

Q-PLEX™ SARS-CoV-2 HUMAN IgG (5-PLEX)

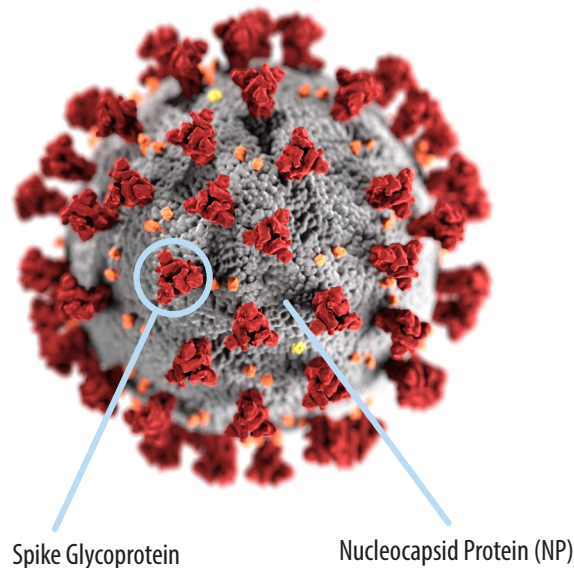


The Q-Plex™ SARS-CoV-2 Human IgG (5-Plex) array simultaneously recognizes human IgG antibodies to S1 and S2 subunits of the spike glycoprotein as well as antibodies specific for the nucleocapsid protein (NP).

QUANSYS 
B I O S C I E N C E S

Principle of the Assay

The Q-Plex™ SARS-CoV-2 Human IgG (5-Plex) array simultaneously recognizes human IgG antibodies to S1 and S2 subunits of the spike glycoprotein as well as antibodies specific for the nucleocapsid protein (NP). Whereas the spike glycoprotein is crucial for the virus' ability to attach to a cell, the NP is the primary protein that makes up the shell, or capsid, of the virus. The assay also detects antibodies towards the Fc region of sheep antibody to control for cross-reactivity between sample and the assay components. Finally, the kit uses detection of anti-human IgG as a positive control to ensure the assay performs to expectations.



| Analyte | Assay Type | Calibrator Range | Upper Limit of Quantification (ULOQ) | Lower Limit of Quantification (LLOQ) | Limit of Detection | Precision (Inter-assay) | Precision (Intra-assay) | Average Linearity |
|-------------------------|------------|---------------------|--------------------------------------|--------------------------------------|--------------------|-------------------------|-------------------------|-------------------|
| SARS-CoV-2 S1 | Indirect | 1,000 - 1.37 (U/mL) | 700 (U/mL) | 5.50 (U/mL) | 0.69 (U/mL) | 10% | 9% | 107% |
| SARS-CoV-2 S2 | Indirect | 1,000 - 1.37 (U/mL) | 700 (U/mL) | 5.50 (U/mL) | 0.69 (U/mL) | 12% | 9% | 104% |
| SARS-CoV-2 Nucleocapsid | Indirect | 1,000 - 1.37 (U/mL) | 300 (U/mL) | 5.50 (U/mL) | 0.69 (U/mL) | 9.5% | 13% | 103% |

**Intra-assay and inter-assay precision are calculated with n=20 and n=10 replicates, respectively.*

Why the nucleocapsid addition?

The ability to measure antibodies towards NP as well as S1 and S2 provides an opportunity to distinguish antibody responses caused by vaccination versus those caused by infection. All currently authorized SARS-CoV-2 functional vaccines, such as the Pfizer and Moderna mRNA vaccines and the Johnson and Johnson DNA vaccine, use the spike glycoprotein as the immunogen

to elicit a protective antibody response in the patient. Thus, detecting antibodies specific for NP in patients that have been vaccinated suggests that they have also been previously infected with SARS-CoV-2. This sort of tool is useful in seroprevalence studies, as well as in studies focused on elucidating the immune responses of vaccinated patients.

| SARS-CoV-2 Spike Proteins S1 and S2 IgG Assay vs. Molecular COVID-19 Test | | |
|---|--------------------|--------------------|
| N = 360 | Confirmed Positive | Confirmed Negative |
| IgG Test Positive | 33 | 0 |
| IgG Test Negative | 1 | 326 |

| SARS-CoV-2 Nucleocapsid IgG Assay vs. Molecular COVID-19 Test | | |
|---|--------------------|--------------------|
| N = 360 | Confirmed Positive | Confirmed Negative |
| IgG Test Positive | 32 | 19 |
| IgG Test Negative | 2 | 307 |

| | S1 and S2 vs. PCR | Nucleocapsid vs. PCR |
|---------------------------------|-------------------|----------------------|
| Sensitivity (PPA) | 97.1% | 94.1% |
| Sensitivity (NPA) | 100% | 94.2% |
| Positive Predictive Value (PPV) | 100% | 62.7% |
| Negative Predictive Value (NPV) | 99.7% | 99.4% |



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