



bioMérieux submits 510(k) to U.S. FDA for the latest versions of the BIOFIRE® FILMARRAY® Gastrointestinal Panels to enhance detection of gastrointestinal pathogens

Marcy l'Étoile, France – June 30th, 2026 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announces the submission of the BIOFIRE® FILMARRAY® Gastrointestinal 1.1 (GI1.1) Panel and the BIOFIRE® FILMARRAY® Gastrointestinal 1.1 (GI1.1) Panel Mid to the U.S. Food and Drug Administration (FDA) for 510(k) review. These PCR* molecular panels test 22 and 11, respectively, of the most common bacteria, viruses, and parasites associated with gastroenteritis, all from one sample, with results available in approximately one hour.

Acute infectious gastroenteritis remains a significant global health concern, driven by a diverse and continually evolving range of viral, bacterial, and parasitic pathogens that inflame the gastrointestinal tract. Clinical manifestations such as diarrhea, vomiting, fever, and abdominal pain are often nonspecific, making diagnostic testing even more critical. The highest disease burden affects young children, older adults, and immunocompromised individuals. Diarrheal diseases continue to rank among the leading causes of mortality in children under 59 months of age, with an estimated 1.7 billion cases occurring worldwide each year¹.

As pathogen populations shift over time through genetic variation, emergence of new strains, and changes in epidemiological patterns, diagnostic technologies must evolve to ensure accurate detection, timely clinical decision-making, and effective public health responses.

In line with bioMérieux's commitment to delivering high-quality diagnostic solutions and its continuous improvement strategy, the company has developed the BIOFIRE® FILMARRAY® GI1.1 Panel and BIOFIRE® FILMARRAY® GI1.1 Panel Mid. These new versions introduce updated capabilities, including enhanced norovirus detection, further strengthening assay specificity.

As PCR molecular testing solutions, these panels are capable of simultaneously detecting 22 and 11 pathogens**, respectively, directly from stool samples of individuals presenting with signs and/or symptoms of gastrointestinal infection. Designed for use on bioMérieux's BIOFIRE® FILMARRAY® 2.0 and TORCH systems, they require about two minutes of hands-on time for setup, with an approximate run time of about one hour.

"bioMérieux is continuously seeking opportunities to further advance our existing product portfolio, both to adapt to the evolving needs of patients and clinicians and to respond to emerging changes in epidemiology. Thanks to strong post-market surveillance efforts and work from research and development scientists, we are happy to bring a revised solution, notably to support the accurate identification of norovirus. Gastroenteritis can be serious, and fast identification of the underlying pathogen is critical for infection prevention and control, and optimal patient care." declared Dr. Charles K. Cooper, Executive Vice President, Chief Medical Officer, bioMérieux.

"In a world where infectious disease threats are constantly evolving, diagnostic innovation plays a critical role in strengthening public health systems. As the global

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leader in gastrointestinal syndromic testing, bioMérieux continues to enhance its molecular offer with the latest generation of the BIOFIRE® FILMARRAY® gastrointestinal panels. These solutions empower clinicians to quickly make informed treatment decisions, limit disease transmission, and improve outcomes for the most vulnerable populations. This strategic investment reinforces our commitment to continuous improvement, supporting healthcare systems to respond more effectively to the challenging landscape of infectious diseases,” commented Jennifer Zinn, Executive Vice President, Clinical Operations, at bioMérieux.

The BIOFIRE® FILMARRAY® GI1.1 Panel will be commercialized across all regions, while the BIOFIRE® FILMARRAY® GI1.1 Panel Mid will be initially available in the United States. Following the 510(k) submission to the U.S. FDA, bioMérieux also intends to seek IVDR CE-marking for the BIOFIRE® FILMARRAY® GI1.1 Panel in Europe.

* Polymerase Chain Reaction

**** BIOFIRE® FILMARRAY® GI 1.1 Panel:**

Bacteria: *Campylobacter* (*C. jejuni*/*C. coli*/*C. upsaliensis*), *Clostridioides* (*Clostridium*) *difficile* (toxin A/B), *Plesiomonas shigelloides*, *Salmonella*, *Vibrio* (*V. parahaemolyticus*/*V. vulnificus*/*V. cholerae*), *Vibrio cholerae*, *Yersinia enterocolitica*, Enteroaggregative *E. coli* (EAEC), Enteropathogenic *E. coli* (EPEC), Enterotoxigenic *E. coli* (ETEC) *lt/st*, Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*, *Shigella*/Enteroinvasive *E. coli* (EIEC)

Viruses: Adenovirus F40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, Sapovirus (I, II, IV, and V)

Parasites: *Cryptosporidium*, *Cyclospora cayetanensis*, *Entamoeba histolytica*, *Giardia lamblia*

BIOFIRE® FILMARRAY® GI 1.1 Panel Mid:

Bacteria: *Campylobacter* (*C. jejuni*/*C. coli*/*C. upsaliensis*), *Clostridioides* (*Clostridium*) *difficile* (toxin A/B), *Salmonella*, *Vibrio* (*V. parahaemolyticus*/*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*, *Giardia lamblia*

¹ WHO. Diarrhoeal disease ; 2024. Available online: ([Diarrhoeal disease](#)). [Accessed on 7 March 2024].

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.



bioMérieux is listed on the Euronext Paris stock market.

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