Exact Diagnostics SARS-CoV-2 S Gene Gamma Variant Control

REF COVG

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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	*In vitro* 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)
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 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. 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:

Biological source material. Treat as potentially infectious.

Universal precautions and proper disposal should be practiced[1]. 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

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SUMMARY OF MUTATIONS:

Exact Diagnostics SARS-CoV-2 Variant 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
	COVA	COVB	COVE	COVG
S13I	-	-	+	-
69-70del	+	-	-	-
D80A	-	+	-	-
144del	+	-	-	-
W152C	-	-	+	-
K417T	-	-	-	+
K417N	-	+	-	-
L452R	-	-	+	-
E484K	-	+	-	+
N501Y	+	+	-	+
A570D	+	-	-	-
D614G	+	+	+	+
H655Y	-	-	-	+
P681H	+	-	-	-
A701V	-	+	-	-
T716I	+	-	-	-
S982A	+	-	-	-
D1118H	+	-	-	-

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