

REF COVG

RUO

Exact Diagnostics SARS-CoV-2 S Gene Gamma Variant Control Summary	
Catalog Number	COVG
Target Analyte	Spike (S) gene of the SARS-CoV-2 Gamma Variant (P.1) 200,000 cp/mL
Mutations Summary	K417T, E484K, N501Y, D614G, H655Y
Internal Control	Human genomic DNA 75,000 cp/mL
Source Material	<i>In vitro</i> transcript (RNA)
Matrix	Synthetic Matrix
Internal Value Assignment Method	Bio-Rad Droplet Digital PCR (ddPCR)
Storage & Shelf Life	-20°C or below for up to 18 months 2-8°C for up to 12 months (unopened) 2-8°C for up to 7 days (opened)
Maximum Number of Freeze-Thaw Cycles	4
Number of Vials Per Kit	1 Vial
Fill Volume	0.25 mL per Vial
Regulatory Status	For Research Use Only. Not for use in diagnostics procedures.

INTENDED USE:

The Exact Diagnostics SARS-CoV-2 S Gene Gamma Variant Control is intended to be validated as an independent external run control and used for research testing with molecular assays targeting mutations in the Spike (S) gene of the SARS-CoV-2 Gamma variant to monitor assay performance. This product is to be used with assays detecting SARS-CoV-2 Gamma variant RNA, and to be processed in the same manner as patient specimens to monitor all steps of molecular assays.

PRODUCT DESCRIPTION:

The Exact Diagnostics SARS-CoV-2 S Gene Gamma Variant Control consists of a synthetic RNA transcript of the Gamma variant SARS-CoV-2 S gene (Lineage P.1) in a matrix simulating transport media. This product also contains human genomic DNA (human gDNA; which includes the human RNase P) for internal control needs, allowing laboratories to monitor the entire process of a molecular assay including extraction, amplification, and detection. The extraction of this product is optional.

The Gamma variant S gene RNA transcript and human genomic DNA are internally targeted to 200,000 copies/mL and 75,000 copies/mL, respectively, using Bio-Rad Droplet Digital PCR (ddPCR) to ensure lot-to-lot consistency.

PROCEDURE:

This product should be treated in the same manner as patient specimens and tested according to the assay manufacturer's or testing laboratory's instructions and recommendations. Assay manufacturer's or testing laboratory's extraction recommendations should be followed.

This product may be used with molecular assays whose workflows utilize previously extracted specimens that have tested positive for SARS-CoV-2. This product can also be used with molecular assays testing for SARS-CoV-2 variants as a first line of testing and requiring extraction.

STORAGE AND STABILITY:

This product may be stored at either -20°C or 2-8°C upon receipt.

This product will be stable until the expiration date when stored at -20°C or below and may be frozen and reused a maximum of four (4) times. Thaw at room temperature and vortex briefly prior to use. Freeze sample immediately after use.

This product will be stable for up to 12 months when stored unopened at 2-8°C, not to exceed the labeled expiration date. Once opened, the product should be discarded after seven (7) days when stored at 2-8°C. Vortex briefly prior to use. Do not freeze opened or unopened vials that have been stored at 2-8°C.

LIMITATIONS:

1. For Research Use Only. Not for use in diagnostics procedures.
2. The Exact Diagnostics SARS-CoV-2 Negative may be validated for use as a diluent.
3. Do not use this product beyond the expiration date.

SAFETY PRECAUTIONS:

1. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.
2. Handle and dispose of all specimens, controls and materials used in testing as though they contain infectious agents.
3. Discard product if packaging is damaged or leaking. Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution.
4. Dispose of any discarded materials in accordance with the requirements of the local waste management authorities. In the event of damage to packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Service.



WARNINGS AND PRECAUTIONS:

Universal precautions and proper disposal should be practiced¹. It is recommended that this product be handled in accordance with Biosafety Level 2 practices as described in the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH)², Biosafety in Microbiological and Biomedical Laboratories, or other equivalent guidelines.^{3,4}

A Safety Data Sheet (SDS) is available for professional users on www.bio-rad.com.

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
2. U.S. Department of Health and Human Services Public Health Service Centers for Disease Control and Prevention and National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories- Sixth Edition HHS Publication (CDC) 300859: June 2020.
3. Clinical and Laboratory Standards Institute (CLSI). Protection of laboratory workers from Occupational Acquired infections; Approved Guideline – Third Edition. CLSI document M29-A3 (ISBN 1-56238-567-4), Clinical and Laboratory Standards Institute Wayne, Pennsylvania 19087-1898, USA 2005.
4. Clinical and Laboratory Standards Institute (CLSI) Clinical Laboratory Waste Management; Approved Guideline – Third Edition. CLSI document GP05-A3 (ISBN 1-56238-744-8), CLSI Wayne, Pennsylvania 19087, USA 2011

BIO-RAD and DROPLET DIGITAL PCR are trademarks of Bio-Rad Laboratories, Inc. in certain jurisdictions.



UNITED STATES Exact Diagnostics LLC
100 South Jones Street, Suite 100,
Fort Worth, Texas 76104

BIO-RAD

**Bio-Rad
Laboratories**

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: **Gladesville, 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 1404 • Fax +7 495 721 1412 **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

SUMMARY OF MUTATIONS:

Exact Diagnostics SARS-CoV-2 Variants Controls

Spike Protein Mutations	Alpha Variant B.1.1.7	Beta Variant B.1.351	Epsilon Variant B.1.427 B.1.429	Gamma Variant P.1	Delta-Kappa Variants B.1.617.1 B.1.617.2 AY sublineages B.1.617.3
	COVA	COVB	COVE	COVG	COVDK
S13I			●		
T19R					●
69-70del	●				
V70F					●
K77T					●
D80A		●			
T95I					●
G142D					●
144del	●				
W152C			●		
E154K					●
E156G					●
157-158del					●
A222V					●
W258L					●
K417T				●	
K417N		●			●
L452R			●		●
T478K					●
E484K		●		●	
E484Q					●
N501Y	●	●		●	
A570D	●				
D614G	●	●	●	●	●
H655Y				●	
P681H	●				
P681R					●
A701V		●			
T716I	●				
D950N					●
S982A	●				
Q1071H					●
D1118H	●				