

CERTIFICATE OF ANALYSIS

Product name: 2019-nCoV CDC Probe and Primer Kit for SARS-CoV-2
Catalog number: KIT-nCoV-PP1-1000

PRODUCT INFORMATION

Kit lot number: 143503
Date of manufacture: 6 March 2020

The following components from this lot were tested and qualified for use by the Centers for Disease Control and Prevention under **EUA200001, CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC):**

2019-nCoV_N1 2019-nCoV_N2 RP

***Note: 2019-nCoV_N3 was not evaluated by the CDC and is not approved for use under EUA200001**

Please refer to: [EUA200001, CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel \(CDC\)](https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations)
<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

Components

Name	Comp. lot no.	Sequence		Purification
2019-nCoV_N1	143514	Fwd Primer	5' GACCCCAAATCAGCGAAAT 3'	AX HPLC
		Rev Primer	5' TCTGGTTACTGCCAGTTGAATCTG 3'	AX HPLC
		Probe	5' FAM-ACCCCGCATTACGTTTGGTGGACC-BHQ-1 3'	Dual HPLC
2019-nCoV_N2	143516	Fwd Primer	5' TTACAAACATTGGCCGCAAA 3'	AX HPLC
		Rev Primer	5' GCGCGACATTCCGAAGAA 3'	AX HPLC
		Probe	5' FAM-ACAATTTGCCCCAGCGCTTCAG-BHQ-1 3'	Dual HPLC
2019-nCoV_N3*	143515	Fwd Primer	5' GGGAGCCTTGAATACACCAAAA 3'	AX HPLC
		Rev Primer	5' TGTAGCACGATTGCAGCATTG 3'	AX HPLC
		Probe	5' FAM-AYCACATTGGCACCCGCAATCCTG-BHQ-1 3'	Dual HPLC
RP	143517	Fwd Primer	5' AGATTTGGACCTGCGAGCG 3'	AX HPLC
		Rev Primer	5' GAGCGGCTGTCTCCACAAGT 3'	AX HPLC
		Probe	5' FAM-TTCTGACCTGAAGGCTCTGCGCG-BHQ-1 3'	Dual HPLC

Amount delivered: 22.5 nmol probe, forward and reverse primer blend per tube

Product delivery format: Dry

Recommended storage conditions: Kits may be stored at +2 to +8 °C, in the dark

Expiry Date: 06 March 2022 (2 years from DOM in dried form, established based on bio similar products)

RELEASE DATA

Test	Specification	Results
Mass Spectrometry	Mass within 2.0% of target mass for each primer and probe	PASS
Purity by UPLC	All primers ≥ 90% purity	PASS
Purity by UPLC	All probes ≥ 90% purity	PASS

Manufactured in an ISO 9001:2015 certified facility.

For Research Use Only. Not for use in diagnostic procedures.

Released by: Jasmin El-Far

Date: 11 March 2020

