bioMérieux receives U.S. FDA clearance for the new version of its molecular test targeting causes of gastroenteritis, BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel Mid

Marcy l'Étoile, France – February 11th, 2025 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announces that its BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel Mid has obtained clearance from the U.S. Food and Drug Administration (FDA). This midplex molecular panel tests for 11 of the most common bacteria, viruses, and parasites associated with gastroenteritis — all from one sample, with results available in approximately one hour.

Acute gastroenteritis, an inflammatory condition of the gastrointestinal tract, is characterized by diarrhea, vomiting, fever, and abdominal pain. This infectious disease can lead to potentially life-threatening health consequences, particularly in children, the elderly, and immunocompromised patients. Globally, diarrheal disease is placed as the third leading cause of death in children under 59 months of age, with approximately 1.7 billion cases of diarrheal disease annually[1]. It presents with many overlapping symptoms that are difficult to distinguish. Furthermore, traditional stool methods can be time-consuming and lack sensitivity, potentially leading to inadequate treatment decisions, unnecessary antibiotic use, inappropriate infection control measures, secondary pathogen transmissions, and suboptimal healthcare resource use[2,3].

The newly FDA-cleared BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel Mid, as a polymerase chain reaction (PCR) testing solution, is capable of simultaneously detecting 11 pathogens* directly from stool samples of individuals presenting with signs and/or symptoms of GI infection. Designed for use on bioMérieux's BIOFIRE® FILMARRAY® 2.0 and Torch PCR platforms, this panel requires about 2 minutes of hands-on time for setup, with an approximate run time of 1 hour.

This new panel complements the bioMérieux's BIOFIRE® GI offering. It is a variation of the existing highplex BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel, targeting 22 pathogens, available since 2014, providing laboratories with a streamlined workflow with fast, comprehensive results that increase diagnostic yield, while improving patient outcomes[2,4,5].

"BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel Mid brings clinicians an additional option in diagnosing infectious gastroenteritis depending on the medical status of patients. Our suite of BIOFIRE® FILMARRAY® Gastrointestinal Panels revolutionizes how we approach gastrointestinal diagnostics. By providing rapid, accurate results, we empower clinicians to make timely, informed decisions, improving patient outcomes and streamlining laboratory workflows," declared Dr. Charles K. Cooper, Executive Vice President, Chief Medical Officer, bioMérieux.

"This new panel broadens bioMérieux's leadership in syndromic molecular testing for gastrointestinal infections. With BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel Mid, we target a category of patients with less severe conditions who are currently addressed by slower and less comprehensive diagnostic solutions. Now clinicians and laboratories have the opportunity to choose either a 22-target panel or an 11-target one,

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enabling them to make timely treatment decisions and reduce empirical treatments," added Jennifer Zinn, Executive Vice President, Clinical Operations, bioMérieux.

BIOFIRE® Gastrointestinal (GI) Panel Mid will be commercially available in the United States at the end of the first half of 2025.

* ***Bacteria:*** *Campylobacter (C. jejuni/C. coli/C. upsaliensis), Clostridioides (Clostridium) difficile (toxin A/B), Salmonella, Vibrio (V. parahaemlyticus/V. vulnificus/V. cholerae), Yersinia enterocolitica, Shiga-like toxin-producing E. coli (STEC) stx1/stx2, Shigella/Enteroinvasive E. coli (EIEC).*
Viruses: Norovirus GI/GII
Parasites: *Cryptosporidium, Cyclospora cayetanensis, Giarda lamblia*

[1] *WHO. Diarrhoeal disease ; 2024. Available online: (Diarrhoeal disease). [Accessed on 18 December 2024].*
[2] *Torres-Miranda, D., Akselrod, H., Karsner, R., Secco, A., Silva-Cantillo, D., Siegel, M.O., et al.* **Use of BioFire FilmArray gastrointestinal PCR panel associated with reductions in antibiotic use, time to optimal antibiotics, and length of stay**. *BMC Gastroenterol. 2020;20(1):246.*
[3] *Yalamanchili, H., Dandachi, D., Okhuysen, P.* **Use and interpretation of enteropathogen multiplex nucleic acid amplification tests in patients with suspected infectious diarrhea**. *Gastroenterology & hepatology. 2018;14:646-52.*
[4] *Meyer, J., Roos, E., Combescure, C., Buchs, N.C., Frossard, J.L., Ris, F., Toso, C., Schrenzel, J.* **Mapping of aetiologies of gastroenteritis: a systematic review and meta-analysis of pathogens identified using a multiplex screening array**. *Scand J Gastroenterol. 2020 Dec;55(12):1405-1410.*
[5] *Axelrad, J.E., Freedberg, D.E., Whittier, S., Greendyke, W., Lebwohl, B., Green, D.A.* **Impact of gastrointestinal panel implementation on health care utilization and outcomes**. *J Clin Microbiol. 2019 Feb 27;57(3):e01775-18.*

ABOUT BIOFIRE® FILMARRAY®

The BIOFIRE® FILMARRAY® Solution is a U.S. FDA-cleared and/or CE-marked closed multiplex PCR and fully-automated system that integrates sample preparation, amplification, and detection. A BIOFIRE® test requires about two minutes of hands-on time and has a total run time of ~45 minutes to ~1 hour, depending on the panel. The BIOFIRE® Panel portfolio includes 7 syndromic panels or panel ranges:

- BIOFIRE® Respiratory Panels (RP2.1 and RP2.1*plus*)
- BIOFIRE® FILMARRAY® Pneumonia (PN) and Pneumonia *plus* (PN*plus*) Panels
- BIOFIRE® Blood Culture Identification 2 (BCID2) Panel
- BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel and Panel Mid
- BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel
- BIOFIRE® Joint Infection (JI) Panel
- BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel

As of December 31th, 2024, the number of BIOFIRE® FILMARRAY® Systems installed globally reached 26,750 units.

ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics since 1963, bioMérieux is present in 45 countries and serves more than 160 countries with the support of a large network of distributors. In 2023, revenues reached €3.7 billion, with over 90% of sales outside of France.

bioMérieux provides diagnostic solutions (systems, reagents, software and services) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are mainly used for diagnosing infectious diseases. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.
www.biomerieux.com.

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bioMérieux is listed on the Euronext Paris stock market.
Symbol: BIM – ISIN Code: FR0013280286
Reuters: BIOX.PA/Bloomberg: BIM.FP

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