

Copan FecalSwab® receives the 510(k) FDA clearance for molecular use with the BD MAX™ Enteric & Extended Enteric Bacterial Panels

Brescia, Italy – 24 Feb 2023

Copan announces the 510(k) FDA clearance of its Copan FecalSwab® for collecting and transporting stool samples to be processed with BD Enteric Bacterial Panel and BD Extended Enteric Bacterial Panel on the BD MAX™ System. This clearance opens new molecular diagnostic opportunities for customers who already use FecalSwab® to maintain enteric pathogens' vitality for microbial culturing.

Copan FecalSwab® is the first and only collection and transport device cleared by the FDA for molecular detection of enteropathogens (bacteria, viruses, and parasites) with BD MAX™ Enteric and Extended Enteric Bacterial Panels and for vitality preservation of enterobacteria for microbial culture applications. Using a fully validated device will help ensure the total quality of the diagnostics process and relieve the laboratories from time and resource consumption in a constantly changing gastrointestinal (GI) diagnostics space. Moreover, labs will now be able to expand their flexibility for GI testing, using the same sample for molecular diagnostics-based tests and traditional methods such as microbial culture.

FecalSwab® is a modified Cary-Blair medium coupled with a FLOQSwabs®. The device was already FDA-cleared and extensively used worldwide to maintain enteric pathogens' vitality for up to 48 hours (24 hours for *C. difficile*) at room temperature for manual and automated culture testing.

Acute gastroenteritis, also known as infectious diarrhea, is a leading cause of morbidity and mortality worldwide. In the U.S., up to 375 million episodes of diarrheal illnesses occur annually, with 3,100 deaths. Young children, older persons, and immunocompromised persons are more vulnerable and have a higher risk of complications.

The BD MAX™ Enteric and Extended Enteric Bacterial Panels (Becton, Dickinson and Company, New Jersey, USA) are nucleic-acid amplification-based assays for the detection of many common enteric bacterial pathogens, such as *Salmonella sp.*, *Campylobacter jejuni/coli*, *Shigella sp.*, and *Shiga toxin-producing Escherichia coli (STEC)*, pathogens collectively cause about 95% of cases for bacterial gastroenteritis. The BD MAX™ Enteric and Extended Bacteria Panels are part of the BD MAX™ Enteric family of assays that allow testing of a specific class of enteric pathogens following IDSA guideline-based patient exposure, risk factors and clinical presentations and can provide results for up to 24 specimens in less than 3 hours.

Copan FecalSwab® will be available for sale with the updated claim in the coming months.

About Copan

Copan is dedicated to developing high-quality and cutting-edge sample collection products for infectious diseases, human genomics, environmental and forensic applications, along with automated workflow solutions. Our ideas drove 40 years of progress in preanalytics, resulting in meaningful products tailored to fit any need. Among them, FLOQ technology revolutionized sample collection, while WASPLab® advanced hardware and A.I. modules leveraged automation and digitalization to redefine full lab automation. Copan's Workflow-Integrated System Environment can accompany your biological samples from the collection to impeccable diagnostics, unlocking your lab's real potential and improving treatment indication and patient care.

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