

Certificate of Analysis

Research Use Only - Not for Use in Diagnostic Procedures

AccuPlex™ SARS-CoV-2 Reference Material

Product Description:

Product	Material Code	Batch Number
AccuPlex™ SARS-CoV-2 Reference Material (Kit)	0505-0126	10481915
Kit Components		
Positive Reference Material	0505-0119	10481962
Negative Reference Material	0505-0123	10481771

Date of Manufacture: 02 APR 2020
 Expiration Date: 30 MAR 2022
 Storage Temperature: 2 - 8 °C

Viral copies/mL as determined by TaqMan digital PCR assays:

QC Testing:

Kit Component	Digital PCR target Sequence(s)	Result (cp/mL)
Positive Reference Material	SARS-CoV-2 genomic RNA sequences (ORF1a, RdRp, E gene and N gene)	5220
Negative Reference Material	Human RNaseP	5794

Real time qPCR testing using nCoV 2019 primers/probes and protocol described in US Centers for Disease Control Assay publication and instructions for use¹.

QC Testing:

Kit Component	Qualitative Result
Positive Reference Material	Positive
Negative Reference Material	Negative


Safety Precautions:

Preparation contains recombinant Sindbis virus. Use the Centers for Disease Control recommended universal precautions.

Approval:


 Prepared By

02 APR 2020
 Date


 QA Verified By

02 APR 2020
 Date

¹ CDC 2019-Novel Coronavirus (2019-nCoV) Real Time RT-PCR Diagnostic Panel Instructions for use. CDC-006-00019 Revision: 01. Effective 2/4/2020.