BioCode® SARS-CoV-2 Assay kit

For use under the Emergency Use Authorization (EUA) only

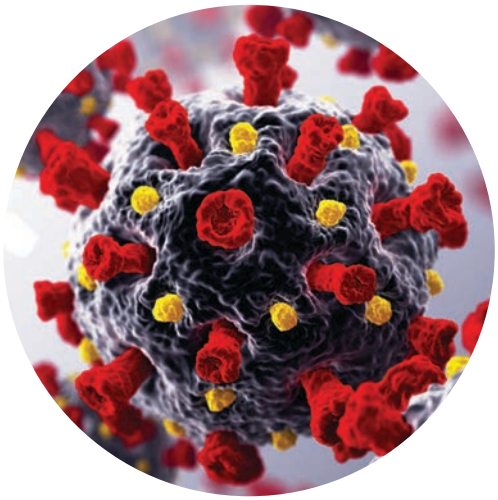
The BioCode® SARS-CoV-2 Assay* is a multiplexed nucleic acid test intended for the qualitative detection of SARS-CoV-2 in upper respiratory specimens such as nasopharyngeal swabs (NPS), oropharyngeal swabs (OPS), and nasal swabs or bronchoalveolar lavage (BAL) from individuals who are suspected of COVID-19 by their healthcare provider.

The test is designed to detect two different conserved regions of SARS-CoV-2 N gene. The Assay does not detect common coronaviruses (OC43, HKU1, NL63, and 229E), MERS-CoV, or SARS-CoV.

The BioCode® SARS-CoV-2 Assay can be run as an independent test or in parallel with other FDA-cleared BioCode® assays on the BioCode® MDx-3000 instrument.

Flexible, High Throughput System

- Delivers up to 564 sample results in a day (188 patient samples in an 8-hour shift)
- Pooled testing of up to 5 individual upper respiratory specimens (NPS, OPS, and nasal swabs)
- Parallel testing with other FDA-cleared BioCode® assays



Ordering Information:

Contact Applied BioCode Customer Service at orders@apbiocode.com

Part No.	Description
41-A0051	BioCode® MDx-3000 System
64-C0304	BioCode® SARS-CoV-2 Assay kit* – (96 samples)
64-C0305	BioCode® SARS-CoV-2 Flu Plus Assay kit** – (96 samples)
63-R0001	BioCode® Respiratory Pathogen Panel*** – (96 samples)

*** FDA Cleared, EU: CE

** This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories; This product has been authorized only for the detection and differentiation of nucleic acid from SARS-CoV-2, Influenza A (with H1 pdm09, H1 seasonal, H3 subtypes), Influenza B and/or Respiratory Syncytial Virus (RSV), not for any other viruses or pathogens; and The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

* The BioCode® SARS-CoV-2 Assay has not been FDA cleared or approved; the test has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
The BioCode® SARS-CoV-2 Assay has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
Emergency use of the BioCode® SARS-CoV-2 Assay is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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