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

Marcy l'Étoile, France – November 9th, 2026 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announces that the BIOFIRE® FILMARRAY® Gastrointestinal 1.1 (GI1.1) Panel has obtained U.S Food and Drug Administration (FDA) 510(k) clearance and IVDR[1] CE marking, and the BIOFIRE® FILMARRAY® Gastrointestinal 1.1 (GI1.1) Panel Mid has received US FDA 510(k) clearance. 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 about 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, which cause an estimated 1.7 billion cases worldwide each year.[2] continue to rank among the leading causes of mortality in children under 60 months of age.

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.

Redesigned norovirus assay and improved *Campylobacter* detection

In line with its commitment to continuous improvements and to delivering high-quality diagnostic solutions, bioMérieux has developed the BIOFIRE® FILMARRAY® GI1.1 Panel and BIOFIRE® FILMARRAY® GI1.1 Panel Mid. These new versions include a redesigned norovirus GI/GII assay and a software-based improvement for *Campylobacter* detection, further strengthening the panels' specificity and providing greater confidence in every result.

These molecular syndromic testing solutions 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.

Helping clinicians make informed decisions

"The regulatory authorizations of these enhanced gastrointestinal panels mark an important milestone in ensuring healthcare providers have access to the most up-to-date diagnostic tools to support patient care. This is particularly important for norovirus, which remains one of the most prevalent and disruptive causes of acute gastroenteritis, and can spread rapidly in communities and healthcare settings. By providing timely and

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reliable diagnostic information, these panels can help clinicians make informed decisions earlier, support infection control efforts, and ultimately improve the patient experience," declared Dr. Charles K. Cooper, Executive Vice President, Chief Medical Officer, bioMérieux.

"At bioMérieux, innovation extends beyond developing new diagnostic solutions. It includes continuously enhancing the performance of technologies within our trusted portfolio used by healthcare professionals every day. As the global leader in gastrointestinal syndromic testing, we leveraged robust post-market surveillance and R&D advancements to develop the latest generation of our BIOFIRE® FILMARRAY® Gastrointestinal Panels. By providing rapid, actionable results, we support better clinical decision-making for improved patient management and deliver greater value to laboratories and clinicians when it matters most," commented Jennifer Zinn, Executive Vice President, Clinical Operations, bioMérieux.

A global commercialization strategy

The BIOFIRE® FILMARRAY® GI1.1 Panel will be deployed across all regions, while the BIOFIRE® FILMARRAY® GI1.1 Panel Mid will be initially available in the United States. In addition to receiving U.S. FDA 510(k) clearance, the BIOFIRE® FILMARRAY® GI1.1 Panel has also been CE marked under the IVDR,[1] enabling commercialization across European markets.

** **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*
*** In Vitro Diagnostic Regulation, in force in the European Union.*

[1] In Vitro Diagnostic Regulation, in force in the European Union.
[2] 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.

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bioMérieux is listed on the Euronext Paris stock market.
Symbol: BIM – ISIN Code: FR0013280286
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