WE'LL SOLVE IT. TOGETHER.

Diagnosis | Confirmation | Surveillance | R&D

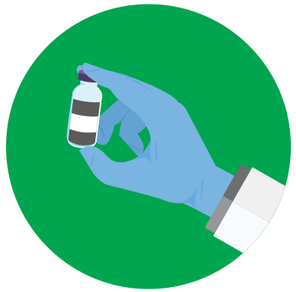
Bio-Rad has joined countless healthcare professionals, diagnostic laboratories and researchers to help end the COVID-19 global pandemic. We are proud to be your partner in delivering the needed tools for identifying individuals exposed to SARS-CoV-2 while also providing resources for research and therapeutic development.

Diagnosis & Confirmation

Our molecular solutions help clinicians diagnose infected individuals and a serology assay aids in the diagnosis of recent or prior SARS-CoV-2 infections.

Surveillance

Our serology assay helps identify people who have been exposed to SARS-CoV-2 and who have developed an adaptive immune response to the virus.

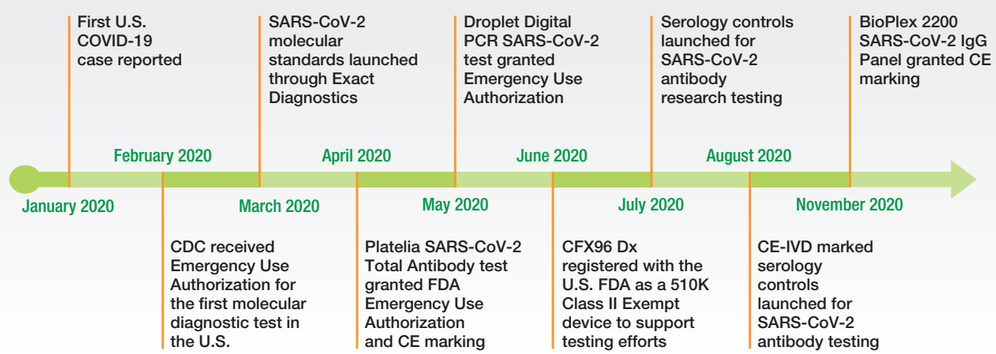


Research & Development

Our portfolio of tools help with coronavirus characterization, immune response studies, and vaccine and therapeutic development.

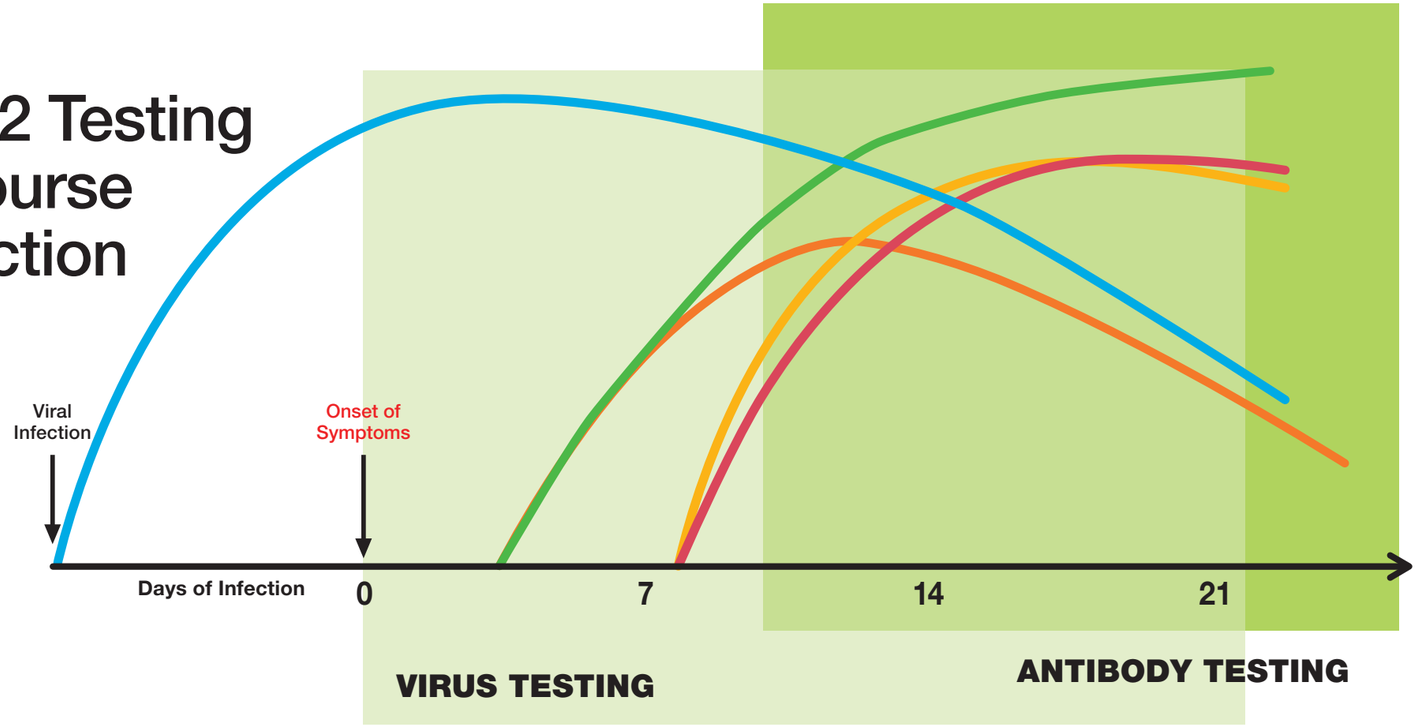
Bio-Rad's Response to COVID-19

As the world turned to fighting the COVID-19 crisis in early 2020, Bio-Rad's leading scientists rapidly joined the cause to accelerate the development of vitally needed SARS-CoV-2 solutions.



BIO-RAD

SARS-CoV-2 Testing Over the Course of Viral Infection



LEGEND

- Viral RNA or Antigen
- IgM Antibody
- IgA Antibody
- IgG Antibody
- Total Antibody
- Virus Testing Phase
- Antibody Testing Phase

Disclaimer: The Viral RNA or Antigen, IgM, and IgG profiles as well as the Virus Testing window are based off of analyses done by Sethuraman et al.[1] All other profiles represent well-known infections associated with viruses. It is unknown how long SARS-CoV-2 antibodies persist following infection.

References
1. Sethuraman et al. (2020) Interpreting Diagnostic Tests for SARS-CoV-2. JAMA 323(22):2249–2251. doi:10.1001/jama.2020.8259.

Molecular Testing

Molecular testing with Real-Time PCR (RT-PCR) or Droplet Digital PCR (ddPCR) detects viral RNA for SARS-CoV-2 and helps identify or confirm active COVID-19 infection to help clinicians diagnose, treat and manage patient care.

Molecular Test

SARS-CoV-2 ddPCR kit for qualitative detection of nucleic acids from SARS-CoV-2

Test Development & Validation

Trusted RT-PCR instruments and reagents are optimized for high-throughput viral detection.

EDX SARS-CoV-2 Molecular Standards
Molecular standards for complete assay validation including extraction, amplification, and detection are available for research use only as well as for CE-IVD use.

Additional Clinical Molecular and Serology Solutions

Bio-Rad offers molecular and serology test applications to assist with workforce and team protection, donor centers, and wastewater and environmental surveillance. (Applications may differ depending on your local regulations and recommendations.)

Serology Testing

Serology testing detects antibodies to SARS-CoV-2 in blood samples (serum and plasma) and helps identify infected individuals who have developed an adaptive immune response to the virus.

Serology Tests

The Platelia SARS-CoV-2 Total Ab immunoassay kit screens for total anti-nucleocapsid (N) antibodies (IgM, IgA, IgG) to SARS-CoV-2 and the BioPlex 2200 SARS-CoV-2 IgG Panel screens, differentiates, and semi-quantitates IgG antibodies to the SARS-CoV-2 RBD, S1, S2, and N proteins.

Quality Control

VIROTROL and VIROCLEAR SARS-CoV-2 are independent quality controls designed to monitor the performance of assays used for the qualitative determination of total IgG/IgM and IgG antibodies to SARS-CoV-2.

Molecular Testing Diagnosis & Confirmation

Real-Time PCR

Reliable RT-PCR molecular testing tools help expand COVID-19 diagnostic capabilities

Real-Time PCR is an accessible, high-throughput molecular testing option that is the method of choice for routine SARS-CoV-2 testing, as recommended by the FDA and WHO.

Trusted supplier of RT-PCR for >30 years

2,000+ CFX systems used for COVID-19 testing

24-hour Supermix room temperature stability

Supporting High-Throughput Testing

The Bio-Rad CFX RT-PCR Systems offer up to five-channel multiplexing in either a 96 or 384-well format. Both research use only and in vitro diagnostic versions are available. View offering >

Reliance One-Step Supermix

1	4x	5	24
tube format	concentrated	targets per sample	hours of room temperature stability

Reliance One-Step Multiplex Supermix has 24-hour room temperature stability for assembled reactions that allow labs to prepare multiple plates simultaneously to feed into high-throughput automated Real-Time PCR systems. Order here >

"The CFX384 Touch Real-Time PCR Detection System offers easy plate setup to analyze and review data as well as user-friendly software."

Greer Massey, Ph.D.
Senior Clinical Research Scientist
Assurance Scientific Laboratories

Reliance SARS-CoV-2 RT-PCR Assay Coming Soon!

Selection Guide

	RT-PCR	ddPCR
Are EUA tests available for SARS-CoV-2 diagnosis?	✓	✓
Can I use this technology to develop LDTs?	✓	✓
Which technology is best for quick turnaround time and high sample volumes?	✓	
Will this help reduce or resolve my indeterminate results* from qPCR?		✓
Which technology should I use if I need more precision and sensitivity?		✓

Droplet Digital PCR

Droplet Digital PCR (ddPCR) counts each target transcript to provide precise, accurate quantification for clear yes/no SARS-CoV-2 results

The high sensitivity and precision of ddPCR technology makes it well suited for screening patient samples with low viral load, including those from individuals in the early stages of infection.

Helping Resolve Indeterminate Results

Droplet Digital PCR is an absolute quantitative* method that individually counts target transcripts. This precise and accurate measurement can provide clear yes/no results when analyzing SARS-CoV-2 samples with low viral concentrations.

4,700+ ddPCR published manuscripts

450+ publications describe the clinical utility of ddPCR

Single-well test for SARS-CoV-2

SARS-CoV-2 ddPCR Kit

Optimized for use with the Bio-Rad QX200 or QXDx AutoDG ddPCR Systems for qualitative detection of nucleic acids for SARS-CoV-2. Order here >

- High sensitivity and precision in low viral abundance samples
- Resistant to inhibition often seen in RT-PCR testing
- Single-well test with three sequences aligned to CDC markers: SARS-CoV-2 N1 and N2 genes, human RPP30 gene

QX200 AutoDG ddPCR Systems

EXACT DX DIAGNOSTICS

SARS-CoV-2 Molecular Standards and Run Controls

To support COVID-19 assay validation, the SARS-CoV-2 Standards enable laboratories to validate testing of the entire process of a molecular assay including extraction, amplification, and detection. The standard contains five gene targets to support compatibility with all SARS-CoV-2 detection assays. Learn more >

*Quantitative values have not been evaluated by the FDA for clinical use.

Serology Testing to Aid in Diagnosis & Surveillance

Platelia SARS-CoV-2 Total Ab Immunoassay

The Platelia SARS-CoV-2 Total Ab immunoassay kit screens for total anti-nucleocapsid antibodies (IgM, IgA, IgG) to the coronavirus SARS-CoV-2, the virus associated with COVID-19. In just one test, total anti-SARS-CoV-2 antibodies can be detected in human serum or plasma samples to reliably determine an adaptive immune response to SARS-CoV-2.

Learn more >

Complementary to Molecular Testing

Serological assays are complementary to molecular tests as highly specific tests, essential for COVID-19 patient testing.

Testing on the System of Your Choice

The Platelia SARS-CoV-2 Total Ab assay is validated and recommended for use on the Bio-Rad EVOLIS system and manual systems (PR4100/PW40/IPS), and can easily be run on other validated manual and automated systems.

High Specificity
> 99%
Testing of 600 specimens
(Blood donors and hospitalized patients)

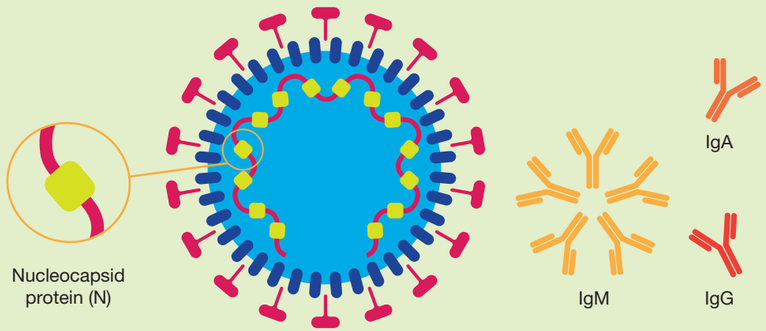
No Cross-Reactivity
Testing of 168 specimens
(Specimens positive for the 4 most common coronaviruses, EBV, CMV, RSV, flu vaccine, and upwards of 25 other medical conditions)

High Sensitivity*
Overall sensitivity: 98%
≤ 8 days: 92%
> 8 days: 100%
Testing of 50 patients

* Post onset of symptoms

Total Antibody Detection

The Total Ab immunoassay format is based on the detection of total antibodies – IgM, IgA, and IgG – against the nucleocapsid protein (N) of SARS-CoV-2, all in one test. The antibodies IgM and IgA are detectable in the case of acute SARS-CoV-2 infection while IgG is detectable in the recovery phase or post infection. Combining the results from these phases delivers a Total Antibody positive result.



Question & Answer

	Yes
Is the test authorized under FDA EUA to aid in the detection of SARS-CoV-2 total antibodies?	✓
Is the assay CE-IVD marked?	✓
Can this test be used to determine seroprevalence (or adaptive immune response)?	✓
Is the test compatible with most manual and fully automated microplate analyzers?	✓

Quality Control

Serological Controls for SARS-CoV-2 Antibody Testing

VIROTROL & VIROCLEAR
Independent quality controls designed to monitor the performance of testing procedures used for the qualitative determination of total (IgG/IgM) and IgG antibodies to SARS-CoV-2. Both are human plasma based.

VIROTROL SARS-CoV-2
An unassayed, reactive quality control for the qualitative determination of total (IgG/IgM) and IgG antibodies to SARS-CoV-2.

VIROCLEAR SARS-CoV-2
An unassayed, non-reactive quality control for the qualitative determination of total (IgG/IgM) and IgG antibodies to SARS-CoV-2.

Serology Testing – Semi-quantitative IgG

BioPlex 2200 SARS-CoV-2 IgG Panel

Semi-quantitative detection of antibody levels to four SARS-CoV-2 structural proteins

The BioPlex 2200 SARS CoV-2 IgG Panel simultaneously screens, differentiates, and semi-quantitates IgG antibody levels to the receptor-binding domain (RBD), spike 1 (S1), spike 2 (S2), and nucleocapsid (N) proteins to provide high quality data about a patient's immunological response to the SARS-CoV-2 virus. Learn more >

BioPlex 2200 System &
SARS-CoV-2 IgG Reagent Pack

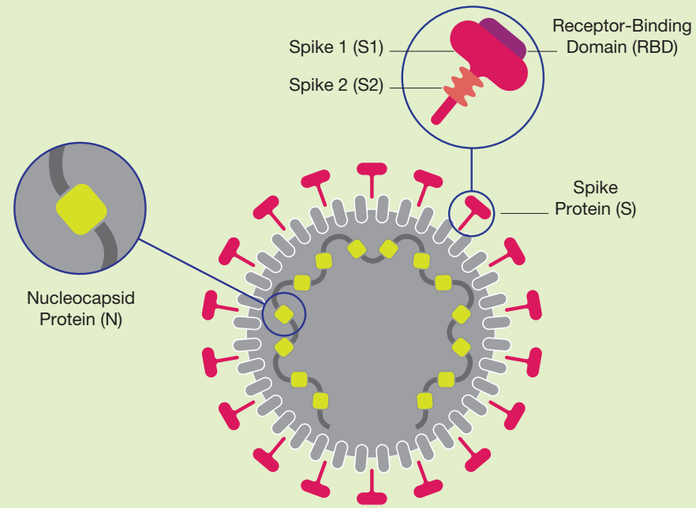
Semi-quantitative Results
U/mL

Clinical Specificity
99.8%*

Fully Automated BioPlex 2200 System

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



RBD* 99.9%

S1* 99.9%

S2* 99.9%

N* 100%

Clinical Specificity

The BioPlex 2200 SARS-CoV-2 IgG Panel is the only fully automated solution that can provide a composite result with high specificity and four individual assay results with ≥99.9% specificity. Individual assay specificities are denoted in their respective beads above.

Clinical Sensitivity

Each bead was designed and optimized to detect antibodies to one of the four SARS-CoV-2 structural proteins included in this panel. For each patient, if one or more of the beads is positive, the patient is SARS-CoV-2 IgG positive.

Clinical Sensitivity
96.3%†

Heterogeneity of COVID-19 Antibody Profiles

The immunological picture of SARS-CoV-2 infection is evolving rapidly, and the BIoPlex 2200 SARS-CoV-2 IgG Panel can provide laboratories with a tool to help assemble this complex puzzle.

*When tested in 1,015 healthy subjects and 542 blood bank donors.
† When tested in 246 patients at ≥15 days symptom onset.

Quality Controls and Standard for SARS-CoV-2 Testing

EDX SARS-CoV-2 Molecular Standard and Run Control for Research and Routine Testing

The **EDX SARS-CoV-2 Standards and Run Controls** are independent reference materials containing five gene targets of SARS-CoV-2 made of In-vitro transcript RNA quantified by ddPCR against a human genomic DNA background. The Standard is used as reference material for research testing of the novel coronavirus allowing laboratories to validate assays. Routine use of the unassayed run controls allows laboratories to evaluate the day-to-day and lot-to-lot variation of their molecular assay and test for operator proficiency. **Learn more >**

EXACT DIAGNOSTICS EDX

BIO-RAD QUALITY CONTROL

Unbiased results with independent SARS-CoV-2 Quality Controls to monitor serology assay performance and Molecular quality controls for routine testing.

VIROTROL and VIROCLEAR SARS-CoV-2 Serological Controls

VIROTROL & VIROCLEAR SARS-CoV-2 Serological Controls are independent, ready-to-use, liquid controls formulated with human plasma for the qualitative determination of total IgG/IgM and IgG antibodies to SARS-CoV-2.

Independent quality controls provide an unbiased, independent assessment of a test system or method performance because they are manufactured independently of the instrument, reagents, and calibrators. The VIROTROL and VIROCLEAR SARS-CoV-2 independent quality controls are compatible with a wide range of test systems and methods including automated immunoassay systems, EIA processors, manual EIA methods, and rapid tests. **Learn more >**

VIROTROL SARS-CoV-2

Reactive for SARS-CoV-2 Total IgG/IgM and IgG Antibodies

An unassayed, reactive serological quality control for the qualitative determination of total IgG/IgM and IgG antibodies to SARS-CoV-2.

- CE-IVD marked
- Unassayed reactive control
- Human plasma based
- 2-year shelf life at 2-8°C
- 60 day open-vial stability at 2-8°C

Analytes

SARS-CoV-2 Total IgG/IgM
SARS-CoV-2 IgG

VIROCLEAR SARS-CoV-2

Non-reactive for SARS-CoV-2 Total IgG/IgM and IgG Antibodies

An unassayed, non-reactive serological quality control for the qualitative determination of total IgG/IgM and IgG antibodies to SARS-CoV-2.

- CE-IVD marked
- Unassayed non-reactive control
- Human plasma based
- 2-year shelf life at 2-8°C
- 60 day open-vial stability at 2-8°C

Analytes

SARS-CoV-2 Total IgG/IgM
SARS-CoV-2 IgG

SARS-CoV-2 Research, Vaccine, and Therapeutic Development Tools & Services

To complement our clinical diagnostic testing solutions for COVID-19 Bio-Rad is dedicated to offering tools and services in these areas:

Research & Discovery

Characterization of SARS-CoV-2 is essential in understanding the viral mechanisms of infection, replication, pathogenesis, transmission, and immune response. Bio-Rad offers solutions that can improve the fundamental knowledge of SARS-CoV-2 and accelerate the discovery of vaccine or therapeutic targets.

- Genotype screening for host susceptibility
- Viral protein characterization
- Viral quantification and genomic variation
- Cellular immune response characterization
- Cytokine profiling

Vaccine Development

Vaccines represent the best hope for COVID-19 management. The pandemic's unprecedented health and economic impact are driving innovation to rapidly develop, evaluate, and produce a vaccine on a global scale. Bio-Rad offers solutions to advance vaccine development and expedite scale-up for your fight against COVID-19.

- Cell line development
- Immune-mediated response
- Viral vaccine titer and potency
- Impurities detection
- Biodistribution

Therapeutic Development

Expediting therapeutic development is critical in the fight against COVID-19. Whether you are developing an antibody, inhibitor, antiviral, or cell therapy, we have solutions to help accelerate your discovery and development without compromising the quality, efficacy, and safety of your therapeutic.

- Cell line development
- Immune-mediated response
- Impurities detection
- Viral load monitoring in clinical trials

Applications may differ depending on your local regulations and recommendations or in accordance with your local regulations and recommendations.

Ordering Information

CATALOG NO.	DESCRIPTION
Real Time PCR	
185-5195	CFX96 Touch Real-Time PCR Detection System ..... 1 system
185-5485	CFX384 Touch Real-Time PCR Detection System ..... 1 system
1845097-IVD	CFX96 Dx Optical Reaction Module ..... 1 each
1841000-IVD	C1000 Dx Thermal Cycler ..... 1 each
12010220	Reliance One-Step Multiplex Supermix ..... 1x 5 mL
Droplet Digital PCR	
186-4100	QX200 AutoDG Droplet Digital PCR System ..... 1 system
17005351	QXDx AutoDG ddPCR System ..... 1 system
12013743	SARS-CoV-2 ddPCR Kit ..... 600 tests
Molecular Standards and Run Controls	
COV019	SARS-CoV-2 Standard*..... 5 x 0.3 mL
COV000	SARS-CoV-2 Negative*..... 5 x 0.3 mL
COV019CE	SARS-CoV-2 Positive Run Control..... 5 x 0.3 mL
COV000CE	SARS-CoV-2 Negative Run Control ..... 5 x 0.3 mL
COVID-19 Serology Tests	
89818B	EVOLIS System ..... 1 system
93500B	EVOLIS Twin Plus System ..... 1 system
72710	Platelia SARS-CoV-2 Total Ab ..... 96 tests
12013798	Platelia SARS-CoV-2 Total Ab ..... 480 tests
COVID-19 Multiplex Serology Test	
660-0000	BioPlex 2200 System..... 1 system
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
COVID-19 Quality Controls	
VIROTROL SARS-CoV-2†	
200300A	Single Level/Tube ..... 1 x 4 mL
200305A	Single Level/Tube ..... 5 x 4 mL
200300B	Single Level/Tube ..... 1 x 4 mL
200305B	Single Level/Tube ..... 5 x 4 mL
200300C	Single Level/Tube ..... 1 x 4 mL
200305C	Single Level/Tube ..... 5 x 4 mL
VIROCLEAR SARS-CoV-2†	
200500	Single Level/Tube ..... 1 x 4 mL
200505	Single Level/Tube ..... 5 x 4 mL

* For research use only. Not for use in diagnostic procedures.
† Refer to myeinserts.com or the package insert of currently available lots for specific analyte and stability claims.

Product availability is subject to country regulation.

For further information, please contact the Bio-Rad office nearest you or visit our website at www.bio-rad.com/covid-19

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