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FDA grants EUA to Singapore's SARS-CoV-2 neutralisation Ab detection kit

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GenScript USA Inc, the world's leading research reagent provider, has announced that the US Food and Drug Administration (FDA) has granted Emergency Use Authorisation (EUA) for the cPass™ SARS-CoV-2 Neutralisation Antibody (Ab) Detection Kit. This is the first commercially available test to specifically detect neutralising antibodies without the use of live virus. Neutralising antibodies, a subset of antibodies that are specifically able to block the ability of the virus to enter a cell, are widely recognised biomarkers of immunity. The test measures the presence of neutralising antibodies in any sample, from those from patients recovering from COVID-19 or those vaccinated against SARS-CoV-2.

The cPass™ kit utilises pure proteins that can be produced in a more reproducible way. The detection of the presence of neutralising antibodies can also be performed in most standard research or clinical diagnostic laboratories with short turnaround time (~1hr), making it broadly available and much more consistent between different facilities. Furthermore, a comparison of the direct clinical performance between the conventional live virus and the cPass™ assay shows results from both tests are strongly correlated.

"Unlike commercially available antibody-based tests that are routinely used for detecting prior exposure to the virus, the cPass™ kit can assess both prior exposure and the presence of neutralising antibodies in convalescent patients," said David Martz, Vice President, New Product Management, Life Science Group, GenScript, "The cPass™ kit is also a valuable tool for assessing vaccine performance. When vaccine companies start phase II or III trials, a standardised test that can detect neutralising antibodies will be needed for a large cohort of patients to evaluate the efficacy of vaccines within different populations and regions."

"The cPass™ test can also be used to screen animals for SARS-CoV-2 infection without modification, as it works in a species-independent manner," added Professor Linfa Wang from the Programme in Emerging Infectious Diseases of Duke-National University of Singapore Medical School, whose team pioneered the development of this novel test platform.