Product insert

2019-nCoV CDC Probe and Primer Kit for SARS-CoV-2

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

Contents

Cat no.	Size	Probe	Forward primer	Reverse primer
KIT-nCoV-PP1-1000	1000 rxns	2.5 nmol	10 nmol	10 nmol

The 2019-nCoV CDC Probe and Primer Kit contains signatures for SARS-CoV-2 where each assay contains 1 probe and 2 primers mixed into the same tube in dried format. Each assay contains 2.5 nmol of probe and 10 nmol of each primer, yielding a total amount of 22.5 nmol per tube.

Storage

2019-nCoV CDC Probe and Primer Assays are shipped dry at ambient temperature. They may be stored at +2 to +8 °C in this state.

Certificates of Analysis (CoA)

CoA for each lot can be found online: www2.lgcgroup.com/2019-nCoV_Probe_Primer_Kits.

Emergency Use Authorization compliance

- Manufactured under an ISO-certified Quality Management System in accordance with the Re-authorised CDC-EUA dated 15 March 2020.
- Incorporated waivers to certain requirements as detailed in Section III of the CDC-EUA.
- The reagent materials, and any other materials furnished by LGC, Biosearch Technologies, were not manufactured by CDC, thus CDC makes no warranties with respect to the quality, performance or stability of the materials sold by the company.
- If this product is being used for diagnostic purposes in the United States under the CDC's Emergency Use Authorization for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, the laboratory must be CLIA-certified and meet the requirements necessary to conduct high-complexity testing as required under the CDC-EUA ("Authorized Laboratory"). An Authorized Laboratory conducting diagnostic testing under CDC's EUA must use LGC, Biosearch Technologies' 2019-nCoV CDC Probe and Primer Kit in conformance with the March 15, 2020 EUA, or as it may be amended, and the Authorized Laboratory agrees, as a condition of receipt of LGC, Biosearch Technologies' 2019-nCoV CDC Probe and Primer Kit, it will comply with the provisions included in the Product Insert and the authorized Instructions for Use, as they may be amended.
  For complete Terms and Conditions, access the March 15, 2020, FDA Letter of Authorization for CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
  Access the approved Instructions for Use for CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel

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- Refer to CDC document "List of Acceptable Commercial Primers and Probes" for lot numbers qualified for use under the CDC-EUA.
- CDC notes that Authorized Laboratories must submit coronavirus testing results reports to HHS/CDC in the form and timing as HHS/CDC may determine.

Research Use Only protocol

- Please access the most current assay protocol published by CDC online.
- Note that the CDC did not qualify the N3 assays. Per 15 March 2020 re-authorised CDC EUA letter, the N3 assay has been excluded, and kits from all future batches of LGC primers and probes will not include the N3 assay.
- To purchase N3 probes and primers, please consider our 2019-nCoV ValuPanel Reagents.
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Resources

- Fact sheet for healthcare providers
- Fact sheet for patients
- General COVID-19 information
- Information for laboratories about COVID-19

Support

Please direct questions and comments on performance of the probes and primers to Biosearch Technologies' Technical Support Team at techsupport@lgcgroup.com.

Please refer all other questions to the CDC helpdesk, respvirus@cdc.gov, including notification to the CDC helpdesk if the Authorized Laboratory observes any differences in performance of the assay in their hands versus the established performance characteristics in the Instructions for Use; and notification to the CDC helpdesk of any adverse events associated with the test or use of Biosearch Technologies' CDC-qualified probe and primer kit.

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