

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: 144604
Date of manufacture: 2 April 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

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>

Components

Name	Comp. lot no.	Sequence		Purification
2019-nCoV_N1	144606	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	144607	Fwd Primer	5' TTACAAACATTGGCCGCAAA 3'	AX HPLC
		Rev Primer	5' GCGCGACATTCCGAAGAA 3'	AX HPLC
		Probe	5' FAM-ACAATTTGCCCCAGCGCTTCAG-BHQ-1 3'	Dual HPLC
RP	144608	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: 2 April 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

The product identified herein is manufactured under LGC ISO certified quality systems in accordance with the Re-Authorized CDC-EUA dated March 15, 2020 [CDC-EUA Letter of Authorization 15 March 2020]. Please note that this product was manufactured under waivers applying to certain manufacturing and labeling requirements as detailed in Section III in the CDC-EUA.

Released by: Jasmin El-Far

Date: 7 April 2020