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Coronavirus •

S'pore test kit gets FDA nod

A Covid-19 antibodies test kit that was developed in Singapore is the first to be approved by the United States Food and Drug Administration (FDA). It can detect whether a person has antibodies that neutralise the coronavirus, can be used to test if vaccines work, check the proportion of the population that has already been infected, and assist in contact tracing.

SEE THE BIG STORY • A6

Duke-NUS Medical School's Professor Wang Linfa with the test kit called cPass, which was invented by a team he led. PHOTO: DUKE-NUS MEDICAL SCHOOL

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Singapore neutralising antibody test kit first to get FDA approval

Test kit can see if vaccines work, check level of infection in population, aid contact tracing

Timothy Goh

A kit that detects whether someone has antibodies which neutralise the coronavirus, invented by local researchers, has become the first of its kind to receive authorisation from the United States Food and Drug Administration (FDA).

Last Friday, the FDA said on its website that it had given emergency use authorisation for the kit, known as cPass.

cPass was invented by a team led by Professor Wang Linfa, director of Duke-NUS Medical School's emerging infectious diseases programme, and co-developed with biotech company GenScript Biotech Corporation and the Agency for Science, Technology and Research's (A*Star) Diagnostics Development Hub (DxD Hub).

It can be used to see if vaccines work, check what proportion of the population has already been infected, and assist in contact tracing by enabling the health authorities to retrace the steps of the virus.

cPass also does not require highly specialised equipment or training to use, and returns results in just an hour.

On Sunday, Prof Wang told The Straits Times that the FDA's approval was extremely significant not just for his team, but for Singapore as well.

He said: "To have the FDA approval as the first and only commercial kit to determine neutralising antibodies for Sars-CoV-2 in the world is a very high bar to reach. This is an incredible recognition for our team and the Singapore research and biotech landscape.

"The total critical mass of Singaporean biomedical R&D is less than 1 per cent of the (world's), and yet we are the international leader in this area for Covid-19."

FDA said it had previously issued emergency use authorisation to some 50 serology tests, which also detect antibodies.

But it added that these kits detect only the presence of binding antibodies, which bind to a virus but do not necessarily decrease its ability to infect and destroy cells.

On the other hand, neutralising antibodies, which cPass detects, are thought to prevent the coronavirus from infecting a patient's cells.

Prof Wang acknowledged – as he has on previous occasions – that just because someone has such antibodies does not mean he is immune to Covid-19.

But "it is agreed that neutralising antibodies definitely play an important role in granting immunity... They are the only biomarker for immunity that we can practically measure on a large scale", he said.

Dr Timothy Stenzel, director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Centre for Devices and Radiological Health, said the ability to detect such antibodies can help researchers gain insights into their impact on patients.

He said: "There are still many unknowns about what the presence of Sars-CoV-2 antibodies may tell us about potential immunity, but today's authorisation gives us another tool to evaluate those antibodies as we continue to research and study this virus."

Prof Wang said that following the FDA authorisation, Duke-NUS, DxD and GenScript will work to expand the application and geographic reach of the kits.

He added that cPass will also play an important role in the search for the origin of the coronavirus as it can detect neutralising antibodies in not just humans, but any species of animals as well.

He said his team has already obtained two grants from the World Health Organisation to work on this.

DxD's chief executive Sidney Yee said the hub is working with labs here to deploy the kits locally.

The Straits Times has approached the Health Ministry for information on this deployment.

Prof Wang said: "Considering we are expecting many vaccines to go into mass deployment in the next three to six months, the mass testing by cPass will form an integral part of the 'exit strategy' for Singapore and all nations globally."

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INCREDIBLE RECOGNITION

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PROFESSOR WANG LINFA, from Duke-NUS Medical School, who says the FDA's approval was extremely significant not just for his team, but for Singapore as well.

Professor Wang Linfa, director of Duke-NUS Medical School's emerging infectious diseases programme, with the cPass test kit. He led the team that invented cPass, which detects whether someone has antibodies that neutralise the coronavirus. PHOTO: DUKE-NUS MEDICAL SCHOOL

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