

CHANGE NOTIFICATION

Subject: Product Discontinuation Notice: 2019 nCoV CDC-Qualified Probe and Primer Kits for SARS CoV-2

Date: 30 August 2021

Dear Valued Customer,

This letter serves as notification that LGC Biosearch will discontinue the following product as of September 30, 2021.

Catalogue number	Product name
KIT-NCOV-PP1-1000	2019-nCoV CDC-qualified Probe and Primer Kits for SARS-CoV-2

Reason for discontinuation:

After December 31, 2021, CDC will withdraw the request to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of EUA200001, CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, the assay first introduced in February 2020 for detection of SARS-CoV-2 only. The CDC decided to discontinue support for this assay due to the availability of commercial options for clinical diagnosis of SARS-CoV-2 infection, including multiplexed and high-throughput options.

The 2019-nCoV CDC-qualified Probe and Primer Kit (cat no. KIT-NCOV-PP1-1000) can be purchased from LGC Biosearch Technologies until September 30, 2021; and can be used under the EUA for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel until December 31, 2021. For RUO or IVD use outside of FDA jurisdiction, the 2019-nCoV CDC-qualified Probe and Primer Kit may be used up to the expiry date of each lot (please note: lot 144604 expires on 2 April 2022, and lots 143503, 143764, 144000 expire in March of 2022). This notification provides advanced notice for clinical laboratories to have time to select and implement one of the many FDA-authorized alternatives. Visit www.fda.gov for a list of authorized COVID-19 diagnostic methods. For a summary of the performance of FDA-authorized molecular methods with an FDA reference panel, visit https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data?ACSTrackingID=USCDC_2146-DM61940&ACSTrackingLabel=Lab%20Alert%3A%20Changes%20to%20CDC%20RT-PCR%20for%20SARS-CoV-2%20Testing&deliveryName=USCDC_2146-DM61940

Laboratories and testing sites should validate and verify their selected assay within their facility before beginning clinical testing.

For suggested replacements for non-clinical testing please see our ValuPanel™ oligonucleotides:

- 2019-nCoV ValuPanel Reagents

Separately delivered primers and probes that are the same sequences as those found in the 2019-nCoV CDC-qualified Probe and Primer Kit. For Research Use Only. Not for use in diagnostic procedures.

- Influenza SARS-CoV-2 Multiplex ValuPanel Reagents



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Separately delivered primers and probes that may be used for a multiplexed method that can facilitate detection and differentiation of SARS-CoV-2 and influenza viruses. For Research Use Only. Not for use in diagnostic procedures.

While we regret any inconvenience this discontinuation may cause, we look forward to fulfilling your future product needs with our quality product lines. Please contact your Sales Account Managers if you have additional questions.

Kind Regards,

Caroline Young

Caroline Young, Quality Manager

30 August 2021

Date