

EDX SARS-CoV-2 Negative Summary	
Catalog Number	COV000
Nonreactive Analytes	SARS-CoV-2
Concentration of Human gDNA	75,000 cp/mL
Matrix	Synthetic Matrix, including Human Genomic DNA (gDNA)
Preservative	Sodium Azide
Storage	-20°C or Below
Fill Volume	0.3 mL
Number of Vials Per Kit	5 Vials
Number of Uses	Single Use
Shelf Life	18 Months from Date of Manufacture
Precautions	Biological Risks
Regulatory Status	For Research Use Only. Not for use in diagnostic procedures.

INTENDED USE:

The EDX SARS-CoV-2 Negative is intended for use as a negative reference material for research testing of the novel coronavirus allowing laboratories to validate assays.

Additionally, EDX SARS-CoV-2 Negative can be validated for use by the laboratory as a negative external run control.

PRODUCT DESCRIPTION:

The EDX SARS-CoV-2 Negative is negative for SARS-CoV-2. The product is formulated in a synthetic matrix and contains human genomic DNA (75,000 cp/mL), allowing laboratories to validate the entire process of a molecular assay including extraction, amplification, and detection.

PROCEDURE:

The EDX SARS-CoV-2 Negative requires an extraction step. The control must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction technique.

The EDX SARS-CoV-2 Negative is not a substitute for the manufacturer's kit controls provided with the assay. EDX SARS-CoV-2 Negative is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations.

STORAGE AND HANDLING:

The EDX SARS-CoV-2 Negative should be stored at -20°C or below.

Thaw EDX SARS-CoV-2 Negative at room temperature and vortex briefly prior to use.

Once thawed, EDX SARS-CoV-2 Negative is stable for 24 hours when stored at 2-8°C. Any remaining materials must be disposed of after one use. Do not reuse. Do not dilute.

Do not use EDX SARS-CoV-2 Negative beyond the expiration date.

LIMITATIONS:

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

WARNINGS AND PRECAUTIONS:

The EDX SARS-CoV-2 Negative should be considered biohazardous. Universal precautions and proper disposal should be practiced¹. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.

Discard product if packaging is damaged or leaking. Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution. Dispose of all materials and liquids used in the procedure as if they contained pathogenic agents.

REFERENCES:

¹ Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission

SYMBOL REFERENCES:



Catalog Number



Lot Number



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



Biological Risks



Do not reuse



Expiration Date



Upper Limit of Temperature



Manufacturer



Caution



Consult Instructions for Use



Exact Diagnostics
100 South Jones Street, Suite 100,
Fort Worth, Texas 76104
United States

BIO-RAD

**Bio-Rad
Laboratories, Inc.**

*Clinical
Diagnostics Group*

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