BioSpectrum
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

Siemens Healthineers obtains first FDA EUA authorization for COV2G Ab test

05 August 2020 | News

The SARS-CoV-2 IgG Antibody Test offers the first EUA-authorized semi-quantitative assay to help clinicians assess the level of an individualâ??s immune response.

SIEMENS Healthineers

German fim Siemens Healthineers has announced that it has received FDA Emergency Use Authorization (EUA) for the SARS-CoV-2 IgG (COV2G) antibody (Ab) test. This is the first antibody test authorized with a semi-quantitative detection claim and the fifth antibody test from the company to receive EUA that offers sensitivity and specificity of greater than 99 %. The COV2G antibody test offers both a positive or negative result for IgG antibodies and reports a numerical result expressed as index value.

The COV2G antibody test, and all SARS-CoV-2 antibody tests from Siemens Healthineers, detect antibodies to S1RBD. Multiple potential vaccines in development for SARS-CoV-2 include the spike protein, specifically S1RBD—a key protein on the surface of the SARS-CoV-2 virus—within their focus.

The COV2G antibody test is available on an expansive installed base of analyzers installed in the U.S. and in countries that accept the CE mark worldwide. SARS-CoV-2 Total antibody assay [COV2T] is currently being used by several reputed clinical laboratories and institutions on the company's reliable high throughput automated chemiluminescence analyzers including Atellica Solution, ADVIA Centaur and Dimension EXL series for sero-surveillance.

SARS-CoV-2 Total antibody assay [COV2T] that detects both IgM and longer-lasting IgG antibodies is available in India since June 2020.