BioCode® MDx-3000

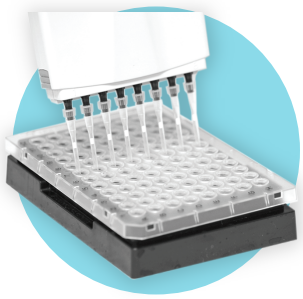
An Automated, High-Throughput Molecular Diagnostic System

The BioCode® MDx-3000 is an easy-to-use automated molecular diagnostic system that integrates the post extraction processes of molecular diagnostic testing. Committed to providing solutions for cost-effective, high throughput testing, Applied BioCode is focused on designing products for a variety of infectious disease testing ideal for moderate to high volume laboratories.

Workflow

Step 1:

Automated DNA/RNA extraction



Step 2:

PCR setup

Step 3:

Automated PCR, detection & results reporting

Transforming Your Experience

Data Masking - Specific target reporting based on clinician's order
Simultaneous Testing - Up to 3 different panels on a single run
Intuitive Interface - Touch screen, handheld scanner & LIS connectivity
User Defined Mode - Supports the use of Laboratory Developed Tests
Post-Run Sterilization - Reduces the potential for contamination

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Applied BioCode

Santa Fe Springs, California 90670, USA Ph: 1-833-BIO-CODE Email: communications@ApBioCode.com Website: www.ApBioCode.com

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Menu

Part No.	BioCode® Product	Targets
63-G0002	Gastrointestinal Pathogen Panel [1]	17
63-R0001	Respiratory Pathogen Panel [1]	17
64-C0304	SARS-CoV-2 Assay [2]	1
64-C0305	SARS-CoV-2 Flu Plus Assay [3]	7
41-A0051	MDx-3000 System [1]	

Contact Information:

Supporting you - wherever you are. Our knowledgeable Service Team is ready to deliver personalized attention to keep your lab running smoothly.

Technical Service: **techsupport@apbiocode.com**

Sales & Customer Service: **orders@apbiocode.com**

[1] FDA Cleared, EU: CE

[2] This product 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.

[3] 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.

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