

Bio-Plex Pro Human SARS-CoV-2 N/RBD/S1/S2 4-Plex Panels

High-Performance Multiplex SARS-CoV-2 Serology Assays for Antibody Response Profiling

MAGNETIC SEPARATION ENABLED

IgA, IgG, and IgM antibodies
against four SARS-CoV-2
antigens:

Nucleocapsid
Receptor binding domain
Spike 1
Spike 2

- Acute Phase Response
- Cancer
- Cardiovascular Disease
- Cytokines, Chemokines,
and Growth Factors
- Neurology
- Toxicology
- Infectious Disease
- Immunoglobulin Isotyping
- **Serology Assays**
- Signal Transduction



Researchers are interested in measuring antibodies specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to determine the exposure rates to the virus in a population, the humoral response to coronavirus disease 2019 (COVID-19) vaccines, and the immune response over time in patients with COVID-19 who have different levels of disease severity. The novelty of symptoms related to COVID-19 inspires a need for researchers to understand how long the humoral and cellular adaptive immune response lasts.

New Challenges, New Solution

These assays provide an efficient way for researchers to simultaneously profile isotype-specific antibody responses to four SARS-CoV-2 antigens: nucleocapsid, receptor binding domain (RBD), spike 1, and spike 2. These qualitative multiplexed immunoassays have been developed to support research validation and ensure high precision, specificity, and sensitivity.

A negative and a positive control are provided. Sample interpretation guidelines offer median fluorescence intensity (MFI) cutoff values to enable determination of which samples are positive for antibodies to a specific SARS-CoV-2 antigen. Representative cutoff values provided were based on 282 SARS-CoV-2-negative samples that were collected before December 2015. An isotype-specific positive control with recombinant antibodies specific to the SARS-CoV-2 antigens is included and can be used to compare MFI values across plates.

Research Assay Features

- Reduced turnaround time
- Reproducible results
- Specific and sensitive for SARS-CoV-2
- Flexible assay configurations
- Antigen-coupled beads and reagents for multispecies studies

Supports Rigorous Assay Validation

- Specificity (cross-reactivity)
- Inter- and intra-assay precision
- Correlation with COVID-19 and healthy serum and plasma samples

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Not for use in diagnostic procedures.

Bio-Plex SARS-CoV-2 Serology Assays Performance Characteristics

Representative Clinical Specificity and Sensitivity

Viral Antigens	Clinical Specificity, %*			Clinical Sensitivity, %**		
	IgA n = 282	IgG n = 282	IgM n = 282	IgA n = 59	IgG n = 65	IgM n = 68
Nucleocapsid	100	99	94	93	100	82
RBD	98	96	95	98	100	97
S1	100	99	96	93	98	99
S2	100	95	94	95	100	94

n, number of samples run.

* Clinical specificity was determined by testing 282 SARS-CoV-2-negative samples that were collected earlier than December 2015.

** Clinical sensitivity was determined by samples from patients who previously had a SARS-CoV-2-positive PCR result.

Assay and Representative Performance Characteristics

Parameter	IgA	IgG	IgM
Reactive species	Human	Human	Human
Compatible sample matrices	Serum, plasma	Serum, plasma	Serum, plasma
Analytical specificity, % analyte cross-reactivity	<5	<5	<5
Intra-assay precision, %CV	<10	<10	<10
Inter-assay precision, %CV	<15	<15	<15

CV, coefficient of variation.

Bio-Plex SARS-CoV-2 Serology Assays Cross-Reactivity Results

Cross-Reactivity Results

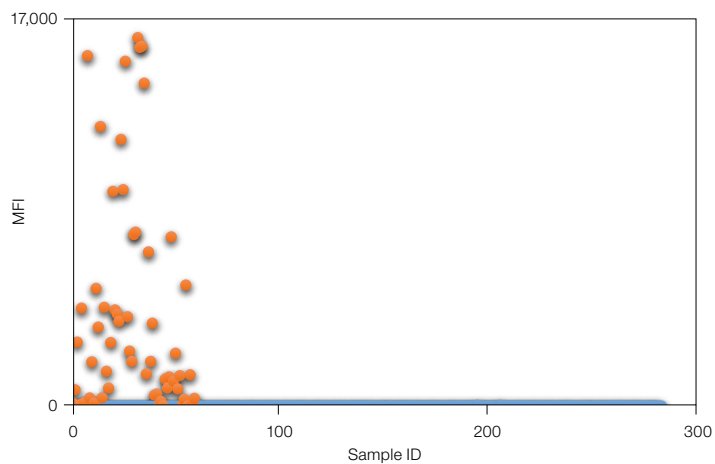
Antibody Positive Sera	Number of Samples	Positive	Negative		
			IgA	IgG	IgM
CMV	3	0	3	3	3
EBV	3*	0	2	1	2
Hepatitis A	1	0	1	1	1
Hepatitis B	1	0	1	1	1
HIV	1	0	1	1	1
HTLV	1	0	1	1	1
Mumps	2	0	2	2	2
Influenza A	2	0	2	2	2
Influenza B	2	0	2	2	2
RSV	2	0	2	2	2
TOXO	1	0	1	1	1
WNV	1	0	1	1	1

* One sample was tested for IgG and two samples were tested for IgA and IgM.

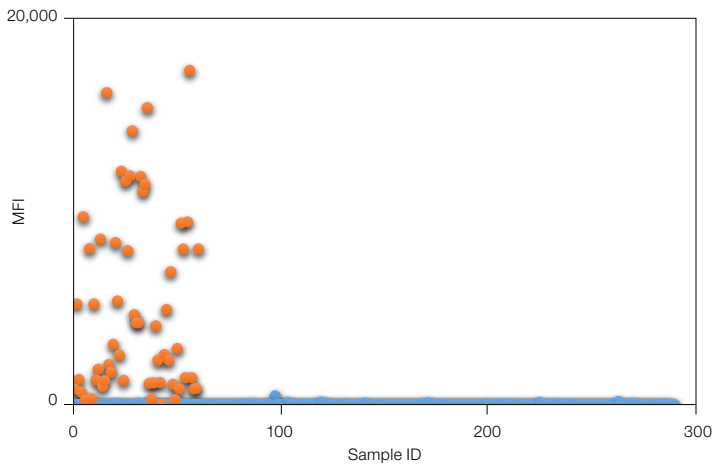
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IgA Antibody Profile of Healthy and Diseased Samples in COVID-19 Infection

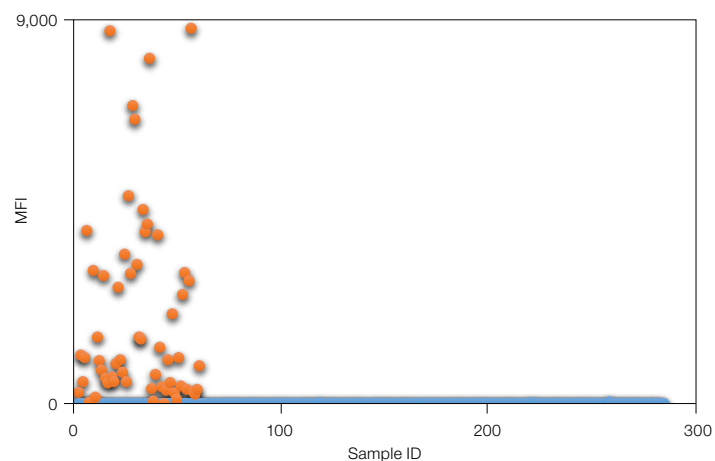
Nucleocapsid



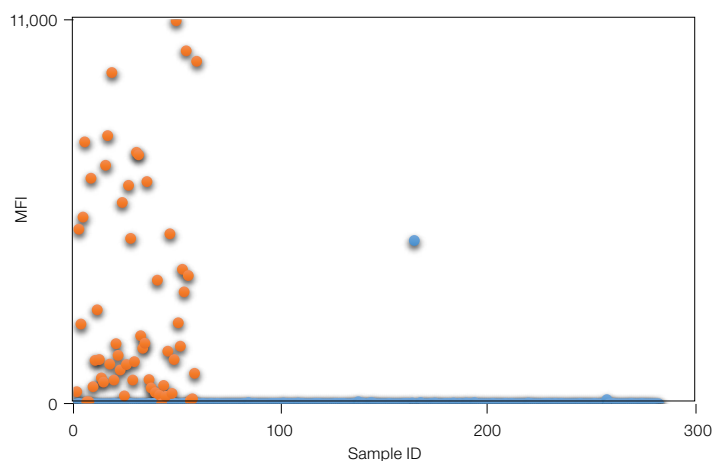
Receptor binding domain



Spike 1



Spike 2

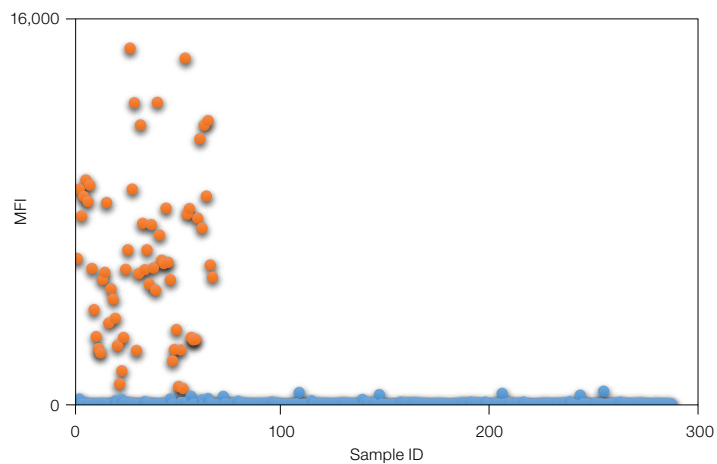


IgA antibody profile against four SARS-CoV-2 antigens. The diseased samples (n = 59) were obtained from donors who were SARS-CoV-2 positive. The healthy samples (n = 282) were collected from healthy donors prior to December 2015. Both serum and plasma samples were included in the study. Healthy (●); diseased (●).

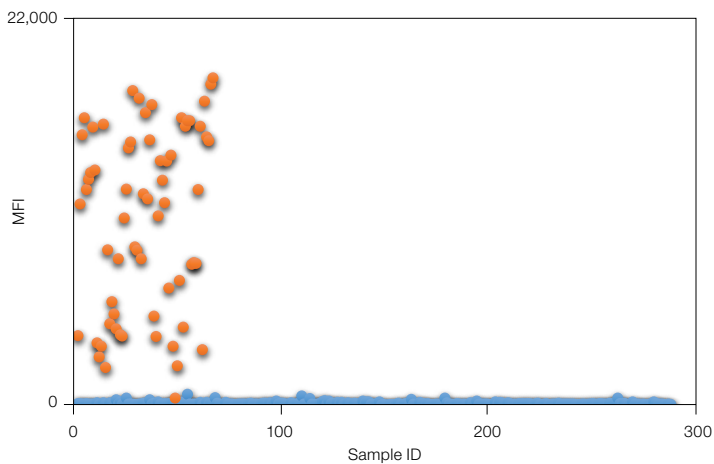
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IgG Antibody Profile of Healthy and Diseased Samples in COVID-19 Infection

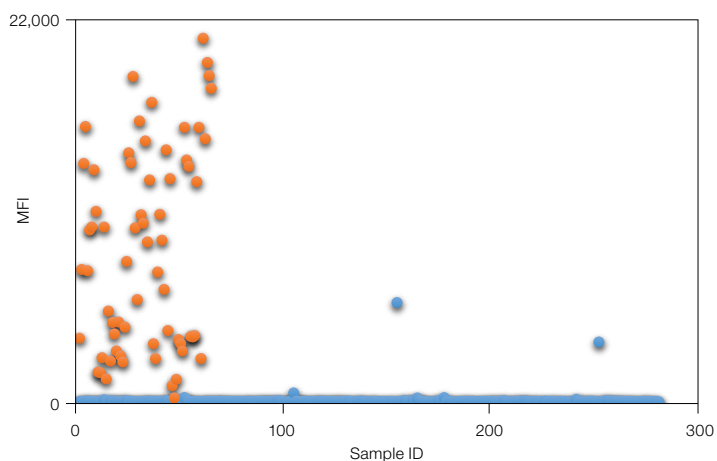
Nucleocapsid



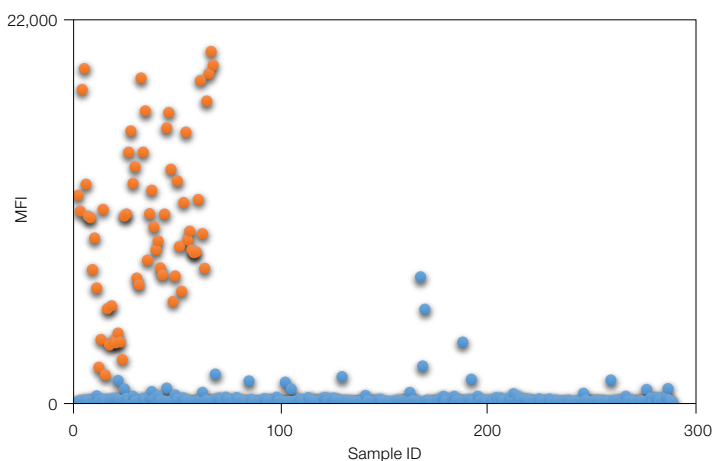
Receptor binding domain



Spike 1



Spike 2

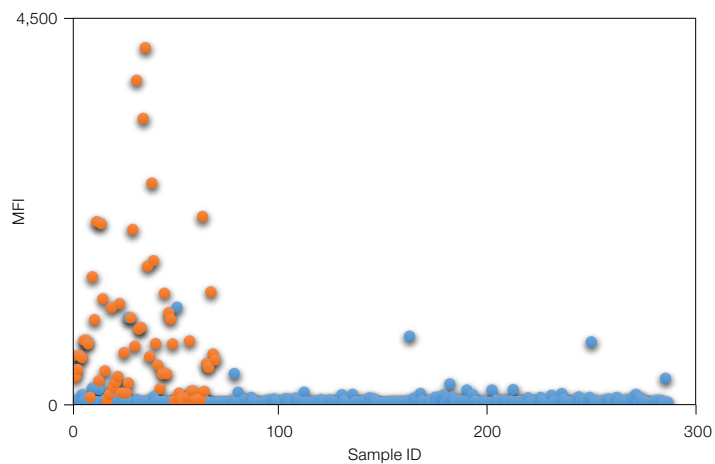


IgG antibody profile against four SARS-CoV-2 antigens. The diseased samples (n = 65) were obtained from donors who were SARS-CoV-2 positive. The healthy samples (n = 282) were collected from healthy donors prior to December 2015. Both serum and plasma samples were included in the study. Healthy (●); diseased (●).

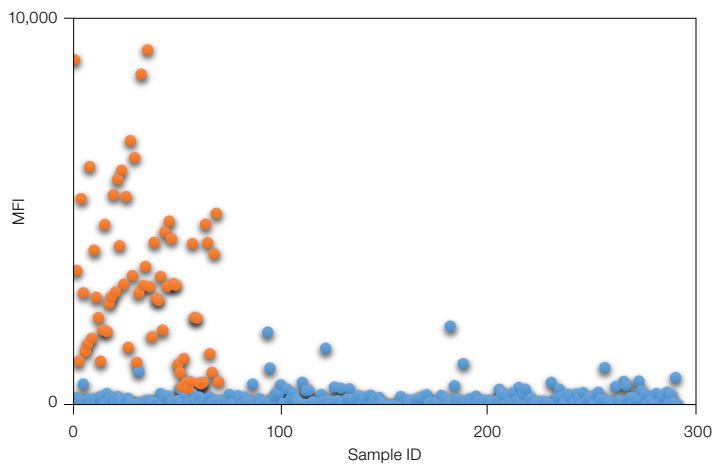
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IgM Antibody Profile of Healthy and Diseased Samples in COVID-19 Infection

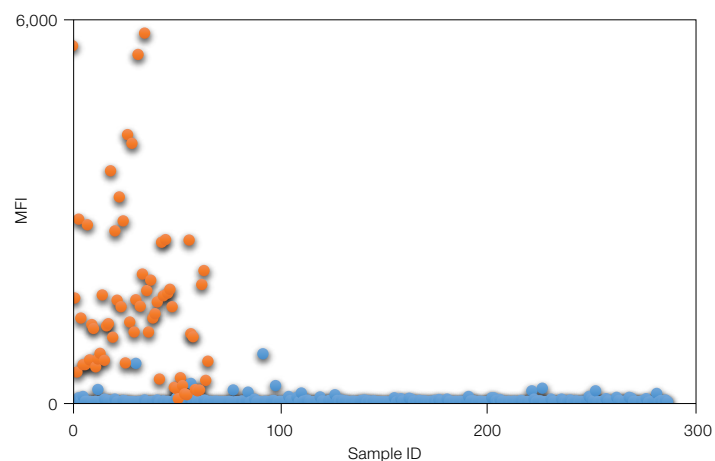
Nucleocapsid



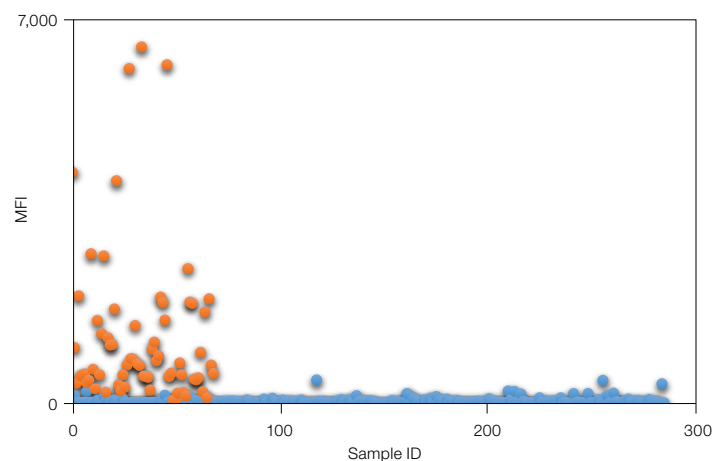
Receptor binding domain



Spike 1



Spike 2



IgM antibody profile against four SARS-CoV-2 antigens. The diseased samples (n = 68) were obtained from donors who were SARS-CoV-2 positive. The healthy samples (n = 282) were collected from healthy donors prior to December 2015. Both serum and plasma samples were included in the study. Healthy (●); diseased (●).

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Ordering Information

Catalog # Description

Multiplex Assays

12014665	Bio-Plex Pro Human IgA SARS-CoV-2 N/RBD/S1/S2 4-Plex Panel, 1 x 96-well
12014634	Bio-Plex Pro Human IgG SARS-CoV-2 N/RBD/S1/S2 4-Plex Panel, 1 x 96-well
12014666	Bio-Plex Pro Human IgM SARS-CoV-2 N/RBD/S1/S2 4-Plex Panel, 1 x 96-well

Singleplex Items

12014667	Bio-Plex Pro SARS-CoV-2 N/RBD/S1/S2 4-Plex Coupled Beads
12014773	Bio-Plex Pro SARS-CoV-2 Nucleocapsid Coupled Beads
12015406	Bio-Plex Pro SARS-CoV-2 Receptor Binding Domain Coupled Beads

Catalog # Description

Singleplex Items (continued)

12014771	Bio-Plex Pro SARS-CoV-2 Spike 1 Coupled Beads
12014772	Bio-Plex Pro SARS-CoV-2 Spike 2 Coupled Beads
12014669	Bio-Plex Pro Human IgA Detection Antibody
12014775	Bio-Plex Pro Human IgA SARS-CoV-2 Positive and Negative Controls
12014668	Bio-Plex Pro Human IgG Detection Antibody
12014774	Bio-Plex Pro Human IgG SARS-CoV-2 Positive and Negative Controls
12014670	Bio-Plex Pro Human IgM Detection Antibody
12014776	Bio-Plex Pro Human IgM SARS-CoV-2 Positive and Negative Controls
12014777	Bio-Plex Pro Human Serology Reagent Kit

Visit [bio-rad.com/SARS-CoV-2Serology](https://www.bio-rad.com/SARS-CoV-2Serology) for more information.

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