Siemens Healthineers offers two fully automated high-throughput serology assays (Total and IgG) that detect antibodies to the S1-RBD region.

- The spike protein and particularly the RBD are the most common target of vaccine designs. Extensive data shows the RBD region of SARS-CoV-2 S1 is both immunodominant and generates multiple antibodies with neutralizing activity.[1-18]
- In data from a published vaccine trial incorporating the entire spike protein in a viral vector, 94-100% of vaccinated subjects developed antibodies to the RBD and demonstrated neutralizing activity.[12] Similar production of anti-RBD IgG has also been reported for a vaccine trial utilizing trimeric spike RBD in a mRNA design.[26]
- As detection of anti-RBD in COVID-19 patients has been specifically linked to neutralizing activity, RBD-specific antibodies have been suggested as a surrogate marker for neutralization and putative immunity.[15]
- Unlike antibodies to the S2 region of spike or the N protein, evidence suggests that antibody to the SARS-CoV-2 S1-RBD will not significantly cross-react with antibody to the commonly circulating seasonal coronaviruses.[15, 19, 20] This may be an important element in differentiating a vaccine response from a current/recent seasonal coronavirus infection.
- The extremely high negative percent agreement (specificity) reported and independently validated for the Siemens Healthineers SARS-CoV-2 IgG assay* (99.9%) and Total assays† (99.8%) is an important factor for assessment of a vaccine response, as minimal false-positives would be anticipated.[22,23]
- In a head-to-head evaluation of 4 commercially available high-throughput SARS-CoV-2 antibody assays, only the Siemens Healthineers Atellica® IM Total antibody assay met both Sensitivity and Specificity targets.[24] Sensitivity is an important parameter for assessing an early immune response in vaccinated subjects.
- There is no indeterminate zone ("grey zone") with the Siemens Healthineers Total and IgG assays, eliminating the need for required repeat testing.

The Siemens Healthineers SARS-CoV-2 IgG (COV2G) assay is a semi-quantitative method

- Qualitative assays provide only a yes or no answer as to the presence of detectable antibodies, and signal strength cannot be directly utilized to assess antibody levels. A semi-quantitative assay provides an established linear reporting range and so directly reflects relative antibody concentration. For example, value of 5 reflects ~50% lower level compared to a value of 10.
- A semi-quantitative assay is important for assessing the level of vaccine response, changes with boost, and duration of response.
- A semi-quantitative assay can be utilized to identify a protective threshold should antibody levels dedicated by our assay prove correlation with protection. Since the Siemens assays measure antibodies to the same antigen that has been associated with neutralization in external studies (anti-RBD), the value may reflect a protected vs. vulnerable state.
- Data from convalescent plasma show that not all antibodies persist equally in recovered patients,[25] so it is important to understand the level of antibody specifically associated with neutralizing capabilities.
- The Atellica® IM and ADVIA Centaur® COV2G assay is linear over its entire analytical measuring range (0.50 - 20.00 Index).

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*Not available for sale in the U.S.

†This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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