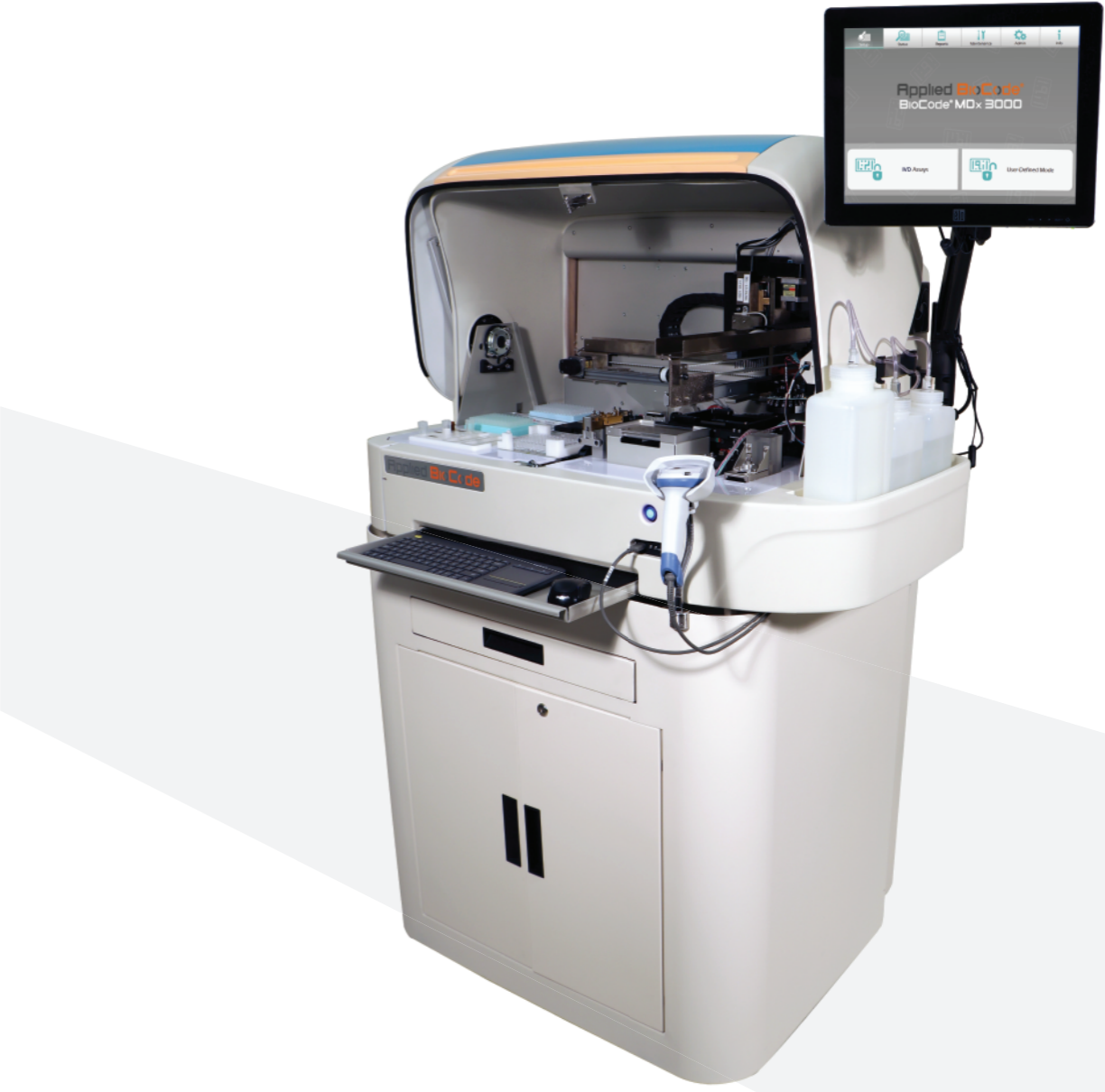


CE  
 510(k)  
**FDA CLEARED**  
 Medical Device  
 ISO 13485:2016 FM 661595



### System Specifications

Communications Interface:	Touch screen, keyboard, hand-held scanner
Communications Ports:	Ethernet, USB
Power Requirements:	100 - 240V; 50/60Hz
System Dimensions:	42" W x 31" D x 61" H

### Current Syndromic Panel

- Gastrointestinal Pathogen Panel\*
- Respiratory Pathogen Panel\*
- SARS-CoV-2 Assay Kit\*\*

### Future Syndromic Panels

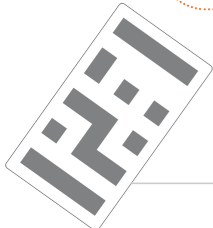
- Vaginitis/Vaginosis Panel
- Fungal Pathogen Panel

BioCode® MDx-3000

\* The high throughput BioCode® MDx-3000 molecular system with BioCode® Gastrointestinal Pathogen Panel (GPP) and with BioCode® Respiratory Pathogen Panel (RPP) have received U.S. Food and Drug Administration 510(k) clearance.  
 \*\* EUA200433 granted 15-JUN-2020; amendment EUA200433/S002 granted 22-OCT-2020. I recommend that we update this brochure.

### Automated Molecular Diagnostic System:

- Highly Multiplexed Syndromic Infectious Disease Panels
- High Throughput - Cost-Effective
- Easy-to-Use - Less Hands-On Time per Sample



0 1 1 0 0 0 0 1 0 1 1 0 0 0 1 0 0 1 1 0 0 0 1 1

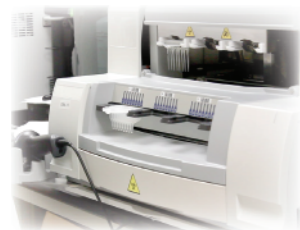
## System

**T**he BioCode® MDx-3000 system is an easy-to-use automated molecular diagnostic system that integrates the post extraction processes of molecular diagnostic testing. The BioCode® MDx-3000 system is based on a 96-well microplate format providing cost-effective, high throughput testing.

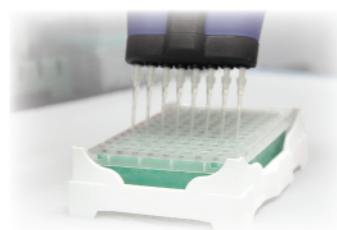
The BioCode® MDx-3000 system automates the PCR amplification, hybridization/target capture and detection steps of molecular testing. Automation, along with a simplified workflow, reduces hands-on time for labor savings and minimizes the potential for sample contamination. Up to 94 patient samples can be completed on the system in approximately 3.5 hours. Up to 3 different assay panels with the same test protocols can be run on the system at the same time.

The BioCode® MDx-3000 will also have a "User-Defined Mode" giving operators the ability to program and run Laboratory Developed Tests (LDT) on the system.

- Automate Your High Volume, High Plex Molecular Assays
- Highly Multiplexed Syndromic Panels
- Easy-to-Use - Less Hands-on Time per Sample
- User-Defined Mode for Laboratory Developed Tests



**STEP 1:**  
Automated DNA/RNA  
extraction.



**STEP 2:**  
PCR setup.



**STEP 3:**  
Load PCR microplate onto BioCode® MDx-3000. The System automates the PCR amplification, hybridization/target capture, and detection process, and reports the results.

## Workflow

## Operation

**N**ucleic acids (DNA/RNA) are extracted from samples using an automated extraction process.

The Patient Sample Work List is downloaded from the LIS into the BioCode® MDx-3000 or simply input by the operator using a barcode scanner, touch screen, or keyboard.

BioCode® MDx-3000 utilizes a BMB-Probe Mix for detection of all targets. To begin the run, the BMB-Probe Mix barcode is scanned to ensure the correct test panel, lot number, and expiration date are valid.

After the extraction and PCR setup steps are completed, the PCR plate is transferred to the BioCode® MDx 3000.

The operator makes sure all consumables are loaded on the system, closes the system door, initiates auto deck-check, and the run begins.

Walk-away automation; Operators are free to do other laboratory tasks during system operation.

Patient test results are displayed as soon as systems detection step is completed. No additional analysis or interpretation is needed.

**A**utomation of key system processes (PCR amplification, hybridization/ target capture, and detection) reduces hands-on time and the potential for sample contamination.

- The 96-well microplate format provides a cost-effective alternative to high volume MDx testing.
- Throughput: 94 patient samples (94 x 18 = 1,692 data points) can be completed on the BioCode® MDx-3000 system in about 3.5 hours.
- The BioCode® MDx-3000 system is user-friendly and takes little operator hands-on time.
- Operators can run the same assay panel or mix up to 3 different assay panels with the same protocols on one plate.
- Operators can program the system to mask results for tests not ordered on the patient.
- The BioCode® MDx-3000 system can be interfaced to your laboratory information system (LIS) to download system worklists and upload patient results.

## Features