

Applied Biocode gets FDA clearance for the Roche MagNA Pure 96 Extraction System

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Applied BioCode has announced that it has received U.S. Food and Drug Administration 510(k) clearance for the use of the Roche MagNA Pure 96* Extraction System with the high throughput BioCode MDx-3000 and Gastrointestinal Pathogen Panel (GPP).

The BioCode Gastrointestinal Pathogen Panel and BioCode MDx-3000 System recently received U.S. Food and Drug Administration 510(k) clearance, using the bioMerieux NUCLISENS easyMAG extraction system. Now, with the addition of the MagNA Pure 96 System, Applied BioCode will have access to higher volume laboratories that utilize the Roche system for sample extraction. The MagNA Pure 96 System can extract DNA/RNA from up to 96 patient samples in approximately 60 minutes. The combination of the BioCode® MDx-3000 system and the Roche MagNA Pure 96 System will allow laboratories to easily process up to 188 patient samples in a single, 8-hour shift.

The comprehensive BioCode Gastrointestinal Pathogen Panel provides results for the 17 most common bacteria, viruses, and parasites that cause infectious diarrhea. The panel includes targets for bacteria: *Campylobacter* (*C. jejuni* and *C. coli*), *Clostridium difficile* toxin A&B, *Salmonella* spp., *Shigella*/Enteroinvasive *E. coli*, Shiga-like toxin producing *E. coli*, *E. coli* O157, Enterotoxigenic *E. coli*, Enteroaggregative *E. coli*, *Vibrio parahaemolyticus*, *Vibrio* spp. (including *Vibrio vulnificus* and *Vibrio cholerae*), *Yersinia enterocolitica*, viruses: norovirus group I/II, adenovirus 40/41, rotavirus A, and parasites: *Giardia lamblia*, *Cryptosporidium* (*C. hominis* and *C. parvum*), *Entamoeba histolytica*.

The BioCode MDx-3000 system offers the high volume laboratory an alternative to high cost, single use, cartridge-based molecular test systems. This user-friendly automated system also offers target masking capabilities within panels to address variation in test ordering patterns and potential changes in panel reimbursement. The BioCode® MDx-3000 system has the

capability to process up to 3 different multiplex panels on the same run. It also offers a User Defined Mode where laboratories can develop their own multiplex assays to run on the system.

The BioCode Gastrointestinal Pathogen Panel was the first of many syndromic infectious disease panels developed for the BioCode MDx-3000 System. Applied BioCode also has a 20-plex Respiratory Pathogen Panel** completing Clinical Trials for the US market.

* The MagNA Pure 96 System is a product of F. Hoffmann-La Roche Ltd.

** In clinical trial, has not been cleared by the FDA.