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Singapore develops highly specific COVID-19 test to detect neutralizing Abs in 1hr

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This test would be instrumental in vaccine and therapeutic development as it is suitable for all antibody isotypes and can be used to determine antibodies in different animal species without any modification.

Singapore researchers have developed a unique and rapid SARS-CoV-2 surrogate virus neutralisation test (sVNT) to determine infection rate, herd immunity, predicted humoral protection, and vaccine efficacy during clinical trials.

According to a study published in *Nature Biotechnology,* the sVNT is capable of detecting the functional neutralising antibodies (NAbs) that can block the binding of the coronavirus spike protein to the angiotensin-converting enzyme 2 (ACE2) host receptor, which mimics the virushost interaction.

The sVNT was developed by scientists from Duke-NUS Medical School, in close collaboration with National Centre for Infectious Diseases (NCID), A*STAR's Institute of Molecular and Cell Biology (IMCB) Singapore, and GenScript Biotech. The scientists in Singapore and China validated the test across two patient cohorts, with a sample size of 250 from China and 375 from Singapore, achieving 99–100 per cent specificity and 95–100 per cent sensitivity.

"The sVNT kit can detect functional NAbs in an hour and differentiate them with binding antibodies (BAbs), without the need for live virus or a biocontainment facility. It also has the ability to detect total receptor binding domain (RBD)-targeting neutralising antibodies in patient samples, in contrast to most SARS-CoV-2 antibody tests published or marketed, which are isotype-specific. This makes the sVNT accessible to the broader community for both research and clinical applications," said Professor Wang Linfa, Director of Duke-NUS' Emerging Infectious Diseases programme. Prof Wang is considered among the most recognised international experts on emerging zoonotic viruses and is currently serving on multiple WHO committees on COVID-19.

Infection or immunity to the virus is diagnosed by the presence of NAbs in a patient's blood sample, which would block the

RBD–ACE2 interaction. There is an urgent need for a robust serological test that detects NAbs, for accurate assessment of COVID-19 infection prevalence and protective immunity at the individual and population level. Antibody tests, such as the conventional virus neutralization test (cVNT) and the pseudovirus-based virus neutralization test (pVNT), remain the only platforms for detecting NAbs. However, both require live viruses and cells, highly skilled operators, and days to obtain results. Other assays, such as the enzyme-linked immunosorbent assay (ELISA) detect Babs but are unable to differentiate between BAbs and NAbs.

The sVNT can also measure NAbs from different animals in a species-independent manner. It can therefore be a powerful tool to investigate the role of animals in the transmission of COVID19 from natural reservoirs to intermediate hosts.

“It is essential to measure the proportion, stability, and reprotection ability offered by COVID-19 antibodies in a patient. Neutralising antibody is the gold-standard serological platform to determine this. Unfortunately, the conventional virus neutralisation assay is laborious, time-consuming and requires Biosafety Level 3 for COVID-19. The sVNT developed by Prof Wang, in collaboration with the national COVID-19 PROTECT study, makes it accessible to all hospital laboratories, and is a great advance in COVID-19 serological assays,” said Associate Professor David Lye, Director, Infectious Disease Research and Training Office (IDRTO), and Senior Consultant, NCID.

Mr David Martz, Vice President of New Product Management, Life Sciences Group, at GenScript. “This is great news for scientists researching herd immunity and vaccine efficacy as they will now have access to this innovative research tool to accurately determine the level of neutralising antibodies in a population.”

The sVNT kit is commercialised by GenScript and offered worldwide under the brand cPass™ for research use only. GenScript has also filed for Emergency Use Authorisation with the US FDA and this filing is currently under review.