

EDX SARS-CoV-2 Standard Summary	
Catalog Number	COV019
Analytes	SARS-CoV-2 RNA Transcripts: Envelope (E) Gene (200,000 cp/mL) Nucleocapsid (N) Gene (200,000 cp/mL) ORF1ab Gene (200,000 cp/mL) RdRP Gene (200,000 cp/mL) Spike Protein (S) Gene (200,000 cp/mL)
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 Standard is intended for use as a 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.

PRODUCT DESCRIPTION:

The EDX SARS-CoV-2 Standard is manufactured with synthetic RNA transcripts containing five gene targets (E, N, ORF1ab, RdRP and S Genes of SARS-CoV-2). The product contains human genomic DNA (75,000 cp/mL), allowing laboratories to validate the entire process of a molecular assay including extraction, amplification, and detection.

The EDX SARS-CoV-2 Standard contains E, N, ORF1ab, RdRP and S genes that are each quantitated at 200,000 cp/mL using Bio-Rad Droplet Digital PCR (ddPCR).

PROCEDURE:

The EDX SARS-CoV-2 Standard requires an extraction step. The standard 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 Standard is not a substitute for the manufacturer's kit controls provided with the assay. EDX SARS-CoV-2 Standard 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 Standard should be stored at -20°C or below.

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

Once thawed, EDX SARS-CoV-2 Standard 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 use EDX SARS-CoV-2 Standard beyond the expiration date.

LIMITATIONS:

The EDX SARS-CoV-2 Standard should not be diluted without appropriate validation. Laboratories can validate use of the EDX SARS-CoV-2 Negative as a suitable diluent for this standard.

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WARNINGS AND PRECAUTIONS:

The EDX SARS-CoV-2 Standard contains synthetic RNA transcripts but 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

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SYMBOL REFERENCES:



Catalog Number



Lot Number



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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*

9500 Jeronimo Road
Irvine, California 92618
(800) 854-6737
FAX (949) 598-1550
bio-rad.com/qualitycontrol

Technical Service:
(800) 854-6737

United States Customer Service: 4000 Alfred Nobel Drive • Hercules, California 94547 • Phone (510) 724-7000 • FAX (510) 741-6373
Also in: **South Granville, Australia,** Phone +61 (2) 9914 2800 • Fax +61 (2) 9914 2888 **Vienna, Austria,** Phone +43 (0) 1 877 89 01 9 • Fax +43 (0) 1 876 56 29 **Temse, Belgium,** Phone +32 (0) 3 710 53 00 • Fax +32 (0) 3 710 53 01 **São Paulo, Brazil,** Phone +55 11 3065-7550 **Montréal, Canada,** Phone +1 514 334 4372 • Fax +1 514 334 0872 **Shanghai, China,** Phone +86 21 6169 8500 • Fax +86 21 6169 8599 **Prague, Czech Republic,** Phone +420 241 431 660 **Symbion Science Park, Denmark,** Phone +45 44 52 10 00 • Fax +45 44 52 10 01 **Helsinki, Finland,** Phone +358 9 804 22 00 **Marnes-la-Coquette, France,** Phone +33 (0)1 47 95 60 00 • Fax +33 (0)1 47 41 91 33 **Munich, Germany,** Phone +49 (0) 89 31884 393 • Fax +49 (0) 89 31884 136 **Athens, Greece,** Phone +30 210 7774396 • Fax +30 210 7774376 **Quarry Bay, Hong Kong,** Phone +85 2 2789 3300 • Fax +85 2 2789 1257 **Budapest, Hungary,** Phone +36 1 459 6190 • Fax +36 1 459 6101 **Haryana, India,** Phone +91 124 4029300 • Fax +91 124 2398115 **Rishon Le Zion, Israel,** Phone +972 03 963 6025 • Fax +972 03 951 4129 **Milan, Italy,** Phone +39 024 94 86 600 • Fax +39 02 21609399 **Tokyo, Japan,** Phone +81 3 6361 7070 • Fax +81 3 5463 8481 **Seoul, Korea,** Phone +82 080 007 7373 • Fax +82 (2) 3472 7003 **Mexico D.F., Mexico,** Phone +52 (55) 5488 7670 • Fax +52 (55) 1107 7246 **Veenendaal, The Netherlands,** Phone +31 (0) 318 540 666 • Fax +31 (0) 318 542 216 **Auckland, New Zealand,** Phone +64 (9) 415 2280 • Fax +64 (9) 415 2284 **Oslo, Norway,** Phone +47 23 38 41 30 • Fax +47 23 38 41 39 **Warsaw, Poland,** Phone +48 22 331 99 99 • Fax +48 22 331 99 88 **Amadora, Portugal,** Phone +351 21 47 27 700 • Fax +351 21 472 7777 **Moscow, Russia,** Phone +7 (495) 721-14-04 • Fax +7 (495) 721-14-12 **Singapore,** Phone +65 6415 3170 • Fax +65 6415 3189 **Johannesburg, South Africa,** Phone +27 11 442 8508 • Fax +27 11 442 8525 **Madrid, Spain,** Phone +34 91 490 6580 • Fax +34 91 590 5211 **Sundbyberg, Sweden,** Phone +46 844 98053 • Fax +46 8 55 51 27 80 **Cressier, Switzerland,** Phone +41 (0) 61 717 9555 • Fax +41 (0) 61 717 9550 **Taipei, Taiwan,** Phone +886 (2) 2578-7189 • Fax +886 (2) 2578-6890 **Bangkok, Thailand,** Phone (662) 651 8311 • Fax (662) 651 8312 **Hertfordshire, United Kingdom,** Phone +44 (0) 1923 471301 • Fax +44 (0) 1923 471340