



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.

Molecular Testing Products

Molecular Standard and Run Controls to monitor presence of E, N, ORF1ab, RdRP and S Genes of SARS-CoV-2.



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)
- 18 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)
- 18 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 manufactured with targets established using ddPCR. 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.

- Manufacturing targets established using ddPCR
- 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 major total and IgG antibody assays and methodologies.

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

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

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

BIO-RAD

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

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