Exact Diagnostics SARS-CoV-2, Flu, RSV Verification Panel

REF COVFLUP200

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Exact Diagnostics SARS-CoV-2, Flu, RSV Verification Panel Summary	
Catalog Number	COVFLUP200
Target Analytes	Influenza A Influenza B Respiratory Syncytial Virus A SARS-CoV-2
Source Material	Whole Viruses
Inactivation Method	Chemical
Matrix	Synthetic Matrix
Internal Value Assignment Method	Bio-Rad Droplet Digital PCR (ddPCR)
Storage	-20°C or Below until Expiration
Shelf Life	18 Months from Manufacture Date
Reusability	Single Use
Number of Vials Per Kit	15 Vials
Fill Volume	1.0 mL per Vial
Vial Type	Barcoded Vials
Regulatory Status	For Research Use Only (Not for use in diagnostic procedures)

Exact Diagnostics SARS-CoV-2, Flu, RSV Verification Panel Components		
Vial Name	**Target Concentration***	**Number of Vials**
Flu A – 3x LOD	900 copies/mL	1 vial
Flu A – 5x LOD	1,500 copies/mL	1 vial
Flu A – 10x LOD	3,000 copies/mL	1 vial
Flu B – 3x LOD	900 copies/mL	1 vial
Flu B – 5x LOD	1,500 copies/mL	1 vial
Flu B – 10x LOD	3,000 copies/mL	1 vial
RSV A – 3x LOD	2,400 copies/mL	1 vial
RSV A – 5x LOD	4,000 copies/mL	1 vial
RSV A – 10x LOD	8,000 copies/mL	1 vial
SARS-CoV-2 – 3x LOD	1,800 copies/mL	1 vial
SARS-CoV-2 – 5x LOD	3,000 copies/mL	1 vial
SARS-CoV-2 – 10x LOD	6,000 copies/mL	1 vial

SARS-CoV-2, Flu, RSV – 3x LOD	Flu A: 900 copies/mL Flu B: 900 copies/mL RSV A: 2,400 copies/mL SARS-CoV-2: 1,800 copies/mL	1 vial
SARS-CoV-2, Flu, RSV – 5x LOD	Flu A: 1,500 copies/mL Flu B: 1,500 copies/mL RSV A: 4,000 copies/mL SARS-CoV-2: 3,000 copies/mL	1 vial
SARS-CoV-2, Flu, RSV – 10x LOD	Flu A: 3,000 copies/mL Flu B: 3,000 copies/mL RSV A: 8,000 copies/mL SARS-CoV-2: 6,000 copies/mL	1 vial

***Target concentrations are listed for informational purposes only. They are relative to LODs considered representative for various molecular assays on market for each of the target analytes. These target concentrations are based on internal value assignments by ddPCR of the inactivated forms of the viruses. This product is unassayed and only carries target manufacturing values. Accepted ranges must be established by the laboratory for each specific molecular assay utilized with this product.**

INTENDED USE:

The Exact Diagnostics SARS-CoV-2, Flu, RSV Verification Panel is intended to be used with SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus molecular assays for applications such as the evaluation of assay performance and the testing of operator proficiency.

PRODUCT DESCRIPTION:

The Exact Diagnostics SARS-CoV-2, Flu, RSV Verification Panel contains chemically inactivated whole viruses and is formulated in a synthetic matrix. This product is intended to simulate patient specimens and test the entire process of a molecular assay including extraction, amplification and detection.

This product is internally value assigned using Bio-Rad Droplet Digital PCR (ddPCR).

PROCEDURE:

The Exact Diagnostics SARS-CoV-2, Flu, RSV Verification Panel is intended to be extracted and should be processed in the same manner as patient specimens and tested according to the assay manufacturer's or testing laboratory's instructions and recommendations. Also follow manufacturer's or testing laboratory's extraction recommendations.

This product is an unassayed control and does not have assigned values. Expected results utilizing this product must be established by the end user for their specific assay.

This product is not a substitute for the manufacturer's kit controls provided with the assay.

Exact Diagnostics SARS-CoV-2, Flu, RSV Verification Panel Kit Configuration				
SARS-CoV-2 3x LOD	Flu A 3x LOD	Flu B 3x LOD	RSV A 3x LOD	SARS-CoV-2, Flu, RSV 3x LOD
SARS-CoV-2 5x LOD	Flu A 5x LOD	Flu B 5x LOD	RSV A 5x LOD	SARS-CoV-2, Flu, RSV 5x LOD
SARS-CoV-2 10x LOD	Flu A 10x LOD	Flu B 10x LOD	RSV A 10x LOD	SARS-CoV-2, Flu, RSV 10x LOD

If during the use of this device or as a result of its use, a serious incident occurs, please report it to Bio-Rad Laboratories and to your national health authority, as required.

STORAGE AND STABILITY:

This product will be stable until the expiration date when stored at -20°C or below.

Completely thaw at room temperature, then vortex briefly before use.

Once thawed, this product is stable for seven (7) days at 2-8°C.

Discard after one use. Do not refreeze.

LIMITATIONS:

1. Do not use this product beyond the expiration date.
2. This product is for Laboratory/Professional use only.
3. It is the responsibility of each laboratory to implement its own quality assurance program to determine the suitability of this product for its particular use and to establish its own target ranges and guidelines for interpretation of results obtained with this product.

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 water and then 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.

Source materials used to produce this product have been treated to inactivate infectious agents. 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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