

## **Certificate of Analysis**

## For In Vitro Diagnostic Use

Product Description: AccuPlex™ SARS-CoV-2 Full Genome w/cRNA

Positive Control 1500 cp/ml Kit

Material Number: 0505-0220

Kit/Vial Batch Number: 10600762

Parent Bulk Batch Number: 10583164

Concentration of SARS-CoV-2 N region at Parent bulk stage (by digital PCR)

12,240 copies/mL

Dilution Factor used to Make Final Bulk 8.16

Final Predicted Bulk Concentration (based on dilution factor)

1500 copies/mL

Qualitative Result: Real time qPCR testing using nCoV 2019 primers/probes and protocol described in US Centers for Disease Control Assay publication and instructions for use<sup>1</sup>.

Positive

Nominal Carrier RNA Concentration:

5 µg/mL

**Expiration Date:** 

2023-12-17

Storage Temperature:

2 - 8 °C

Volume per vial:

0.3 mL

Safety Precautions:

Preparation contains recombinant Sindbis virus. Use the

US Centers for Disease Control recommended

universal precautions for handling the material.

Approval:

04 MAR 2022

Prepared By Date

A ラルー 08 MAR 2022

QA Verified By Date

CDC 2019-Novel Coronavirus (2019-nCoV) Real Time RT-PCR Diagnostic Panel Instructions for use. CDC-006-00019 Revision: 06. Effective 12/01/2020.