Siemens gets EUA for semi-quantitative antibody test

November 2020—Siemens Healthineers received FDA emergency use authorization for the SARS-CoV-2 IgG antibody test. It is the first antibody test authorized with a semiquantitative detection claim.

The test offers a positive or negative result for IgG antibodies and reports a numerical result expressed as index value. With this numerical value, clinicians can establish a baseline and be better equipped to assess changes of an individual's immune response to the SARS-CoV-2 virus, the company said in a statement. Comparison of numerical results will help determine how SARS-CoV-2 antibodies develop in an individual and persist over time.

The COV2G test offers 100 percent sensitivity and 99.9 percent specificity and is available on the Atellica Solution and Advia Centaur XP and XPT families of analyzers.

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