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MP Biomedicals, A*STAR co-develop rapid Ab test kit for SARS-COV-2

29 July 2020 | News

ASSURE® antibody test kit rapidly (15 minutes) identifies individuals who are asymptomatic, have mild symptoms or those who are previously exposed to SARS-CoV-2 virus

MP Biomedicals Asia Pacific Pte Ltd in collaboration with Singapore's A*STAR has developed ASSURE® SARS-CoV-2 IgG/IgM rapid antibody test kit to detect IgG and IgM antibodies in an individual infected by SARS-CoV-2. The kit produces accurate results in as little as 15 minutes and employs a lateral flow format similar to those used in home pregnancy tests. ASSURE® was developed and manufactured in Singapore. It can be deployed at or near the point of patient care and has been distributed to regions such as Europe, Africa and South America. MP Biomedicals intends to file for Emergency Use Authorization (EUA) from the US FDA for this product as well.

Studies have shown that levels of IgG and IgM appear to be correlated with the severity of COVID-19. By detecting IgG and IgM antibodies ASSURE® proves to be a good biomarker in samples such as human blood, plasma or serum for confirming positive or past infection.

Aligned with the current recommendation by the World Health Organization, point-of-care or rapid serology tests including ASSURE® rapid antibody test kit should not be used in the clinical diagnosis of COVID-19 infections or in the evaluation of persons with acute respiratory symptoms, especially within the first 14 days of illness. This is to avoid giving patients false reassurance that they do not have the infection, arising from a negative result. However, ASSURE® rapid antibody test kit can help to determine whether an individual has been previously exposed to the virus and generated antibodies as a result. This can help identify asymptomatic individuals or those with only mild symptoms who were not subjected to RT-PCR testing.

The technology behind the ASSURE® rapid antibody test kit utilizes proprietary synthetic SARS-CoV-2 proteins. These proteins bind to the IgG and IgM antibodies if the antibodies are present in the specimen samples. MP Biomedicals used it to develop the product based on their lateral flow platform. The Diagnostics Development (DxD) Hub, a national platform hosted by A*STAR's commercialization arm, A*ccelerate, co-developed the validation protocols and quality controls. The ASSURE® rapid antibody test kit was evaluated by the National University Hospital’s (NUH) Department of Laboratory Medicine, and demonstrated good results for both serum and whole blood. The sensitivity of the kit performed well as compared to commercial immunoassays, when tested with convalescent blood from recovered COVID-19 patients in the clinic.

The ASSURE® rapid antibody test kit has been granted Provisional Authorisation by the Health Sciences Authority (HSA) for

its intended use in Singapore.