BioSpectrum ASIA EDITION
the business of Bio & Health Sciences

GenScript receives FDA EUA to use cPass test in convalescent plasma screening

12 February 2021 | News

Data also supports use of novel test for immunity surveillance of recovered and vaccinated individuals

GenScript USA Inc., the world's leading life science research tools and services provider, announced today that it has received Emergency Use Authorization by the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) for use of the cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit in convalescent plasma screening. The cPass kit is the first FDA authorized test that specifically detects COVID-19 neutralizing antibodies without the use of live virus. Neutralizing antibodies block the ability of the virus to infect a cell and are widely recognized biomarkers of immunity.

"Since the cPass kit was authorized for emergency use by the FDA late last year, more than 300 organizations have adopted it to detect these critical antibodies," said David Martz, vice president of new product management in Life Science Group at GenScript. "We are excited to expand the use of this assay for convalescent plasma screening and look forward to bringing it to health care facilities to help increase the effectiveness of convalescent plasma treatment, ultimately helping patients to recover more quickly from COVID-19."

Convalescent plasma from patients who have recovered from COVID-19 may contain antibodies that fight the virus and is often used as a transfusion treatment for patients hospitalized with COVID-19 to speed recovery. However, successful treatment with convalescent plasma has been variable and new tools are needed to help gauge its effectiveness. The cPass kit identifies the functionality and level of antibodies in convalescent plasma prior to its use in treatment. Convalescent plasma that contains functionally active antibodies that neutralize COVID-19 - rather than binding antibodies that don't block the virus - could be more effective than plasma with low or no neutralizing antibodies.

"Neutralizing antibodies represent the first line of defense against SARS CoV-2 infection by blocking the virus from binding to host cells, thus inhibiting viral propagation. The cPass test specifically detects neutralizing antibodies post-vaccination to assure a robust, efficacious and prolonged immune response," added said Sean Taylor, scientific manager at GenScript. "A newly published article in the Journal of Clinical Microbiology describes and contrasts this novel, high-throughput assay with other commercial IgG-specific and live virus neutralization tests, making the case for its use in immunity surveillance of infected, recovered and vaccinated individuals as well as convalescent plasma screening."

The novel cPass test detects neutralizing antibodies in patient samples without the use of live virus. The conventional method to measure neutralizing antibodies in the patient samples requires the use of live cells and obtaining results takes multiple days and high safety level environment (BSL3). In contrast, the cPass kit utilizes pure proteins that can be performed in most

standard laboratories with short turnaround time (~1hr).

In addition to the FDA EUA, the cPass kit is CE marked in Europe, authorized by ANVISA in Brazil, Health Sciences Authorities in Singapore and Ministry of Health and Prevention in the United Arab Emirates. GenScript remains committed to supporting the global healthcare community in combatting COVID-19 infections, with a broad portfolio of research and development tools and diagnostics, including the novel cPass kit.