SARS-CoV-2 Human IgG Quantitative (4-Plex)

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

QUANSYS BIOSCIENCES

Q-Plex™ Human IgG Quantitative (4-Plex) Array Key Attributes:

- Identifies individuals with an adaptive immune response to SARS-CoV-2, indicating prior infection
- 97% sensitivity, in comparison to the gold standard of PCR
- Assay recognizes IgG antibodies to subunits S1 and S2 of the viral Spike protein
- Reactivity to both S1 and S2 reduces false negative results, increasing assay sensitivity
- Results in 2 hours
- ELISA based assay
- 96-well format compatible with automation
- The Q-Plex SARS-CoV-2 Human IgG (4-plex) Assay is available for immediate use

Test Applications

- Vaccine development- quantify antibody response to spike protein subunits
- Determine antibody levels post COVID-19 recovery

- Determine COVID-19 prevalence in a defined population
- Quantify individual antibody response to an infection or a vaccination

General Information

The Q-Plex™ SARS-CoV-2 Human IgG (4-plex) array simultaneously recognizes human IgG antibodies to S1 and S2 of the spike protein. The spike protein recognizes a cell surface receptor to which the virus binds and inserts its "coding" information into the cell. Inclusion of the S2 subunit as a target, in this assay, decreases the false positive test rate, providing additional test accuracy. "High quality tests are essential as we work to better understand the SARS-CoV-2 pandemic. In addition, improved quality and accuracy of the assay is vital to correctly evaluate the spread of this pandemic, which varies across communities," noted Adam Brown, CEO of Quansys Biosciences.

Performance Characteristics

SARS-CoV-2 IgG Assay vs. Molecular COVID-19 Test		
N=254	Confirmed Positive	Confirmed Negative
IgG Test Positive	33	0
IgG Test Negative	1	220

Estimated Sensitivity (PPA)	97%
Estimated Specificity (NPA)	100%
PPV	100%
NPV	100%

Note: A sample is considered positive for reactive antibodies to SARS-CoV-2 when both the S1 and S2 concentrations are above their respective cutoffs.

Human SARS-CoV-2 S1 IgG Quantitative Assay

Assay Range:	1000 - 1.3 U/mL
Lower Limit of Detection:	1.3 U/mL
Negative/Positive Cutoff:	7 U/ml
Precision:	Intra-assay 9%, Inter-assay 13%
Linearity:	93-113%, average 102%

Human SARS-CoV-2 S2 IgG Quantitative Assay

Assay Range:	1000 - 1.3 U/mL
Lower Limit of Detection:	1.3 U/mL
Negative/Positive Cutoff:	24 U/ml
Precision:	Intra-assay 8%, Inter-assay 10%
Linearity:	92-107%, average 100%

Precision

Intra-assay (n=18)			Inter-assay (n=6)		
	Concentration (U/mL)	%CV		Concentration (U/mL)	%CV
Sample 1	6.5	12%	Sample 1	106.75	10.2%
Sample 2	118.2	7%	Sample 2	6.36	15.4%
Sample 3	1.1	6%	Sample 3	5.49	13.0%
Average Intra-assay CV:		9%	Average Inter-assay CV:		13%

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Dilutional Linearity

	% Recovery		
Dilution Factor	*1:100*	*1:200*	*1:400*
Sample 1	97%	100%	97%
Sample 2	100%	111%	113%
Sample 3	108%	101%	93%
Average % Linearity:			102%
% Linearity Range:			93 - 113%

	% Recovery		
Dilution Factor	*1:100*	*1:200*	*1:400*
Sample 1	104%	93%	95%
Sample 2	97%	106%	106%
Sample 3	107%	102%	92%
Average % Linearity:			100%
% Linearity Range:			92 - 107%

SARS-CoV-2 Kit

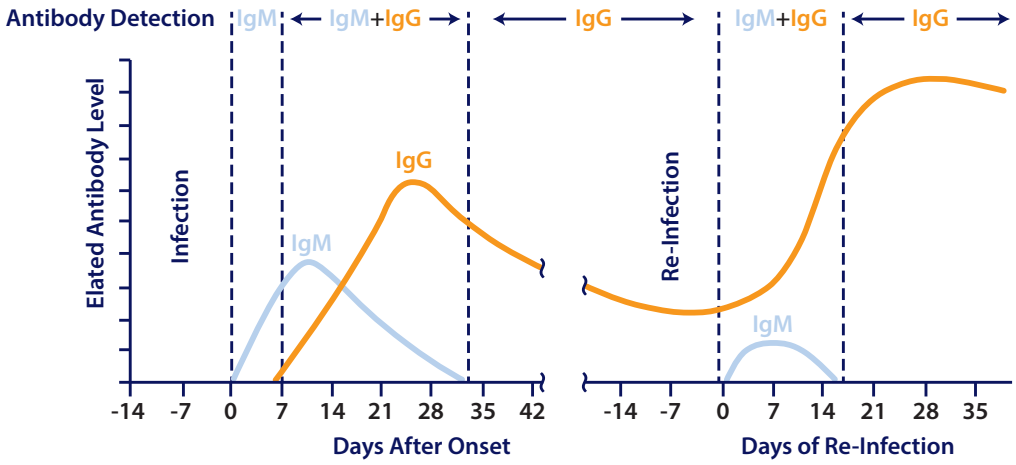
Catalog #	Product Name	
711649HU	SARS-CoV-2 Human IgG Quantitative (4-Plex)	Call for pricing

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 2µl
Total Wash Steps:	3
Multiplex Format:	96-well solid plate
Catalog No:	711649HU

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 40 to 80 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 established.



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