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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.

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.