

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: 10600825

Parent Bulk Batch Number: 10601075

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

13,182 copies/mL

Dilution Factor used to Make Final Bulk 8.79

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 use1.

Positive

Nominal Carrier RNA Concentration: 5 µg/mL

Expiration Date: 2024-05-04

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:

02 JUN 2022

Prepared By Date

7-1-1 02 JUN 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.