



# 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:	10538822
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 use <sup>1</sup> .	Positive
Nominal Carrier RNA Concentration:	5 µg/mL
Expiration Date:	2023-01-04
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:

03 AUG 2021

Prepared By

Date

03 AUG 2021

QA Verified By

Date

<sup>1</sup> CDC 2019-Novel Coronavirus (2019-nCoV) Real Time RT-PCR Diagnostic Panel Instructions for use. CDC-006-00019 Revision: 06. Effective 12/01/2020.