Q-Plex™ SARS-CoV-2 Human IgG (4-Plex)

The Q-Plex™ SARS-CoV-2 Human IgG (4-Plex) is a multiplexed serological assay to be used in research and larger surveillance studies.

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Principle of the Assay

Quansys Biosciences' SARS-CoV-2 Human IgG (4-Plex) Q-Plex multiplex assay is a qualitative enzyme-linked immunosorbent assay that detects IgG antibodies to SARS-CoV-2 in human serum or plasma. SARS-CoV-2 is the novel coronavirus that causes COVID-19. The SARS-CoV-2 virus has several structural proteins including two spike proteins, S1 and S2. When an individual is infected with the SARS-CoV-2 virus, their immune system produces antibodies to these viral proteins. The typical immune response produces detectable antibody levels ~8-10 days following the onset of symptoms.

The SARS-CoV-2 Human IgG (4-Plex) Q-Plex Multiplex ELISA detects IgG antibodies to both the S1 and S2 spike proteins present in a blood sample. If antibodies are detected, the result will be considered positive. If antibodies are not detected, the result will be considered negative. The assay only detects IgG antibodies, not other classes of antibodies such as IgM or IgA.

The multiplex assay allows for simultaneous indirect ELISA on the following four printed spots:

1- SARS-CoV-2 Spike Glycoprotein (S1), a recombinant antigen which contains amino acids 1-674 of subunit 1. Spike S1 is expressed in mammalian HEK293 cells with a Sheep Fc-Tag.

2- SARS-CoV-2 Spike Glycoprotein (S2) is a recombinant antigen which contains the Spike subunit 2 protein, amino acids 685-1211. Spike S2 is expressed in mammalian HEK293 cells with a Sheep Fc-Tag.

3- Sheep Fc, is a negative control to ensure no cross-reactivity occurs between human IgGs in the sample and the Fc-Tag on the SARS-Cov-2 Spike proteins.

4- Anti-Human IgG is a positive control to ensure the kit performs and the IFU was followed correctly.

Assay Validation

The Quansys SARS-CoV-2 Human IgG (4-Plex) ELISA tests for IgG antibodies to either the SARS-CoV-2 S1 protein or the SARS-CoV-2 S2 protein. Our validation studies identified measurable improvement in clinical performance when results from the S1 and S2 assays are considered together rather than single assays (see assay validation data below). Quansys recommends that a sample should only be considered positive for the presence of SARS-CoV-2 reactive IgGs when antibodies reactive to both S1 and S2 are detected.

Negative samples, collected prior to August 2019, and known positive samples collected from individuals who tested positive for COVID-19 on a molecular test at least 14 days prior to sample collection were used to determine clinical sensitivity and specificity.

SARS-CoV-2 Spike 1 Protein IgG Assay vs. Molecular COVID-19 Test		
N = 576	**Confirmed Positive**	**Confirmed Negative**
IgG Test Positive	33	2
IgG Test Negative	1	540

The S1 reactive antibody assay demonstrates:
Estimated Sensitivity (PPA)= 97.1%,
Estimated Specificity (NPA) = 99.6%.

SARS-CoV-2 Spike 2 Protein IgG Assay vs. Molecular COVID-19 Test		
N = 576	**Confirmed Positive**	**Confirmed Negative**
IgG Test Positive	33	22
IgG Test Negative	1	520

The S2 reactive antibody assay demonstrates:
Estimated Sensitivity (PPA) = 97%,
Estimated Specificity (NPA) = 96%.

Evaluating the S1 and S2 simultaneously allows for greater clinical sensitivity and specificity.

SARS-CoV-2 IgG Assay (Combined Result from S1 & S2) vs. Molecular COVID-19 Test		
N = 576	**Confirmed Positive**	**Confirmed Negative**
IgG Test Positive	33	0
IgG Test Negative	1	542

The combined S1 & S2 reactive antibody assay demonstrates:
Estimated Sensitivity (PPA) = 97%,
Estimated Specificity (NPA) = 100%.

What Does PPA, NPA, and PPV Values Represent When Evaluating COVID-19 antibody tests.

Sensitivity (PPA) = Positive Percent Agreement. Suppose that a population who developed antibodies after being exposed to the COVID-19 virus received an antibody test. The percentage of that population who test positive for antibodies is the PPA. A test with low PPA tells people that truly have antibodies that none are present.

Specificity (NPA) = Negative Percent Agreement. Suppose that a population was never exposed to COVID-19 and therefore never developed antibodies. The percentage of that population who test negative is the NPA. A test with low NPA tells people that they have antibodies when none are truly present.

PPV = Positive Predictive Value. Suppose that a population tested positive for antibodies. The percentage of that tested population who truly have antibodies is the PPV. A test with low PPV says that antibodies are detected when none are truly present (false positive). Higher PPV means higher confidence in a positive result.

For example: Using a PPV of 99.7% as an example, one can assume that for every 1,000 positive test results, that 3 of them are false positive.

In the context of COVID-19, false positive results are especially concerning. Although time will tell whether the presence of COVID-19 antibodies indicates immunity, for many other diseases the presence of antibodies indicates a level of immunity. For such diseases, false positive antibody test results may cause an individual to modify their behavior and put themselves and potentially others at unnecessary risk for disease. Antibody tests with high PPV prevent such situations from occurring. When selecting an antibody test, patients should choose tests with high PPV.

How Does the SARS-CoV-2 (4-Plex) Antibody Test Compare to Other COVID-19 Antibody Tests on the Market?

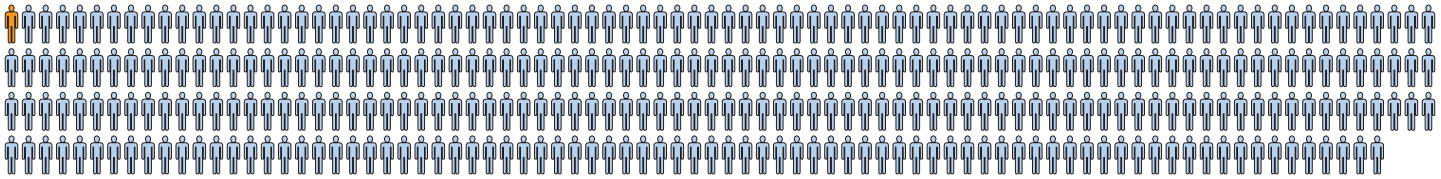
	Quansys Biosciences	FDA Requirements	Biotech Company 1	Biotech Company 2	Biotech Compnay 3	Biotech Company 4	Biotech Company 5	Biotech Company 6
Sensitivity (PPA)	97	90	100	100	99	97.6	93.8	93.5
Specificity (NPA)	100	95	99	99.6	99	99.3	96	94.4
PPV	99.7	48.6	84	92.9	84.4	88	55.2	46.8

Information collected from the U.S. Food & Drug Administration website, FDA.gov. Information current as of 05/22/2020.

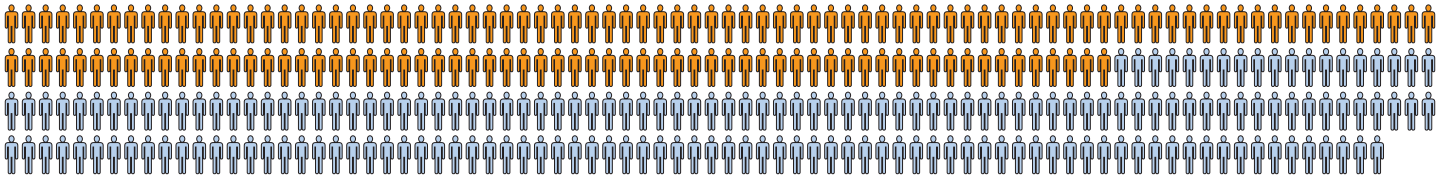
Quansys PPV = 99.7
333 positive test results with 1 false positive.

False Positive
Individual did not have COVID-19 and tested positive for antibodies.

True Positive
Individual had COVID-19 and tested positive for antibodies.



Biotech Company 5 PPV = 55.2
333 positive test results with 149 false positives



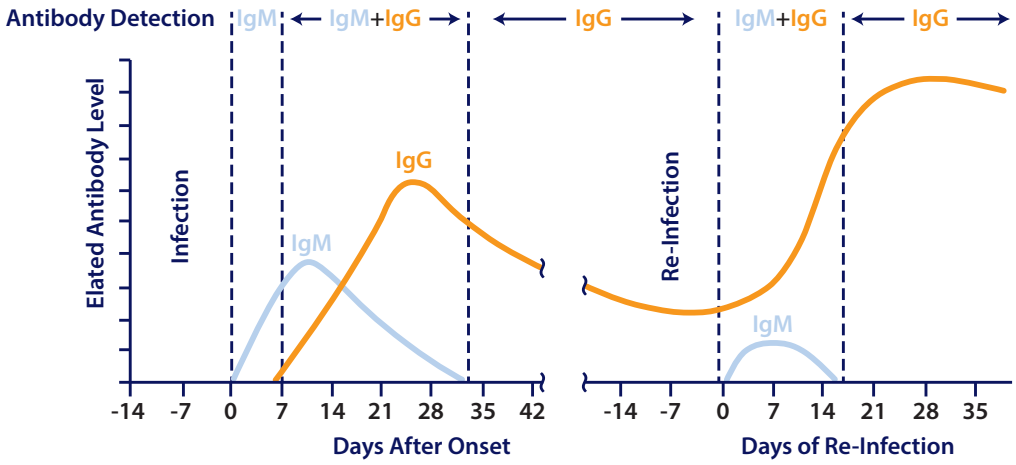
Catalog #	Product Name	
691649HU	Q-Plex SARS-CoV-2 Human IgG (4-Plex)	Call for pricing

Q-Plex SARS-CoV-2 Human IgG (4-Plex) details	
Species:	Human
Assay Type:	Indirect
Detection Method:	Chemiluminescent
Sample Type:	Human Serum, Plasma, Whole Blood
Assay Length:	2 hours, RT
Volume Required Per Well:	Min. 2 µL
Total Wash Steps:	3
Multiplex Format:	96-well solid plate
Within Plate Reproducibility:	8% CV
Between Plate Reproducibility:	10% CV
Catalog No:	691649HU

Q-View™ Imager generated image demonstrating typical sample results and reproducibility (samples shown were run in duplicates in each row). Samples can be run in duplicate or singlet allowing 45 to 90 unique samples to be run simultaneously on the same plate.

Why IgG

With the goal of producing a highly specific and precise assay, Quansys' R&D intentionally developed the SARS-CoV-2 antibody test to detect IgGs from non-acute disease phase individuals. IgM testing serves a purpose in understanding the initial immune response days after and during infection. However, known issues with IgM testing specificity coupled with the natural decline of IgM levels through disease course diminishes their utility for periods beyond the first few weeks of infection. Focusing on IgGs, simplifies interpretation, and more easily permits the flexibility of the Q-Plex platform to add additional viral antigens from the parent strain or mutant strains, while maintaining high levels of specificity. Moreover, the Q-Plex platform is built for quantitation and long term/ periodic monitoring of IgG levels will be possible when calibration standards are created.



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