

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: 10571852

10x Bulk Batch Number: 10531206

Concentration of SARS-CoV-2 N region

at 10X bulk stage (as determined by

digital PCR)

14,440 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: 2023-FEB-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:

Krif 9 Start 15 OCT 2021

Prepared By Date

A--, X--- 15 OCT 2021

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.