NEWS RELEASE

Bruker Introduces Additional Key Products for Diagnosis and Susceptibility Testing of Invasive Fungal Diseases (IFD) into European Clinical Microbiology Markets

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Fungiplex® Candida fast identification assay and MICRONAUT™-AM antifungal susceptibility testing (AFST) further expand Bruker´s product range in Invasive Fungal Disease (IFD) testing

BELGRADE, Serbia, Oct. 6, 2017 /PRNewswire/ -- At the Trends in Medical Mycology (**www.timm2017.org**) conference, Bruker today introduces the new, CE-IVD marked Fungiplex® Candida fast diagnostic assay, a multiplex real-time PCR test for the rapid identification of the most common pathogens associated with invasive candidiasis. The new Fungiplex Candida assay does not require any culture steps, and typically gives results in just 2-3 hours directly from patient blood, plasma or serum samples.

Bruker also introduces the CE-IVD marked MICRONAUT®-AM (antimycotics) test plate for the automated or manual antifungal susceptibility testing (AFST) of yeasts from cultures. MICRONAUT®-AM is from the product range of recently acquired MERLIN Diagnostika GmbH, a leader in speciality susceptibility testing products across a range of human and veterinary application areas.

The Bruker microbiology portfolio is led by the MALDI Biotyper (MBT) platform for fast proteomic fingerprinting, a market-leading family of products providing rapid, broad-based molecular identification of microorganisms like bacteria, yeasts and fungi from cultures. Both new IFD tests further expand Bruker's microbiology business, and re-inforce Bruker's additional focus on rapid identification of invasive fungal diseases, followed by antifungal susceptibility testing.

With the previous launch of the CE-IVD marked Fungiplex Aspergillus fast identification assay at ECCMID 2017, Bruker announced a new focus on rapid detection of fungal infections in at-risk patients, especially the immuno-

compromised, allowing the development of effective treatment strategies to deliver improved patient outcomes. Such IFD diagnostic tools have the additional benefits of reducing prophylactic antifungal drug treatments, reducing the likelihood of antifungal resistance and bringing down the overall cost of care for at-risk patients.

The new Fungiplex Candida assay is a multiplex real-time PCR test for the most common pathogens associated with invasive candidiasis (IC), a major cause of morbidity and mortality in health care environments. The sensitivity of blood culture for diagnosing IC is low, typically reported at 50%, and is coupled with slow turnaround times of 2-3 days. Delayed diagnosis and delays to the initiation of appropriate treatment are associated with high mortality and extended hospital stays. The Fungiplex Candida assay enables the early identification of Candida infection without the need for blood culture and is validated against DNA extracted from whole blood, serum and plasma. Fungiplex Candida detects the main causative pathogens of IC: C. albicans, C. parapsilosis, C. tropicalis, C. dubliniensis, and differentiates C. krusei and C. glabrata.

The Fungiplex Candida assay reports the identification results in less than 2 hours from DNA extraction and displays excellent clinical performance, in a user friendly format compatible with existing laboratory equipment. This assay delivers the potential to aid earlier diagnosis, reduce hospital spend and improve patient outcomes.

Dr. Lewis White, Principal Clinical Scientist at NPHS Microbiology Cardiff, commented on the new Fungiplex Candida assay: "Fungal diseases such as invasive candidiasis pose an extremely serious healthcare risk to immunosuppressed patients, especially within the intensive care unit. Current diagnostic methods, including culture, struggle due to low sensitivity. Expensive prophylactic and empiric drug use is common, whereas PCR, as a key component of combined biomarker surveillance strategies, has the potential to prevent the overuse of unnecessary antifungals and allows the targeted use of antifungal drugs. Bruker's Fungiplex Candida real-time PCR assay, when combined with appropriate recommendations on DNA extraction, provides a standardised approach that displays excellent analytical performance and clinical sensitivity and specificity, with the potential to improve the diagnosis and treatment of at-risk patients. With the standardization of Candida PCR previously lacking, this new commercial option provides users with a validated and quality controlled alternative to be used in combination with serological tests."

The principle of the MICRONAUT™ system for specialty antimicrobial susceptibility testing is the phenotypic detection of microbial growth inhibition in the presence of antibiotics. Its microdilution procedure is a standardized, globally accepted reference method for the determination of minimal inhibitory concentrations (MICs). The MICRONAUT-AM plate allows for the antifungal susceptibility testing (AFST) of nine antimycotics (including anidulafungin, caspofungin and posaconazol) in up to eleven concentrations, and provides a standardized workflow for analysis with visual or photometric interpretation.

Dr. David Eustace, Head of IFD Business Unit at Bruker Daltonics, added: "The combination of the Fungiplex Candida and Fungiplex Aspergillus real-time PCR assays for the rapid detection of IFDs without culture, coupled with the introduction of MICRONAUT-AM high-performance MIC-based antimycotic susceptibility products, complement the existing MALDI Biotyper product family in the field of invasive fungal disease testing. This expanding IFD portfolio has the capability of meeting a wide range of customer needs, delivering high quality solutions to improve patient outcomes at every stage of the IFD treatment pathway."

About the Bruker MALDI Biotyper (MBT) Platform

The MALDI Biotyper family of systems enables molecular identification of microorganisms like bacteria, yeasts and fungi. Classification and identification of microorganisms is achieved reliably and quickly using proteomic fingerprinting by high-throughput MALDI-TOF mass spectrometry. The MALDI Biotyper uses a molecular approach based on specific proteomic fingerprints from bacterial strains. Many published studies have highlighted the greater accuracy and lower cost offered, as well as typically much faster time-to-result (TTR).

Applications of various MALDI Biotyper solutions include clinical routine microbial identification, environmental and pharmaceutical analysis, taxonomical research, food and consumer product safety and quality control, as well as marine microbiology. In many European and international laboratories the MALDI Biotyper has replaced classical biochemical testing for bacterial identification in the past few years due to the accuracy, speed, extensive species coverage, ease of use and cost effectiveness of the system. Traditional biochemical techniques detect different metabolic properties of microorganisms, can take many hours or even days for completion, and they often lack specificity.

The robust MALDI Biotyper requires minimal sample preparation and offers low consumables cost. The products of the MALDI Biotyper family are available in a research-use-only (RUO) version, as the U.S. FDA-cleared MALDI Biotyper CA System, or in an IVD-CE version according to EU directive EC/98/79. The MALDI Biotyper also has medical device registrations in numerous other countries. RUO versions of the MALDI Biotyper allow selected, high-value antimicrobial resistance tests.

About Bruker Corporation (NASDAQ: BRKR)

For more than 55 years, Bruker has enabled scientists to make breakthrough discoveries and develop new applications that improve the quality of human life. Bruker's high-performance scientific instruments and high-value analytical and diagnostic solutions enable scientists to explore life and materials at molecular, cellular and microscopic levels. In close cooperation with our customers, Bruker is enabling innovation, productivity and customer success in life science molecular research, in applied and pharma applications, in microscopy, nano-

analysis and industrial applications, as well as in cell biology, preclinical imaging, clinical phenomics and proteomics research, clinical microbiology and molecular pathology research. For more information, please visit: **www.bruker.com**

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