

BD Receives FDA 510(k) Clearance and CE-IVDR Certification for High-Throughput Enteric Bacterial Panels on BD COR™ System

FRANKLIN LAKES, N.J., Nov. 3, 2025 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX) a leading global medical technology company, today announced it has received U.S. Food and Drug Administration (FDA) 510(k) clearance and Conformité Européenne (CE) marking in the European Union for its Enteric Bacterial Panel* (EBP) and Enteric Bacterial Panel *plus** (EBP *plus*) for the BD COR™ System.

By leveraging advanced Polymerase Chain Reaction (PCR) technology with streamlined testing for a broad range of gastrointestinal (GI) bacterial pathogens from a single stool swab sample, the panels simplify workflows helping clinicians deliver timely, targeted care.

GI infections cause billions of illnesses and more than 1.7 million deaths globally each year, disproportionately affecting young children, older adults, and immunocompromised peopleⁱ. In the United States, diarrhea accounts for an estimated 179 million outpatient visits, 500,000 hospitalizations, and more than 5,000 deaths annually, resulting in approximately one episode of acute diarrheal illness per person per yearⁱⁱ. These figures highlight the urgent need for rapid, accurate diagnostics to improve outcomes and support antimicrobial stewardship.

"Traditional GI tests can take days, and when patients are experiencing symptoms such as diarrhea or vomiting, delays can be potentially life-threatening," said Nikos Pavlidis, worldwide president of BD Diagnostic Solutions. "With EBP and EBP*plus*, clinicians choose the panel that best fits their clinical needs to quickly identify specific pathogens from a single swab, streamlining lab workflows and enabling targeted treatment to help protect vulnerable patients."

BD EBP for BD COR™ System offers a wide range of targets for enteric bacterial pathogens, including *Salmonella* spp., *Campylobacter* spp. (*jejuni* and *coli*), *Shigella* spp./Enteroinvasive *Escherichia coli* (EIEC), and Shiga toxin-producing *Escherichia coli* (STEC).

BD EBP *plus* for BD COR™ System is the only high-throughput, bacterial-only molecular panel that detects Enterotoxigenic *Escherichia coli* (ETEC), heat-labile enterotoxin (LT) and heat-stable enterotoxin (ST) genes, enabling improved patient management through rapid identification for targeted treatment of this major cause of diarrheal illness and helping reduce unnecessary antibiotic useⁱⁱⁱ. The panel also identifies *Plesiomonas shigelloides*, *Vibrio* spp. (*V. vulnificus*, *V. parahaemolyticus*, *V. cholerae*), and *Yersinia enterocolitica*.

The panels are run on the BD COR™ System, which automates molecular lab workflows with capacity for nearly 1,650 tests while delivering up to 1,000 sample results in 24 hours with barcode-driven traceability and remote system management. It offers up to seven hours of walk-away time, requires under 15 minutes to load, and uses room-temperature reagents that require no reconstitution, maximizing efficiency and minimizing manual interaction.

BD also offers the BD MAX™ Enteric Bacterial, Extended Enteric Bacterial, Enteric Viral and Enteric Parasite targeted syndromic panels for timely, accurate detection of the most common bacterial, viral and parasitic pathogens responsible for infectious diarrhea.

"With the BD MAX™ System, BD has long supported flexible, efficient, reliable enteric pathogen testing with more than 10 assays across respiratory, hospital acquired infection, sexually transmitted infection, and women's health testing for hospitals, clinics, and reference labs," said Pavlidis. "The addition of these two enteric panels to the BD COR™ system enables high-volume laboratories to advance their standard of care and optimize operational workflows."

About BD

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its more than 70,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes,

lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit [bd.com](https://www.bd.com) or connect with us on LinkedIn at www.linkedin.com/company/bd1/, X (formerly Twitter) [@BDandCo](https://twitter.com/BDandCo) or Instagram [@becton_dickinson](https://www.instagram.com/becton_dickinson)

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ⁱ <https://bmcpublikealth.biomedcentral.com/articles/10.1186/s12889-024-21270-6>

ⁱⁱ <https://www.aafp.org/pubs/afp/issues/2022/0700/acute-diarrhea.pdf>

ⁱⁱⁱ <https://pmc.ncbi.nlm.nih.gov/articles/PMC5925700/pdf/e00148-18.pdf>

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