



## COVID-19 Quality Control Solutions



# We'll Solve It. Together.

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.



## Molecular Testing

### EDX SARS-CoV-2 Molecular Standards

Molecular standards for complete assay validation including extraction, amplification, and detection are available for research use only.

### EDX SARS-CoV-2 Run Controls

The SARS CoV-2 Run Controls from the Exact Diagnostics product line contain genomic DNA and allow laboratories to evaluate the day-to-day and lot-to-lot variation of their molecular assay and test for operator proficiency.



## Serology Testing



### Independent 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.

### Serology Test

The Platelia SARS-CoV-2 Total Ab immunoassay kit screens for total anti-nucleocapsid antibodies (IgM, IgA, IgG) to SARS-CoV-2.

## Molecular Testing Products

Molecular Standards with five gene targets of SARS-CoV-2: *In-vitro* transcript RNA quantified by ddPCR against a human genomic DNA background.



### SARS-CoV-2 Standard and Negative

The Standard is used as reference material for research testing of the novel coronavirus allowing laboratories to validate assays. Additionally, the EDX SARS CoV-2 Standard can be validated for use by the laboratory as an external run control.

- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic matrix, including Human Genomic DNA (gDNA)
- 12 month shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C

For Research Use Only. Not for use in diagnostic procedures.

#### Targets

SARS-CoV-2 Genes  
E  
N  
ORF1ab  
RdRP  
S

#### Quantitation

Standard . . . . . 200,000 cp/mL  
Negative. . . . . 75,000 cp/mL



### SARS-CoV-2 Positive and Negative Run Controls

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.

- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic matrix, including Human Genomic DNA (gDNA)
- 12 month shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C

IVD/CE Mark. Available outside the US only.

#### Targets

SARS-CoV-2 Genes  
E  
N  
ORF1ab  
RdRP  
S

## Multiplex Molecular Controls

Whole organism SARS-CoV-2, Influenza A, Influenza B, Respiratory Syncytial Virus (A) run control, with a human genomic DNA background.

### SARS-CoV-2, Flu, RSV Positive and Negative Run Control

The EDX SARS-CoV-2, Flu, RSV Run Controls have been calibrated using digital PCR. Routine use of the Run Controls allow laboratories to evaluate day-to-day and lot-to-lot variation of their multiplex molecular assay and test for operator proficiency.

- Calibrated with digital droplet PCR
- Human genomic DNA (gDNA) background
- High quality matrix to ensure lot-to-lot reproducibility
- 2 year shelf life from date of manufacture

IVD/CE Mark.

#### Targets

##### Whole Organism:

Influenza A-H1N1  
Influenza B  
Respiratory Syncytial Virus A  
SARS-CoV-2



## Serology Testing Products

Serology quality controls that are optimized for all major total and IgG antibody assays and methodologies.



### VIROTROL SARS-CoV and VIROCLEAR SARS-CoV

Unassayed, reactive (VIROTROL) and non-reactive (VIROCLEAR) serological quality controls for the qualitative determination of total (IgG/IgM) and IgG antibodies to SARS-CoV-2.

- Human plasma based
- 2 year shelf life at 2-8°C
- 30 day open-vial stability at 2-8°C

For Research Use Only.

Not for use in diagnostic procedures.

#### Analytes

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

### VIROTROL SARS-CoV-2 and VIROCLEAR SARS-CoV-2

Unassayed, reactive (VIROTROL) and non-reactive (VIROCLEAR) serological quality controls for the qualitative determination of total IgG/IgM and IgG antibodies to SARS-CoV-2.

**Formulated into 3 separate classes to challenge the assay cutoff of a broad range of methodologies.**

- Human plasma based
- 2 year shelf life at 2-8°C
- 60 day open-vial stability at 2-8°C

IVD/CE Mark

#### Analytes

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

## Ordering Information

Catalog No. Description

### Molecular Testing

For research use only. Not for use in diagnostic procedures.

#### SARS-CoV-2 Standard

COV019 Standard . . . . . 5 x 0.3 mL

#### SARS-CoV-2 Negative

COV000 Negative . . . . . 5 x 0.3 mL

IVD/CE Mark. Available outside the US only.

#### SARS-CoV-2 Positive Run Control

COV019CE Positive Control . . . . . 5 x 0.3 mL

#### SARS-CoV-2 Negative Run Control

COV000CE Negative Control . . . . . 5 x 0.3 mL

IVD/CE Mark.

#### SARS-CoV-2, Flu, RSV Positive and Negative Run Control

COVFLU Positive . . . . . 5 x 1.0 mL

COVFLUNEG Negative . . . . . 5 x 1.0 mL

Refer to myeinserts.com or the package insert of currently available lots for specific analyte and stability claims.

Catalog No. Description

### Serology Testing

For research use only. Not for use in diagnostic procedures.

#### VIROTROL SARS-CoV

12013881 Single Level/Tube . . . . . 1 x 4 mL

#### VIROCLEAR SARS-CoV

12013883 Single Level/Tube . . . . . 1 x 4 mL

IVD/CE Mark.

#### 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

## List of Popular Instruments, Assays, Methods and Bio-Rad Controls

Manufacturer/Instrument	Assay/Method	Product Name Catalog Numbers	VIROTROL SARS-CoV-2			VIROCLEAR SARS CoV-2
			200300A 200305A	200300B 200305B	200300C 200305C	200500 200505
Abbott ARCHITECT i System	SARS-CoV-2 IgG		●			●
Babson Diagnostics	aC19G1 SARS-CoV-2 IgG		●			●
Beckman Coulter	Access SARS-CoV-2 IgG		●			●
bioMérieux VIDAS	Anti-SARS-CoV-2 IgG		●	●		●
Bio-Rad Laboratories	Platelia SARS-CoV-2 Total Ab		●			●
Cellex Rapid Test	qSARS-CoV-2 IgG/IgM Rapid Test		●			●
Diasorin Liaison	SARS-CoV-2 S1/S2 IgG		●			●
EuroImmun	Anti-SARS-CoV-2 ELISA IgG		●			●
Ortho VITROS	Anti-SARS-CoV-2 IgG		●			●
ECi/ECiQ/3600/5600/XT/7600	Anti-SARS-CoV-2 Total				●	●
Roche Cobas e411/e601/e602/e801	Elecsys Anti-SARS-CoV-2			●		●
Siemens Atellica IM	SARS-CoV-2 Total (COV2T)			●		●
Siemens ADVIA Centaur	SARS-CoV-2 Total			●		●

The controls listed here include analyte(s) that may be appropriate for use on the test systems noted.

Content is provided as a guide and for informational purposes only. Results and specific performance characteristics may vary with different manufacturers' test kits and assay procedures, different lots of the same test kit, and different lots of the control material. Please note that not all products may be available in all countries. Refer to the product insert for current product claims.

A Complete COVID-19 Offer.  
We make the tools. You'll win the fight.  
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