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Siemens Healthineers obtains first FDA EUA authorization for COV2G test

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The SARS-CoV-2 IgG Antibody Test offers the first EUA-authorized semi-quantitative assay to help cliniciansassess the level of an individual's immune response.

SIEMENS Healthineers

German firm Siemens Healthineers has announced that it has received FDA Emergency Use Authorization (EUA) for the SARS-CoV-2 IgG (COV2G) antibody 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.