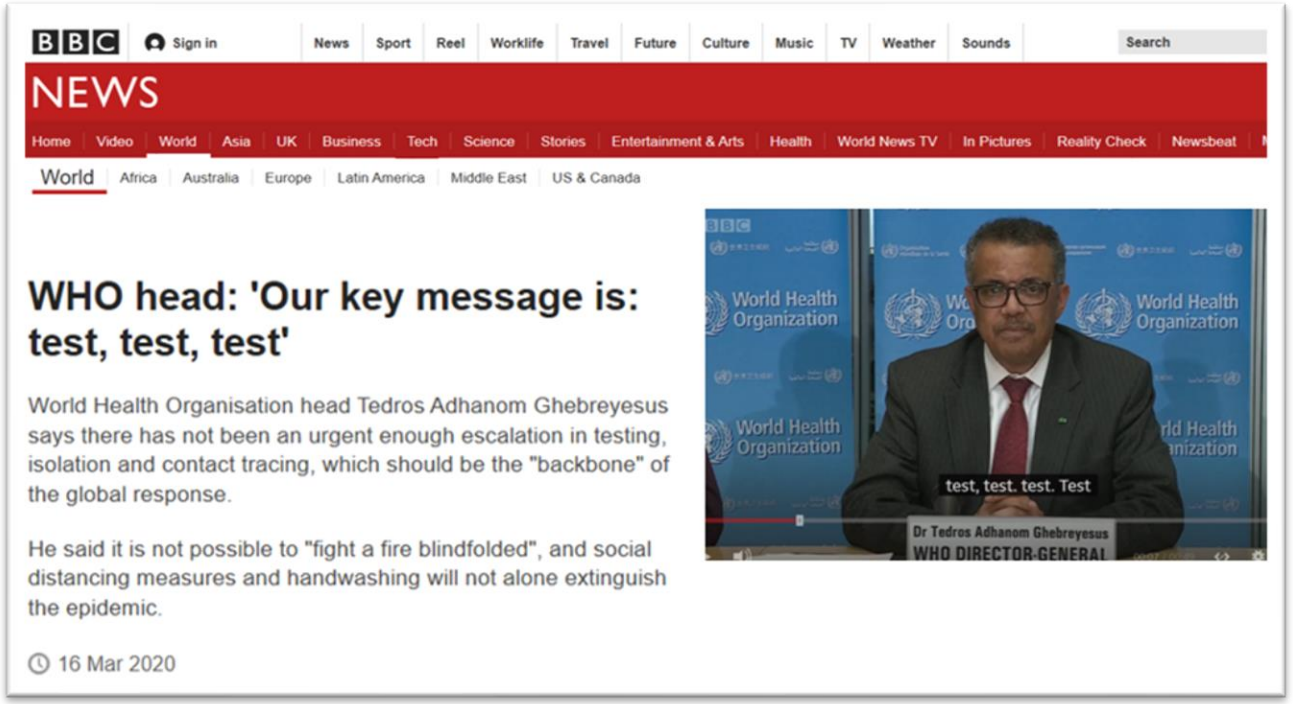

JN MEDSYS
ProTect™ COVID-19 PCR Kit
Accurate detection of the Sars-CoV-2 virus

Managing COVID-19: testing is still the key

The coronavirus disease 2019 (COVID-19) is an infectious disease of the respiratory system that is caused by the SARS-CoV-2 virus, which is closely related to the SARS virus. The outbreak started in Wuhan at the end of 2019 and to date (16 March 2020), has infected about 170,000 people worldwide and resulted in more than 6,000 deaths. The epicenter of the outbreak has also shifted from Hubei, China to Europe. WHO has also officially declared the outbreak a pandemic. To contain the outbreak, it is essential to diagnose infected patients so that they can be isolated and treated. The ability to gain access to affordable and good quality diagnostic kits is critical.

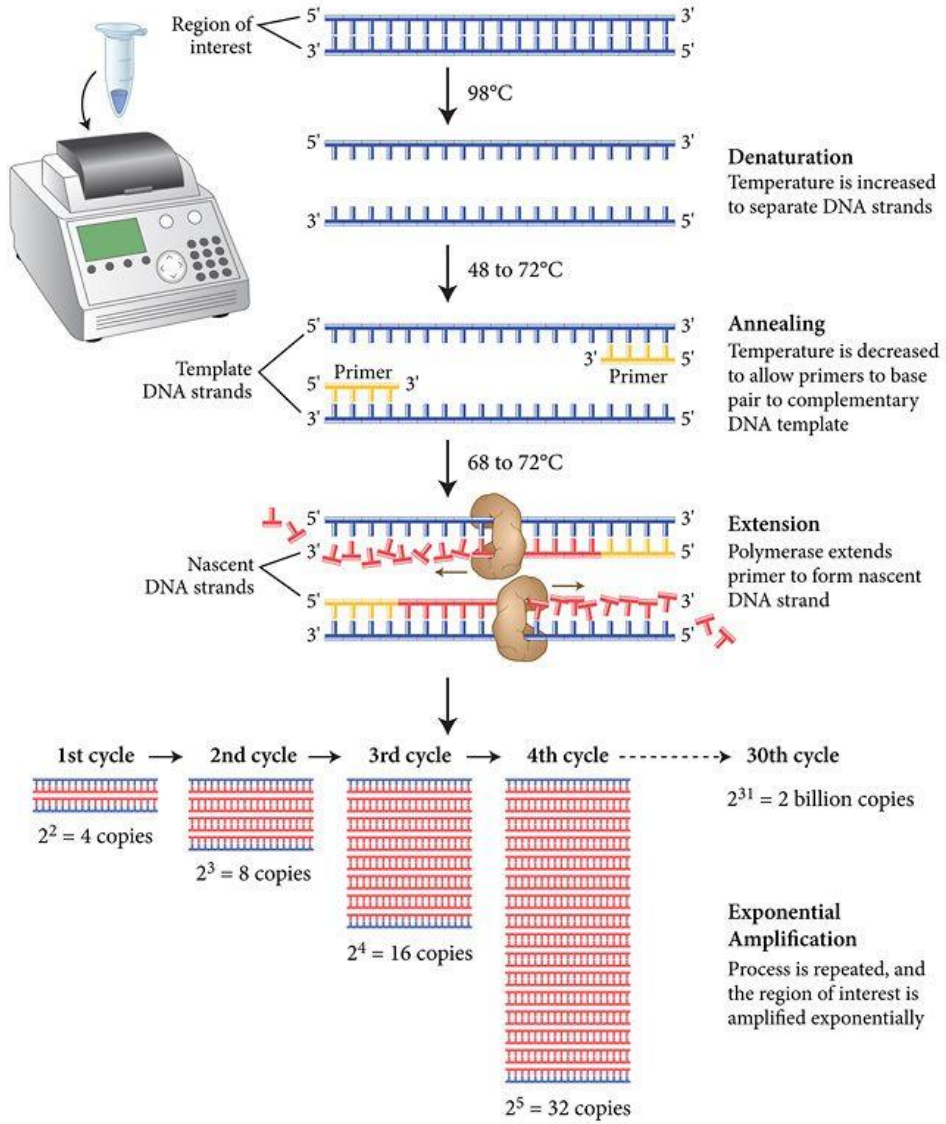


PCR is still the gold standard for COVID-19 testing

What is PCR?

It stands for polymerase chain reaction. It is a method to identify the presence of the virus. It “searches” for a particular gene unique to the virus. Once that gene is found, it then makes many copies of that gene (much like a photocopying machine). Eventually, the process makes millions of copies of that gene, which then generates sufficient fluorescent signals to be detected.

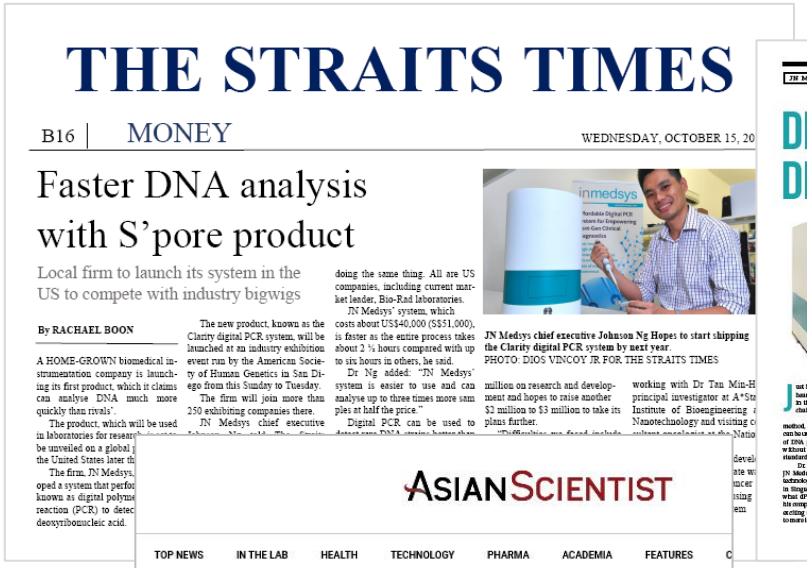
PCR can detect the presence of the virus once the person is infected. Hence, it is still the most accurate method for COVID-19 infection.



About JN Medsys

JN MEDSYS

JN Medsys is a Singapore based manufacturer of high-quality PCR and digital PCR products which comprises instruments, consumables and assay kits. It has ISO13485 Quality Management System that allows it to research, develop, manufacture and commercialise the products for in-vitro diagnostics purposes.



THE STRAITS TIMES

B16 | MONEY

WEDNESDAY, OCTOBER 15, 20

Faster DNA analysis with S'pore product

Local firm to launch its system in the US to compete with industry bigwigs

By RACHAEL BOON

A HOME-GROWN biomedical instrumentation company is launching its first product, which it claims can analyse DNA much more quickly than rivals'.

The product, which will be used in laboratories for research, will be unveiled on a global [illegible] the United States later th

The firm, JN Medsys, [illegible] oped a system that perfor[illegible] known as digital polyme[illegible] reaction (PCR) to detec[illegible] deoxyribonucleic acid.

doing the same thing. All are US companies, including current market leader, Bio-Rad laboratories.

JN Medsys' system, which costs about US$40,000 (S$51,000), is faster as the entire process takes about 2 ½ hours compared with up to six hours in others, he said.

Dr Ng added: "JN Medsys' system is easier to use and can analyse up to three times more samples at half the price."

Digital PCR can be used to

The new product, known as the Clarity digital PCR system, will be launched at an industry exhibition event run by the American Society of Human Genetics in San Diego from this Sunday to Tuesday.

The firm will join more than 250 exhibiting companies there.

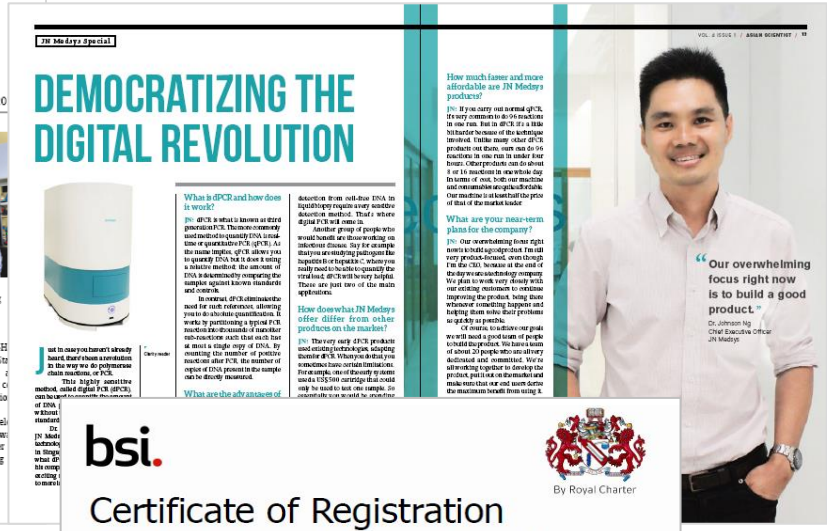
JN Medsys chief executive

JN Medsys chief executive Johnson Ng Hopes to start shipping the Clarity digital PCR system by next year.
PHOTO: DIOS VINCOY JR FOR THE STRAITS TIMES

million on research and development and hopes to raise another $2 million to $3 million to take its plans further.

"[illegible]

working with Dr Tan Min-H[illegible] principal investigator at A*St[illegible] Institute of Bioengineering [illegible] Nanotechnology and visiting [illegible]



ASIANSCIENTIST

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Developing Diagnostics In Double-Quick Time

JN Medsys has developed two new coronavirus diagnostic kits to meet the surge in demand for COVID-19 diagnostics.

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AsianScientist (Mar. 20, 2020) – All over the world, countries are sinking into a public health crisis as the COVID-19 outbreak develops into a global pandemic. Highly infectious, the coronavirus SARS-CoV-2 can spread from person to person even before symptoms appear. Accurate, widespread diagnosis is therefore critical to curbing new viral outbreaks, allowing infected individuals to be identified and quickly quarantined to stop the train of transmission.

South Korea, one of the first countries to experience the epidemic outside China, has shown that widespread testing might be a good solution to contain the virus. The country's elaborate testing program, which saw more than 270,000 people tested thus far, has helped to slow down the influx of new cases since its record high of 909 cases on February 29, 2020.

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

JN Medsys Pte Ltd
217 Henderson Road
#02-08
Singapore 159555

Holds Certificate No: **MD 698251**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacturing, installation, servicing and distribution of analytical instruments, assay kits and reagents for In Vitro Diagnostic applications

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2018-11-02
Latest Revision Date: 2018-11-02

Effective Date: 2018-11-02
Expiry Date: 2021-11-01

Page: 1 of 1

...making excellence a habit.

PROTECT™ COVID-19 PCR KIT

The **ProTect™ COVID-19 RT-qPCR kit** from JN Medsys is a nucleic acid test that detects for the virus that causes COVID-19. It identifies the genetic material of the SARS-CoV-2 virus isolated from infected patient samples using the reverse transcription quantitative polymerase chain reaction method. Known as the gold standard method, it provides high sensitivity and specificity to identify the virus even at low copies. It allows the accurate identification of the virus isolated from respiratory specimens of infected patients.

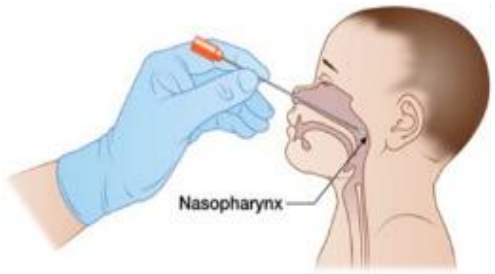
Target multiple genes on the virus

The kit is developed based on the United States Center for Disease Control and Prevention (CDC)'s recommended protocol, and detects for multiple genes on the virus RNA, which includes the specific regions of the COVID-19 virus (N1 and N2). Different countries have different protocols for detecting the virus. The reason for targeting multiple genes is to ensure that first, the kit can cover all the different strains of the virus. Second, when the virus starts to mutate over time, and the mutation site unknown, it may be more accurate to detect for multiple targets. The detection of multiple genes may help to increase the accuracy of the tests by reducing the incidences of false negative.

Country	Institute	Gene targets	Number of targets
US	US CDC	Three targets in N gene	3
Germany	Charité	RdRP, E, N	3
China	China CDC	ORF1ab and N	2
France	Institut Pasteur, Paris	Two targets in RdRP	2
Hong Kong SAR	HKU	ORF1b-nsp14, N	2
Japan	National Institute of Infectious Diseases	Pancorona and multiple targets, Spike protein	2
Thailand	National Institute of Health	N	1

Source: WHO

Detection workflow



1. Specimen collection

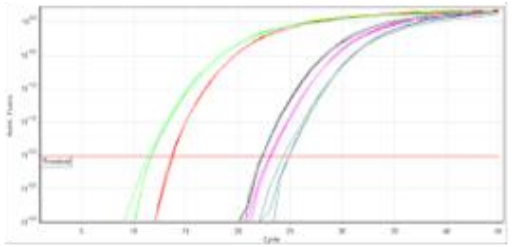
A nasopharyngeal specimen is collected from the patient using a nasal swab

2. RNA extraction

The specimen is then processed to extract out the RNA from the SARS-CoV-2 virus. This requires the use of a specialised RNA extraction kit and a centrifuge.

3. Polymerase chain reaction (PCR)

The extracted RNA is the put through a process called polymerase chain reaction. Here specific genetic signatures of the SARS-CoV-2 virus are being identified. If it is present, the process make many copies of the gene fragments. This process requires a specialised PCR kit and a real-time PCR instrument.



4. Results

If the virus is present, the real-time PCR instrument will detect fluorescent signals coming from the PCR reaction. This will confirm the presence of the virus.

Features of the kit

Submitted for US FDA Emergency Use Authorisation

Sensitivity down to 10 copies/reaction

Approved by Singapore HSA

Clinically validated at Singapore hospital

Detects multiple genes for better accuracy

Competitively priced to encourage mass usage

Detects all strains of the virus

Results in under 1.5 hours

Manufactured in Singapore under ISO13485 standards

Performance

Test principle	One-step RT-PCR (Taqman®-based)
Limit of detection (LOD)	10 copies/reaction
Precision	< 2%
Dynamic range	6 log
Specificity	Specific to the SARS-CoV-2 virus based on *in silico* sequence analysis
Efficiency	> 95%

Regulatory approval

Singapore
Health Sciences Authority

Health Sciences Authority
11 Outram Road Singapore 169078
Tel: 65 6213 0838 Fax: 65 6213 0749
Website: www.hsa.gov.sg

HSA 600:36/01

25 March 2020

JN Medsys Pte Ltd
217 Henderson Road
#02-08
Singapore 159555

Dear Low Huiyu

RE: STATUS OF SUPPLY OF MEDICAL DEVICES IN SINGAPORE

This letter serves to confirm that the following medical device product(s) have been issued Provisional Authorisation for supply in Singapore and may be exported from Singapore.

No.	Device Proprietary Name	Intended Use
1	ProTect™ COVID-19 RT-qPCR Kit (10024) (10027)	The ProTect™ Coronavirus Disease 2019 (COVID-19) RT-qPCR kit by JN Medsys provides all necessary reagents for the in vitro qualitative detection of SARS-CoV-2 from upper respiratory nasopharyngeal specimens. The test is targeting SARS-CoV-2 N1, N2 and N3 genes and the human RNase P control gene.

Product Owner: JN Medsys Pte Ltd
217 Henderson Road
#02-08
Singapore 159555

Manufacturing Site: JN Medsys Pte Ltd
217 Henderson Road
#02-08
Singapore 159555

Page 1 of 2

Health Products Regulation Group • Blood Services Group • Applied Sciences Group

European Union
CE mark

Obelis EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: BS 9087-2020
Order No.: BS 9053-2020

BELGIUM

Date: 24/04/2020

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: JN MEDSYS PTE LTD

ADDRESS: 217 HENDERSON ROAD, #02-08, SINGAPORE 159555

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 23/04/2020 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 1 DEVICE)

As of the 24/04/2020, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

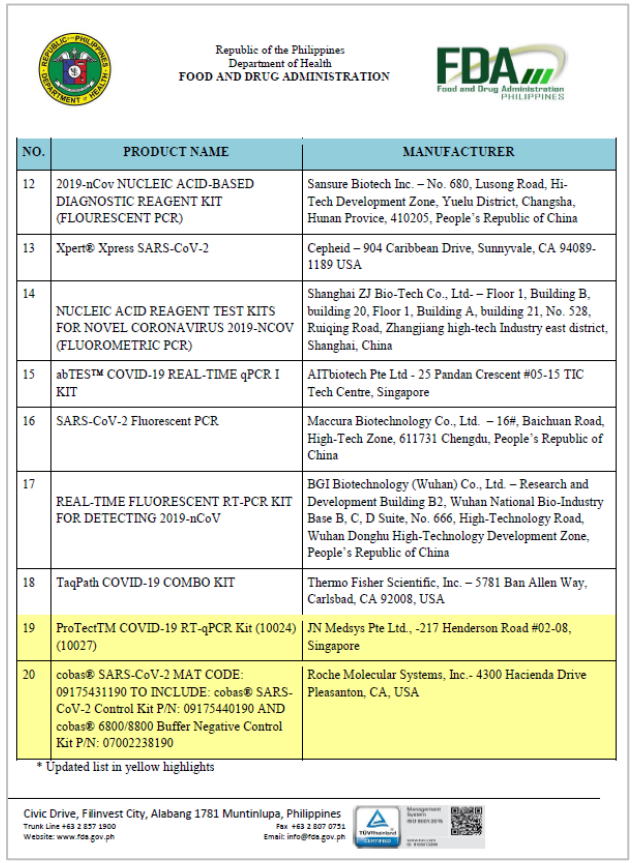
Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

Registered Address: Bd. Général Wahis 53-1030 Brussels | Registered Office Address: Bd Brand Whitlock 30, B–1200 Brussels- Belgium
T: + 32 (0) 2 732 6004 | F: + 32 (0) 2 732 6003 | Email: mail@obelis.net | Website: www.obelis.net
V3 – ID: 00454716 – 22/02/2019

Philippines FDA



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

NO.	PRODUCT NAME	MANUFACTURER
12	2019-nCov NUCLEIC ACID-BASED DIAGNOSTIC REAGENT KIT (FLOURESCENT PCR)	Sansure Biotech Inc. – No. 680, Lusong Road, Hi-Tech Development Zone, Yuelu District, Changsha, Hunan Provice, 410205, People's Republic of China
13	Xpert® Xpress SARS-CoV-2	Cepheid – 904 Caribbean Drive, Sunnyvale, CA 94089-1189 USA
14	NUCLEIC ACID REAGENT TEST KITS FOR NOVEL CORONAVIRUS 2019-NCOV (FLUOROMETRIC PCR)	Shanghai ZJ Bio-Tech Co., Ltd- – Floor 1, Building B, building 20, Floor 1, Building A, building 21, No. 528, Ruiqing Road, Zhangjiang high-tech Industry east district, Shanghai, China
15	abTES™ COVID-19 REAL-TIME qPCR I KIT	AITbiotech Pte Ltd - 25 Pandan Crescent #05-15 TIC Tech Centre, Singapore
16	SARS-CoV-2 Fluorescent PCR	Maccura Biotechnology Co., Ltd. – 16#, Baichuan Road, High-Tech Zone, 611731 Chengdu, People's Republic of China
17	REAL-TIME FLUORESCENT RT-PCR KIT FOR DETECTING 2019-nCoV	BGI Biotechnology (Wuhan) Co., Ltd. – Research and Development Building B2, Wuhan National Bio-Industry Base B, C, D Suite, No. 666, High-Technology Road, Wuhan Donghu High-Technology Development Zone, People's Republic of China
18	TaqPath COVID-19 COMBO KIT	Thermo Fisher Scientific, Inc. – 5781 Ban Allen Way, Carlsbad, CA 92008, USA
19	ProTectTM COVID-19 RT-qPCR Kit (10024) (10027)	JN Medsys Pte Ltd., -217 Henderson Road #02-08, Singapore
20	cobas® SARS-CoV-2 MAT CODE: 09175431190 TO INCLUDE: cobas® SARS-CoV-2 Control Kit P/N: 09175440190 AND cobas® 6800/8800 Buffer Negative Control Kit P/N: 07002238190	Roche Molecular Systems, Inc.- 4300 Hacienda Drive Pleasanton, CA, USA

* Updated list in yellow highlights

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900
Website: www.fda.gov.ph
Fax +63 2 807 0751
Email: info@fda.gov.ph

Clinical samples validation

COMPARISON STUDIES AT A SINGAPORE HOSPITAL

The ProTect™ kit was validated with clinical samples from a local hospital in Singapore. This hospital has been doing COVID-19 testing using another PCR kit. Overall there is a high degree of agreement (~ 95%) between the two different kits.

		ProTect™ Kit		
		Positive	Negative	Total
Clinical Data From Local Hospital	Positive	27	2	29
	Negative	1	28	29
	Total	28	30	
		Positive Percentage Agreement = 96.4%	Negative Percentage Agreement = 93.3%	
		Overall Rate of Agreement = 94.8%		

ProTect in the news

ASIAN SCIENTIST

TOP NEWS IN THE LAB HEALTH TECHNOLOGY PHARMA ACADEMIA FEATURES C

Developing Diagnostics In Double-Quick Time

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SHARE TWEET SHARE

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THE BUSINESS TIMES

S$1.00 A SINGAPORE PRESS HOLDINGS PUBLICATION | www.businesstimes.com.sg | @BTbreakingnews | CO REGN NO 198402868E | MCI (P) 039/08/2015 Tuesday April 14, 2020

Camtech, JN Medsys to boost supply of Covid-19 test kits

By Vivienne Tay
vtay@sph.com.sg
@VivienneTayBT

Singapore

TWO Singapore firms, Camtech Diagnostics and JN Medsys, are planning to boost the production of two Covid-19 test kits after obtaining provisional authorisation from Singapore's Health Sciences Authority (HSA).

This comes as demand for diagnostic test kits rises amid the novel coronavirus outbreak in various countries globally.

To meet the projected demand, Camtech Holdings is planning to expand manufacturing in Singapore for the two test kits, according to Kuok Meng-Han, the group's founder and managing director.

Camtech Diagnostics is the research and product development arm of local technology company Camtech Holdings. The latter is an investor in life science firm JN Medsys.

The companies jointly announced on Tuesday that they have obtained provisional authorisation from Singapore's HSA for two Covid-19 test kits – a rapid test kit which produces results in 10 minutes, and a nucleic acid test kit which takes two hours to produce results but has more than 95 per cent accuracy in identifying the coronavirus.

Having a provisional authorisation from HSA allows companies to supply their Covid-19 test kits to healthcare institutions, private hospitals, medical clinics and clinical laboratories in Singapore.

In addition to HSA's provisional licence, JN Medsys has also obtained approval for its test kit from the Food and Drug Administration of the Philippines. It is also in the process of getting approval from the US Food and Drug Administration.

The announcement added that JN Medsys kits have been clinically validated in Singapore and abroad.

Camtech Diagnostics' Covid-19 test is called the Covid-19 IgG/IgM rapid qualitative screening test, which can be a tool in helping to screen and identify asymptomatic carriers of the coronavirus. That said, the test should not be used for confirmatory testing or as a sole basis of diagnosis, the statement noted.

Meanwhile, JN Medsys' test kit is a nucleic acid test that detects the virus which causes Covid-19. Called the ProTect Covid-19 RT-qPCR Kit, the PCR kit identifies the genetic material of the Covid-19 virus isolated from infected patient samples using the reverse transcription quantitative polymerase chain reaction method.

This method is also known as the gold standard method due to its high sensitivity and specificity to identify the virus even at low copies.

The PCR kit also uses protocol from the United States Centers for Disease Control and Prevention.

Johnson Ng, JN Medsys chief executive officer, added that PCR kits have been deployed to China, Malaysia and Indonesia. The PCR kits will be distributed to Asean, Europe and South America soon.

"Digital PCR is already a core product for our existing business, and we have now extended our business line to PCR kits to cater to worldwide demand," he added.

Both Camtech Diagnostics and JN Medsys previously received Spring Singapore innovation grant funding, as well as private investment from local angel investors.

FAQs

- **The kit detects for COVID-19. How does it work?**

The ProTect™ kit detects for the presence of the SARS-CoV-2 virus which causes COVID-19. It does that by detecting for the genetic material of the virus, which in this case is the ribonucleic acid (RNA). The kit targets multiple genes of the virus. Once it "finds" these genes, it makes many copies of that genes using a process known as polymerase chain reaction. As more copies of those genes are being made, it generates fluorescent signals that can be detected using a real-time PCR instrument. The PCR is a very accurate and sensitive test as it can detect for very low copies of the virus. Currently, the detection of the SARS-CoV-2 virus using PCR is the recommended method used by most countries for confirmation of COVID-19 infection in patients.

- **What is the entire process for detecting for the virus?**

First, a nasopharyngeal specimen is collected using a nasal swab. The swab is then immersed into a transport medium. Second, RNA extraction is carried out on the specimen. This process lyses the viral particles to release the RNA and then purifies it. This step must be carried out with an RNA extraction kit and a bench-top centrifuge. Third, the extracted RNA is put through the PCR process. If specimen contains the SARS-CoV-2 virus, the real-time PCR process will show a positive result, confirming the presence of the virus.

- **How long does it take?**

The entire process from RNA extraction to PCR can be conducted in under 2 hours, with the PCR process requiring about 1h 15min.

- **How is this different from the rapid test kits that can be performed in 15 minutes?**

The rapid test kits that can generate results in 15 min detects for the antibodies present in an infected person. An infected person takes about a week to generate these antibodies in response to the viral infection. During this period, the rapid test may return a negative result due to the lack of antibodies even though the patient might be infected.

FAQs

- **What equipment do I need?**

A real-time PCR instrument is needed. We recommend the following:

- ThermoFisher Scientific QuantStudio series (3, 5, 6 and 7) instruments and 7500 real-time system
- Bio-Rad CFX96 Touch™ Real-time PCR System
- Roche LightCycler® 96 and 480 Systems

- **On which real-time PCR instrument has this been validated? Is it compatible with others?**

The kit has been validated on ThermoFisher Scientific's QuantStudio 3 and Roche's LightCycler 480 II.

- **How is this kit different from the Fortitude kit from A*Star?**

Both the ProTect™ and A*Star's Fortitude 2 use the PCR method to detect for the SARS-CoV-2 virus. The Fortitude 2 detects for a single gene on the virus. The ProTect™ detects for multiple genes on the virus, in accordance to the US Communicable Disease Center (CDC) protocol. Detecting for multiple genes on the virus ensures that the kit can detect 100% of all the different strains of the virus. It also ensures that the kit can still detect the virus even if it mutates.

- **Which targets on the SARS-CoV-2 virus does it detect?**

It detects for the N gene of the SAR-CoV-2 virus, in accordance to US CDC recommended protocol.

- **Each kit has how many tests?**

Each kit has 100 tests.

FAQs

- **What is the dimension and weight of each kit?**
  Each is contained in 2 small boxes. Each box is 73 x 49 x 54 (H) mm. Two boxes bundled together will be 73 x 98 x 54 (H) mm, weighing 100g

- **What is the storage condition for the kits?**
  The kits are to be stored at -20^{o}C and repeated freeze thawing of the reagents are to be avoided.

- **What is the shipping condition for the kits?**
  The kits are shipped in dry ice in a temperature controlled carton box. Each small carton measures 54 x 42 x 40 cm and weighs 25kg (including the dry ice) and can fit about 12 kits. For larger volume, we ship in specialised containers in a pallet.

- **How much is it to ship 1,000 tests?**
  The price varies depending on destination. Price can also fluctuate depending on availability of flights.

- **What countries can we export to?**
  We currently can export to most places worldwide, subject to availability of freight.

- **What should I do if I need a bulk order of a million test?**
  Due to the size of the order, please contact us to discuss the delivery schedule

- **What is the expected lead time?**
  Lead-time is dependent on the quantity of orders.

JN MEDSYS

The **ProTect™ COVID-19 PCR kit** provides all the necessary reagents for the accurate and sensitive detection of the Sars-CoV-2 virus using reverse transcription real-time polymerase chain reaction (RT-qPCR).

Contact sales@jnmedsys.com to order now or visit https://jnmedsys.com/kits/ to find out more.

Accurate

Made in Singapore

IVD

Provisional authorisation from Singapore HSA

Affordable

Based on US CDC protocol