

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)
<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