

Source: The Straits Times, Front Page

Date: 16 May 2020

Singapore team invents test kit that detects virus antibodies in 1 hour

Local researchers have invented a test kit that can tell if someone has antibodies that neutralise the coronavirus – in just one hour. Such a test is crucial in the war against Covid-19 and can be used for contact tracing, assessment of herd immunity and vaccine development.

It was announced yesterday that

Duke-NUS Medical School would be co-developing and manufacturing the test kits together with biotechnology company GenScript Biotech Corporation and the Agency for Science, Technology and Research's Diagnostics Development Hub.

The kits specifically detect the

presence of neutralising antibodies, which play a key role in the body's defence against Covid-19.

When the coronavirus attacks a person, proteins on its shell attach themselves to cells in the body.

Neutralising antibodies bind themselves with the proteins before this happens, thus preventing the virus from infecting the cell.

Duke-NUS Medical School's Professor Wang Linfa, the kit's inventor, said tests currently available cannot be rolled out on a mass scale. His test, however, does not require a live virus or live cells. This means the test can be carried out much quicker, more safely, and on a

larger scale than existing ones.

Professor Teo Yik Ying, dean of the National University of Singapore's Saw Swee Hock School of Public Health, said: "This is a terrific development that significantly shortens the time taken to determine whether one has previously been infected and thus possesses the neutralising antibodies that may prevent a re-infection.

"Presently, there are a few unknowns with regard to whether prior infection immediately confers immunity against re-infection, and even if so, how long this immunity lasts. This test kit is a crucial resource in allowing the world to learn about these unknowns."

Timothy Goh

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Duke-NUS to co-develop, produce one-of-its-kind test kit with partners

New antibodies test, known as cPass, is available to hospitals in S'pore

Timothy Goh

Duke-NUS Medical School has come up with a test kit that takes just an hour, instead of the usual several days, to detect if someone has antibodies which can neutralise the coronavirus that causes Covid-19.

The new test, which The Straits Times first reported on earlier this month, can be used to see if potential vaccines work, to check what proportion of the population has already been infected and for contact tracing, which is critical as Singapore eases up on circuit breaker measures.

Known as cPass, the first-of-itskind test is available to hospitals here.

When someone is infected with the virus, the body produces hundreds, if not thousands, of different antibodies, which bind with the virus and are known as binding antibodies. However, not all of them can neutralise the virus. This is the role of neutralising antibodies, which bind with proteins on the virus' shell, preventing it from attaching itself to a person's cells.

There are currently Covid-19 tests for such antibodies, but they require the use of a live virus, cells, highly skilled operators, and complex laboratory procedures that require several days to obtain results.

In contrast, the cPass mimics key parts of the testing process chemically and does not require the use of a live virus or cells, said Duke-NUS' Professor Wang Linfa, at a virtual press conference yesterday. It can be carried out in most research or clinical labs, he added.

Prof Wang, who led the team that invented the test, is director of Duke-NUS' emerging infectious diseases programme. The role of antibodies in granting immunity from Covid-19 is currently still being researched.

But Prof Wang said: "We are in the phase of a pandemic where every nation is discussing an exit strategy... in most cases, neutralising antibodies equal protection, or are the best indicator of protection (from the virus)."

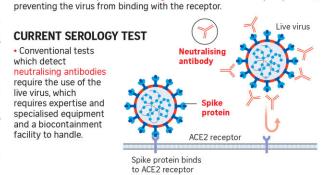
He added: "It's not a perfect indicator or biomarker for protection (from Covid-19), but it's as good as you can get right now... We have to be realistic, either you do nothing or do something. And if you want to do something, cPass is the only one that can do it."

Duke-NUS also announced yesterday that it will be co-developing and manufacturing the kit with biotechnology company GenScript Biotech Corporation and the Agency for Science, Technology and Research's Diagnostics Development Hub (DxD Hub).



The cPass test kit can detect antibodies capable of neutralising the coronavirus in patients in an hour, instead of the usual several days. The test can be used to see if potentia vaccines work, among other things РНОТО: **GENSCRIPT** BIOTECH CORPORATION

Sars-CoV-2, the coronavirus which causes Covid-19, infects people by binding the proteins on its shell – known as spike proteins – to a cell surface protein called the ACE2 receptor. Neutralising antibodies bind to the spike proteins,

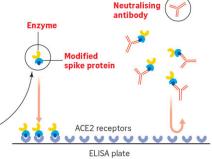


NEW SEROLOGY TEST: cPass™

Current versus new test

 Duke-NUS' test removes the need for a live virus by mimicking key parts of the process chemically. Instead of a human cell, the ACE2 receptors are spread on an ELISA plate.
 The key part of the

virus' spike protein is modified by pairing it with an enzyme that causes the mixture to change colour when it binds with the ACE2 receptors.



 If neutralising antibodies are present, they will prevent the modified spike protein – and the enzyme – from binding with the receptors, and there will be reduced or no colour change.

Sources: DUKE-NUS, GENSCRIPT, A*STAR STRAITS TIMES GRAPHICS



Professor Wang Linfa from Duke-NUS Medical School led the team that invented the test.

There are also plans to partner local biotech companies to increase the production of the test kits.

DxD Hub validated the kit with clinical samples of patients, and developed the manufacturing protocol and quality controls to secure its provisional authorisation by the Health Sciences Authority.

GenScript was responsible for proof-of-concept research, product design and development and optimisation, and will now play a central role in the commercialisation process using its global network and manufacturing capacity to launch cPass in Singapore and around the world.

Prof Wang said he came up with the idea for the kit on March 10. Proof of concept data was obtained 10 days later, and by April 24, kits were being shipped to the World Health Organisation's diagnostic labs for assessment.

cPass received provisional authorisation from the Health Sciences Authority on May 8.

"Fighting Covid-19 is like in wartime, where everything has to progress very fast... We could do

that due to this three-way partner-

ship," said Prof Wang.
Professor Peter Preiser, associate vice-president (biomedical and life sciences) at Nanyang Technological University, said the test kit would help identify those who were exposed to the virus but did not develop symptoms.

"The ability of this kit to determine the level of neutralising antibodies will provide valuable information on whether a person could be protected against a future infection. This information would be useful to identify the best approach on how to reopen the economy without risking a second wave of infections." he said.

Professor Teo Yik Ying, dean of NUS' Saw Swee Hock School of Public Health, called the test kit a "terrific development".

Knowledge gained from tests conducted by the kit could alter a country's strategies against Covid-19, he said, allowing them to know when to relax their posture.

Prof Teo noted that the test can be deployed in field settings with limited resources.

"This is important for countries where the rural regions typically do not have access to advanced laboratory set rups." he said

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He added: "Presently there are a few unknowns with regard to whether prior infection immediately confers immunity against reinfection, and even if so, how long this immunity lasts for. This cPass test kit is a crucial resource in allowing the world to learn about these unknowns."

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USEFUL FOR DEVELOPING NATIONS

The cPass developed by our team can be used for contact tracing, reservoir or intermediate animal tracking, assessment of herd immunity, longevity of protective immunity and efficacy of different vaccine candidates. It does not require a biosafety containment facility, which makesit immediately accessible to the global community, including many developing nations.

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PROFESSOR WANG LINFA, director of Duke-NUS' emerging infectious diseases programme.

KEY IN FIGHT AGAINST PANDEMIC

This innovative cPass diagnostic kit will be instrumental in supporting the fight against the global pandemic.



DR SIDNEY YEE, DxD Hub's chief executive.

HELPFUL TO GOVERNMENTS

The test results will be of great help to governments in guiding the resumption of work since it is extremely useful for quick and reliable surveillance to determine how widely a population has gained immunity to the Sars-CoV-2 virus. **Detection of** neutralising antibodies determines who can more safely go back to work or to more social life.

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DRZHU LI, chief strategy officer of GenScript.

Home tests may not be as accurate, sensitive as lab tests, cautions expert

Home test kits to detect Covid-19 have their limitations, cautioned Professor Wang Linfa, director of the emerging infectious diseases programme at Duke-NUS Medical School

"I know the general public thinks it's great to have a home kit, but...

I'm convinced you can never produce a home kit as accurate, as sensitive as a lab-based test," he said vesterday.

A recent attempt in the UK to use such kits on a mass scale fell flat, after the authorities announced that at least 3.5 million such kits were

too inaccurate to be used.

Earlier this month, the Health Sciences Authority (HSA) removed the online listings of a number of illegal test kits with inherent limitations which might have resulted in incorrect or misleading findings.

HSA said: "Self-directed use of sha

such unapproved test kits by consumers can lead to a false sense of security and risk the spreading of Covid-19 unknowingly due to false negative readings, or result in delay in seeking appropriate treatment."

Prof Wang said there might also be operational issues associated with such tests.

with such tests.

He said: "In a finger prick test, when you take blood and put it on the apparatus, do you do it yourself, or ask your brother, or your mother, or your grandfather to do it?"

"Because if that person's hand is shaking, you will have a drop of

blood in the air, and you may infect the person trying to help you if you're actually (infected)." Prof Wang acknowledged home

Prof Wang acknowledged home test kits may still have their uses – such as mass testing to see what proportion of a population is infected – but felt that it might not be helpful in other situations, such as letting individual people know whether they are immune to the virus.

"They have their uses. But you have to (know) what question you are asking," he said.

Timothy Goh