

BioFire Obtains CE IVD Mark for FilmArray® Blood Culture Identification Panel



BioFire Diagnostics, Inc. announced today that it obtained the CE IVD Mark under the European Directive on In Vitro Diagnostic Medical Devices for its FilmArray Blood Culture Identification (BCID) Panel.

The BCID Panel tests positive blood cultures and can identify more than 100 blood pathogens known to cause sepsis. Sepsis, a serious medical condition, has a mortality rate ranging from 10% to 38%.

With each hour that sepsis goes untreated there is an eight percent increase in mortality, making timely diagnosis and administration of appropriate therapy imperative for positive patient outcomes. The FilmArray BCID Panel is designed to help hospitals identify bloodstream infection-causing organisms more rapidly than conventional identification methods. Studies show that a quicker time to sepsis organism identification and appropriate therapy leads to reduced mortality rates, shorter hospital stays, and lower overall costs.

With an easy procedure requiring only two of minutes of hands-on time, the BCID Panel can identify pathogens in nine out of 10 positive blood cultures in about one hour, and is the only test that provides results for gram-positive bacteria, gram-negative bacteria, and yeast causing bloodstream infections. In addition, the BCID Panel detects four antimicrobial resistance genes, (mecA, vanA, vanB and blaKPC) known to confer resistance to methicillin/oxacillin, vancomycin, and carbapenems. Identification of these resistance markers will provide physicians with information that can help to guide selection of appropriate antimicrobial treatment in a more timely manner.

Chief Executive Officer Kirk Ririe noted, "The addition of the BCID panel expands BioFire's infectious disease diagnostic menu, and the FilmArray continues to provide the fastest way to better results. We are confident that the BCID Panel will assist hospitals in lowering patient mortality rates and shortening patient stays. With the dramatically increased efficiency it offers, the panel should also help reduce costs - an ever-increasing focus in today's healthcare market."

Source: BusinessWire

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