

KIT-NCOV-PP1-1000 Discontinuation FAQ Sheet

When will Cat No. KIT-NCOV-PP1-1000 be discontinued?

The product will be discontinued on September 30, 2021; and will not be available for purchase after that date.

Why is Cat No. KIT-NCOV-PP1-1000 being discontinued?

After December 31, 2021, the 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 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. Visit www.fda.gov for a list of authorized COVID-19 diagnostic methods.

Until what date can I use Cat No. KIT-NCOV-PP1-1000?

For clinical testing, the kit 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 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).

Do you sell alternative oligonucleotides panels?

Please see our ValuPanel[™] oligonucleotides for recommended RUO alternatives for non-clinical testing: <u>2019-nCoV ValuPanel Reagents</u>:

Separately delivered primers and probes that are the same 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:

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.

Where can I find more information about FDA-authorized diagnostic alternatives?

Visit <u>www.fda.gov</u> for a list of authorized COVID-19 diagnostic methods. Laboratories and testing sites should validate and verify their selected assay within their facility before beginning clinical testing. For more information please see the <u>CDC's Lab Alert</u>.

The CDC is encouraging public health laboratories (PHLs) to adopt the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay, which enables surveillance of both influenza and SARS-CoV-2.

The CDC will no longer distribute the 2019 nCoV Real-Time RT-PCR Diagnostic Panel to domestic PHLs through the International Reagent Resource (IRR), effective September 30, 2021.

Note: The CDC Flu SC2 Multiplex Assay is not available to laboratories outside of the Public Health system, and is not available to clinical or commercial labs.