

Certificate of Analysis(Revised) Research Use Only - Not for Use in Diagnostic Procedures

Product Description:

Product	Material Code	Batch Number
AccuPlex™ SARS-CoV-2, Flu A/B and RSV Verification Panel	0505-0183	10521728

Date of Manufacture: 14 OCT 2020

Expiration Date: 16 OCT 2022

Storage Temperature: 2 - 8°C

Average viral copies/mL for Member 1 determined using TaqMan® digital PCR Assays run on the BioRad QX200 system:

Kit Component	Analyte	Quantitative Result (cp/mL)
Member 1	SARS-CoV-2	97,000
	Flu A	120,000
	Flu B	98,000
	RSV	100,000

Qualitative Testing:

QC Testing:

Kit Component	CDC Flu SC2 Multiplex qPCR Assay ¹	Cepheid Xpert® Xpress SARS- CoV-2 Assay	Cepheid Xpert® Xpress Flu/RSV Assay
Member 1	SARS-CoV-2 POSITIVE; Flu A POSITIVE; Flu B POSITIVE	POSITIVE	Flu A POSITIVE; Flu B POSITIVE; RSV POSITIVE
Member 2	SARS-CoV-2 POSITIVE; Flu A POSITIVE; Flu B POSITIVE	POSITIVE	Flu A POSITIVE; Flu B POSITIVE; RSV POSITIVE
Member 3	SARS-CoV-2 POSITIVE; Flu A POSITIVE; Flu B POSITIVE	POSITIVE	Flu A POSITIVE; Flu B POSITIVE; RSV POSITIVE
Negative	SARS-CoV-2 NEGATIVE; Flu A NEGATIVE; Flu B NEGATIVE	NEGATIVE	Flu A NEGATIVE; Flu B NEGATIVE; RSV NEGATIVE

Safety Precautions:

Preparation contains recombinant Alphavirus. Use the Centers for Disease Control recommended universal precautions.

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¹ Real time qPCR testing using CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay Instructions for use. Document #: LB-126. Effective July 9, 2020 and published primer/probe sequences.

Approval:

Calherine france 25 JAN 2021

Mimpour M Gradlos 25 JAN 2021

QA Verified By / Date