BioCode® SARS-CoV-2 Flu Plus Assay kit

Detect and differentiate four pathogens from one sample, all in one test

The BioCode® SARS-CoV-2 Flu Plus Assay** is a multiplexed nucleic acid test intended for the qualitative detection and differentiation of RNA from SARS-CoV-2, Influenza A, Influenza B, and/or Respiratory Syncytial Virus (RSV) in nasopharyngeal swabs.

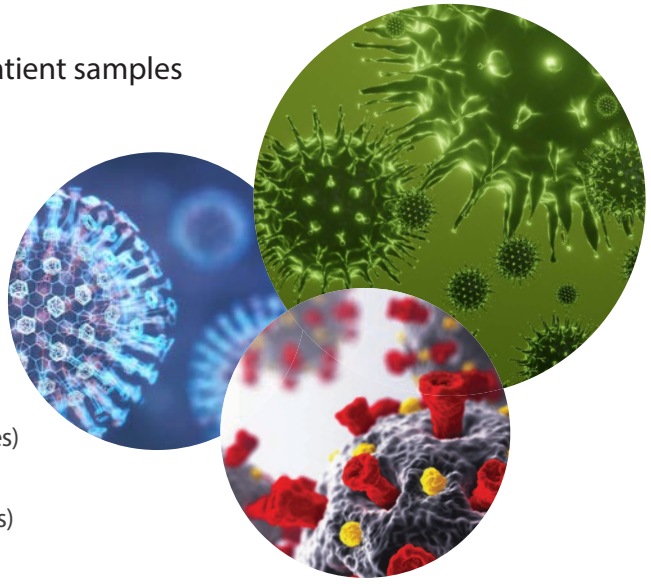
The test is performed on the BioCode® MDx-3000 automated system. It can be run as an independent assay or in parallel with our FDA-cleared BioCode® Respiratory Pathogen Panel for a more complete respiratory infection profile of patients.

Multiplex Panel of Viruses of Respiratory Indications

- Differentiates between SARS-CoV-2, Flu A, Flu B, and RSV
- Identification of influenza A with H1 pdm09, H1 seasonal, H3 subtypes
- Data Masking option enables select target reporting based on clinician's order ǂ

BioCode® MDx-3000 Workflow Delivers:

- Flexible sample testing throughput, process up to 188 patient samples in an 8-hour shift
- Reliable and affordable testing



Ordering Information:

Contact Applied BioCode Customer Service at orders@apbiocode.com

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

*** FDA Cleared, EU: CE

ǂ Results must include SARS-CoV-2.

** 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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