BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

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

November 10, 2020 | News

This is the first commercially available test to specifically detect neutralising antibodies without the use of live virus.



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.