

BioPlex 2200 SARS-CoV-2 IgG Panel

Multiplex immunoassay to screen and differentiate IgG antibodies
to four SARS-CoV-2 structural proteins

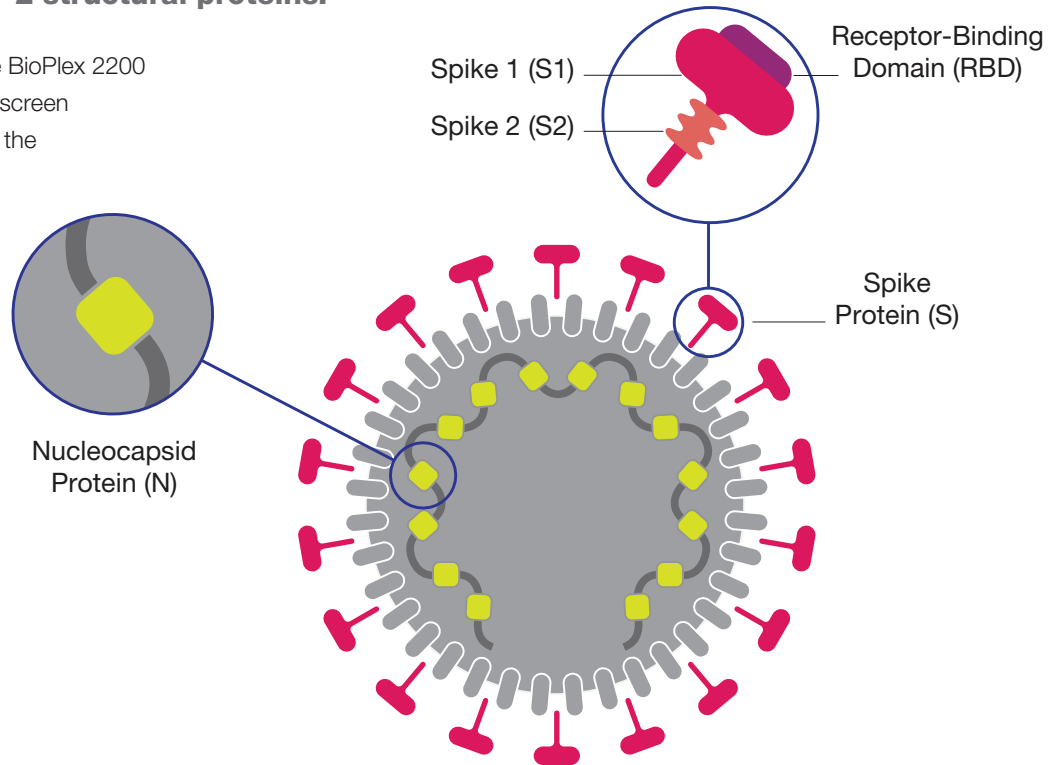


The Power of Multiplex Technology

The BioPlex 2200 SARS-CoV-2 IgG Panel provides a composite total result as well as individual antibody levels to four SARS-CoV-2 structural proteins.

By using multiplex technology, the BioPlex 2200 SARS-CoV-2 IgG Panel is able to screen and differentiate IgG antibodies to the receptor-binding domain (RBD), spike 1 (S1), spike 2 (S2), and nucleocapsid protein (N) of the SARS-CoV-2 coronavirus.

COVID-19 patients can create antibodies to any or all of the four antigen targets in the panel.



4 Corresponding Beads Coated with Target Antigens	Multiplex Panel Results
RBD	RBD (U/mL)
S1	S1 (U/mL)
S2	S2 (U/mL)
N	N (U/mL)
SVB	Internal QC Beads
ISB	

Composite Result

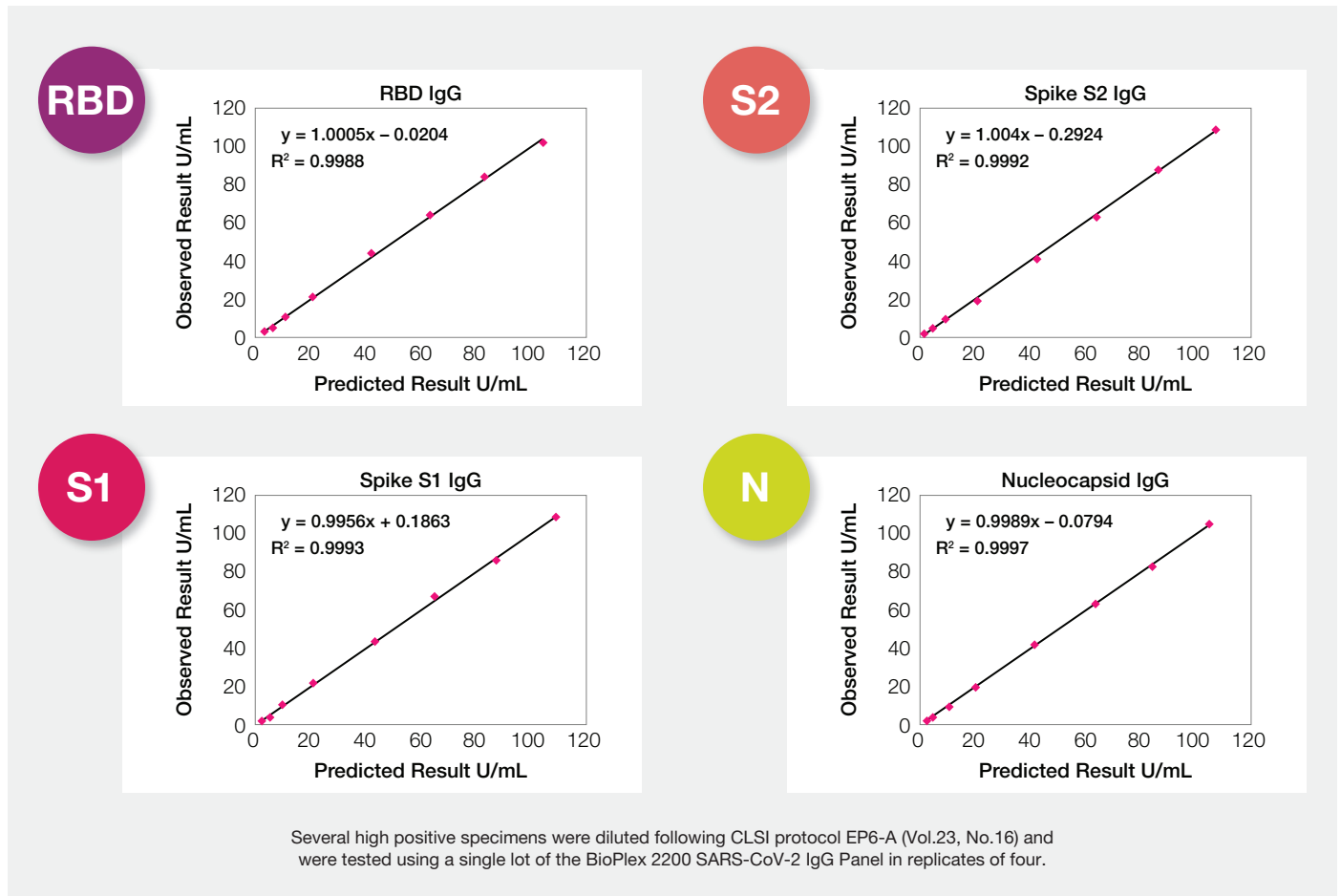
CoV-2 IgG Composite (Pos/Neg)

High Quality, Semi-Quantitative Results

- Qualitative SARS-CoV-2 IgG composite result
- Semi-quantitative results for each of the four SARS-CoV-2 IgG antibody targets

Semi-Quantitation of Four Target Antibodies

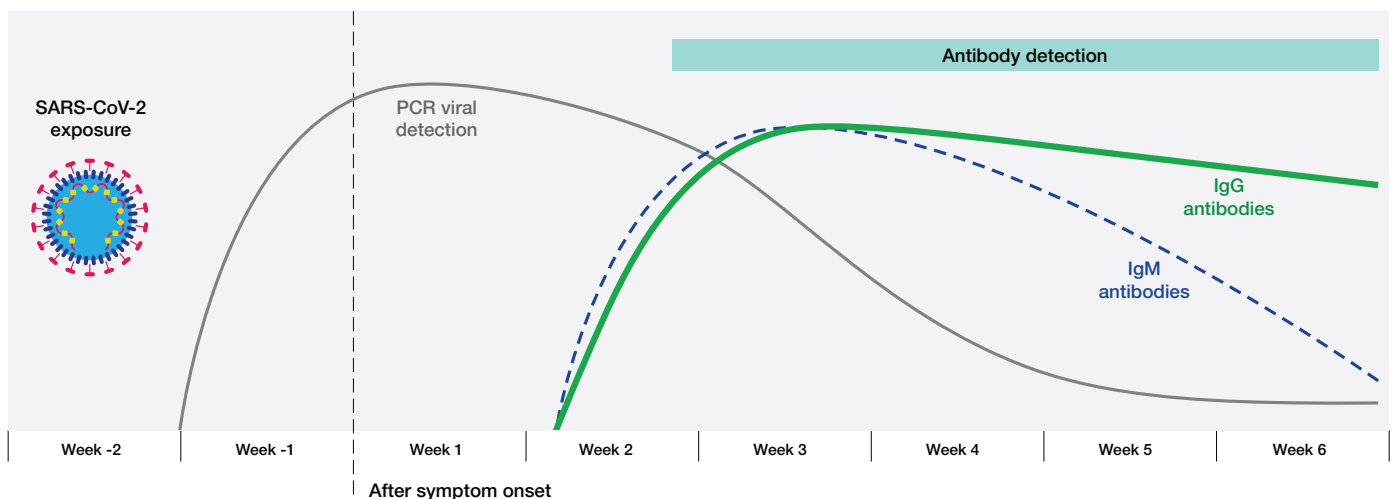
Excellent linearity and precision allow for confidence in the BioPlex 2200 SARS-CoV-2 IgG Panel results and for reliable longitudinal analysis of patient samples.



Humoral Response to the SARS-CoV-2 Virus

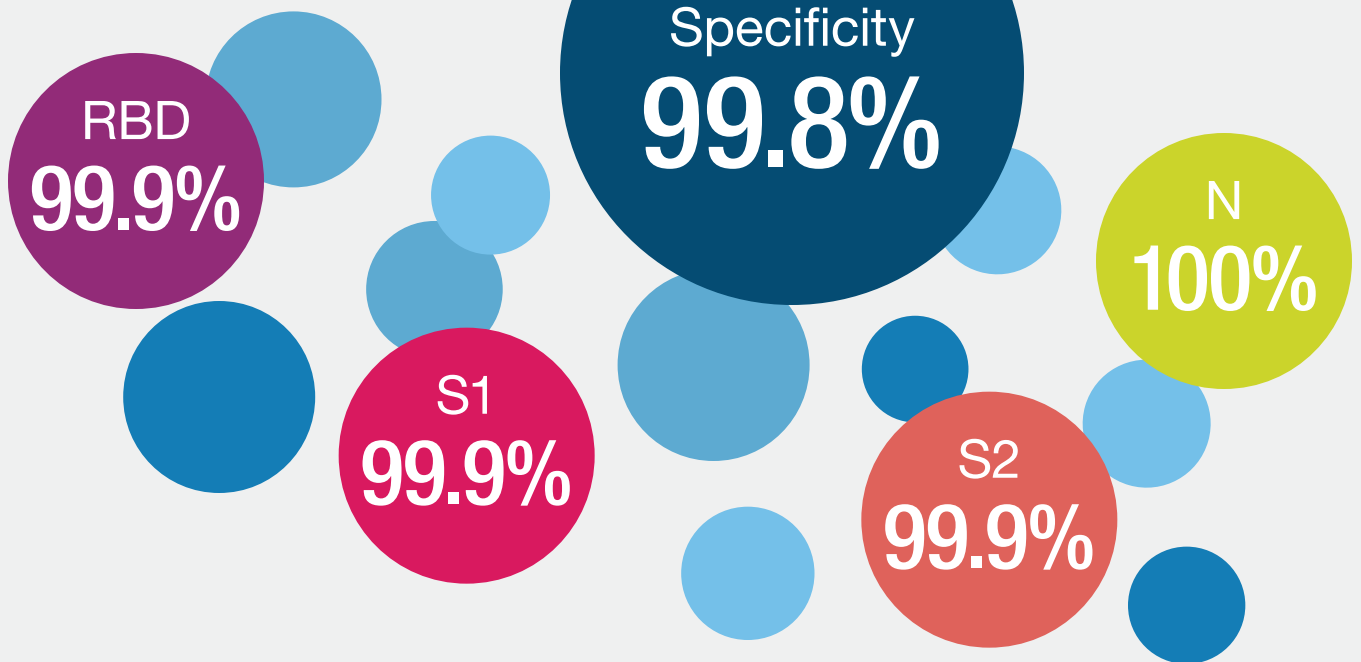
The BioPlex 2200 SARS-CoV-2 IgG Panel is designed for the exclusive detection of IgG antibodies

- IgG antibodies appear to rise nearly concurrently with IgM antibodies in COVID-19 patients^{1,2}
- IgG antibodies are the more specific antibody class, ideal for a semi-quantitative assay
- IgG antibodies are the more stable antibody class, ideal for longitudinal analysis of the immune response



Estimated course of SARS-CoV-2 markers over time¹

Clinical Specificity and Sensitivity



Clinical Specificity

Serologic methods have important public health uses for monitoring and responding to the COVID-19 pandemic. To do this, it is imperative that SARS-CoV-2 immunoassays minimize the chances of false-positive results, particularly in low prevalence populations.

The BioPlex 2200 SARS-CoV-2 IgG panel is the only fully-automated serological testing solution which can provide a composite SARS-CoV-2 IgG antibody result with high specificity and four individual assay results with $\geq 99.9\%$ specificity. Clinical specificity for the BioPlex 2200 SARS-CoV-2 IgG Panel was evaluated in a cohort of 1,015 health subjects and 542 blood bank donors.

Clinical Sensitivity

Clinical sensitivity was evaluated in a cohort of 246 patients at ≥ 15 days post symptom onset.

Clinical Sensitivity
96.3%

Cross-Reactivity








Sample Type	N	% Specificity
Anti-229 (alphacoronavirus)	20	100%
Anti-NL63 (alphacoronavirus)	20	100%
Anti-OC43 (betacoronavirus)	20	100%
Anti-HKU1 (betacoronavirus)	20	100%
2008 Flu Validation Panel	36	100%
Other Potential Cross-Reactants	962	99.7%
Cross-Reactivity Total	1,078	99.7%

Unique Serological Responses to SARS-CoV-2

The diversity of patient response to a SARS-CoV-2 infection is still not fully understood. With the BioPlex 2200 SARS-CoV-2 IgG Panel, semi-quantitative results will be provided for each of the panel's four SARS-CoV-2 target IgG antibodies as well as a composite qualitative positive/negative result. This will allow for the comparison of different patient immune responses and for tracking those responses over time for longitudinal analyses.

Heterogeneity of COVID-19 Patient Antibody Profiles

Example of three patient antibody profiles from PCR-positive patient samples

					Result
Patient 1 	(+) 19 U/mL	(-) 8 U/mL	(+) 27 U/mL	(+) 52 U/mL	Positive
Patient 2 	(-) 6 U/mL	(-) 2 U/mL	(+) 64 U/mL	(-) 9 U/mL	Positive
Patient 3 	(+) 23 U/mL	(+) 15 U/mL	(-) 2 U/mL	(+) 57 U/mL	Positive

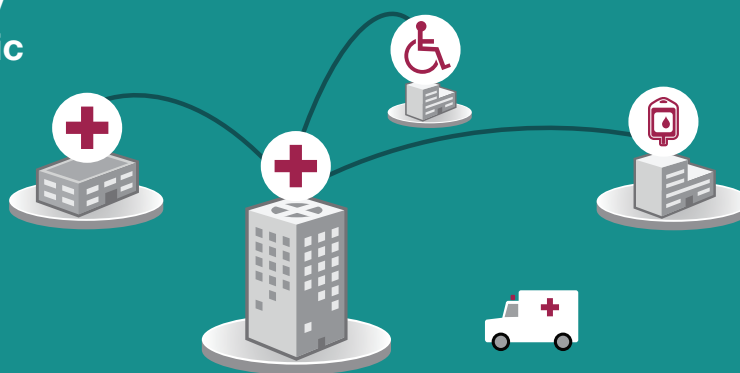
<10 U/mL = negative, ≥10 U/mL = positive, dynamic range = 1–100 U/mL

What the heterogeneity in SARS-CoV-2 immunity means, and how these intricacies translate to clinically actionable results are questions that scientists are only just beginning to answer. Bio-Rad is confident that a single antigen target is unlikely to hold the answers to these complex questions, but the four targets working together may. The immunological picture of SARS-CoV-2 infection is evolving rapidly, and the BioPlex 2200 SARS-CoV-2 IgG Panel can provide laboratories with the tools needed to help assemble this complex puzzle.

Role of the Clinical Laboratory During the COVID-19 Pandemic

Supporting Scientific Discovery

The semi-quantitative detection of the four antibodies targeted in the BioPlex 2200 SARS-CoV-2 IgG Panel can provide more information to clinical laboratories working to help support vaccine development,^{3,4,5} convalescent screening,^{3,6} and population testing.^{3,7}

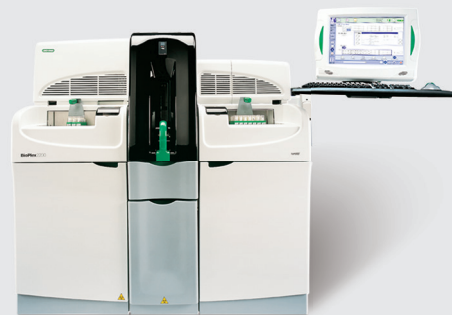


BioPlex 2200 System

More Results, Less Effort.

The BioPlex 2200 System provides the opportunity to maximize efficiency and result reporting flexibility for SARS-CoV-2 antibody testing.

With over 50 assays available today and more in development, the BioPlex 2200 System can help consolidate platforms for your autoimmune, infectious disease, and vitamin D testing.



BioPlex 2200 SARS-CoV-2 IgG Reagent Pack

Contains all the necessary reagents to process 200 samples per pack



BioPlex 2200 SARS-CoV-2 IgG Calibrator Set

Set of multiplexed and ready-to-use calibrators for SARS-CoV-2 IgG testing on the BioPlex 2200 System



BioPlex 2200 SARS-CoV-2 IgG Control Set

Set of negative and positive controls for SARS-CoV-2 testing on the BioPlex 2200 System

REFERENCES

- Sethuraman N et al. (2020). Interpreting diagnostic tests for SARS-CoV-2. JAMA 323(22):2249–2251.
- Borremans B et al. (2020). Quantifying antibody kinetics and RNA detection during early-phase SARS-CoV-2 infection by time since symptom onset." eLife 9:e60122.
- IDSA (2020). IDSA COVID-19 Antibody Testing Primer. <https://www.idsociety.org/globalassets/idsa/public-health/covid-19/idsa-covid-19-antibody-testing-primer.pdf>, accessed September 17, 2020.
- Jackson LA et al. (2020). An mRNA vaccine against SARS-CoV-2—preliminary report. [published online ahead of print, 2020 Jul 14]. New England Journal of Medicine. doi:10.1056/NEJMoa2022483.
- Krammer F and Simon V (2020). Serology assays to manage COVID-19. Science 368(6495):1060–1061.
- Pinto D et al., (2020). Cross-neutralization of SARS-CoV-2 by a human monoclonal SARS-CoV antibody. Nature 18:1–6.
- Pollán M et al. (2020). Prevalence of SARS-CoV-2 in Spain (ENE-COVID): a nationwide, population-based seroepidemiological study. The Lancet 396(10250):535–544.

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Ordering Information

Catalog No.	Description	
12014192	BioPlex 2200 SARS-CoV-2 IgG Reagent Pack, 200 tests	1 pack
12014193	BioPlex 2200 SARS-CoV-2 IgG Calibrator Set	1 set
12014195	BioPlex 2200 SARS-CoV-2 IgG Control Set	2 sets



Bio-Rad Laboratories, Inc.

For further information, please contact the Bio-Rad office nearest you or visit our website at www.bio-rad.com/diagnostics

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