

Neutralising antibody test kit developed locally gets FDA nod

✔ **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 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' emerging infectious diseases programme, and co-developed with biotech company GenScript Biotech Corporation and the Agency for Science, Technology and Research's Diagnostics Development 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* 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."

Prof Wang acknowledged that just because someone has such antibodies does not mean they are 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."

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Professor Wang Linfa, director of Duke-NUS' emerging infectious diseases programme, with the cPass kit invented by his team.

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