

Certificate of Analysis

Research Use Only - Not for Use in Diagnostic Procedures

AccuPlex™ SARS-CoV-2 Reference Material Kit v2

Product Description:

Product	Material Code	Batch Number
AccuPlex™ SARS-CoV-2 Reference Material Kit v2	0505-0133	10488294
Kit Components		
Positive Reference Material	0505-0137	10488286
Negative Reference Material	0505-0123	10481937

Date of Manufacture: 27 APR 2020

Expiration Date: 23 APR 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, S gene, E gene and N gene)	5175
Negative Reference Material	Human RNaseP	3951

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 Alphavirus. Use the Centers for Disease Control recommended universal precautions.

Approval:

Prepared By  Date 28 April 2020

QA Verified By  Date 28 APR 2020

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.