

## **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: 10599246

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)

1,500 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

Preparation contains recombinant Sindbis virus. Use the

Safety Precautions: US Centers for Disease Control recommended

universal precautions for handling the material.

Approval:

Prepared By 24 FEB 2022

Date

A-3-- 24 FEB 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.