



NEWS RELEASE

## Bruker Introduces New Clinical Microbiology Assays and Kits at ECCMID

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- First CE-IVD Kit for MALDI Biotyper-based Functional Testing of High Risk Carbapenemase Antibiotic Resistance (MBT STAR),
- CE-IVD MBT Mycobacteria IVD Library & Software for identification of 164 mycobacteria species,
- Further Enhancements for MALDI Biotyper-based Microbial Subtyping for Clinical Research, and
- Novel CE-IVD Genetic Assays with 2-3 Hours of Time to Result for Invasive Aspergillosis and Carbapenem Resistance Gene Testing without Culture;

VIENNA, April 21, 2017 /PRNewswire/ -- At the 27th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), Bruker tomorrow will introduce important new clinical microbiology assays and consumables kits to further enhance the **MALDI Biotyper® (MBT)** platform. Bruker will also introduce novel, real-time PCR assays and kits for fast molecular testing of invasive aspergillosis and carbapenem resistance.

With our new **MBT STAR®-Carba IVD** kit, Bruker expands the **MALDI Biotyper** workflow beyond accurate and very broad microbial identification to additional fast functional testing of resistance against selected antibiotics of high clinical relevance. The **MBT STAR-Carba IVD** kit is the first validated diagnostic assay for mass spectrometry-based resistance testing on the market. It offers rapid turnaround time, and also gives information on the resistance mechanism. Independent of the resistance gene(s) involved, this novel assay detects the bacterial antibiotic resistance mechanism, e.g. the degradation of carbapenems, from isolates or from positive blood cultures. Specifically, the **MBT STAR-Carba IVD** assay is testing against carbapenem-resistance in Gram-negative bacteria, thus addressing a currently urgent healthcare problem. The **MBT STAR-Carba IVD** Kit and Software Module for the automated data interpretation are labeled according to EU directive EC/98/79. Bruker is planning to further expand the portfolio of **MBT STAR** assays in the future for the detection of additional resistance mechanisms.

Bruker is also announcing important enhancements for routine MALDI Biotyper microbiology fast identification workflows, including a **MBT Mycobacteria IVD Library** and **Software Module**, labeled according to EU directive EC/98/79, which make mycobacteria identification available for clinical diagnostic purposes. The new library covers 164 out of currently 180 described mycobacteria species, and it is by far the most comprehensive library for MALDI-based mycobacteria identification on the market.

For research use only, Bruker is further broadening its application portfolio of the **MBT Subtyping Module**. This MALDI subtyping module now also enables the automated differentiation between *Mycobacterium chimaera* and *Mycobacterium intracellulare*, and between the pathogenic *Listeria monocytogenes* and other *Listeria* species.

Professor Dr. Sören Schubert from the Max-von-Pettenkofer Institute at the Ludwig-Maximilians University in Munich, Germany stated: "I am impressed by the continuous innovations that Bruker offers on the **MALDI Biotyper** platform. The new diagnostic **MBT STAR-Carba IVD** assay is of significant clinical relevance, because carbapenemase producing bacteria are a growing healthcare concern and rapid, functional analysis is very important. This novel assay for rapid resistance testing for selected antibiotics can be run on the same **MALDI Biotyper** platform which has been successfully used for identification of bacteria and fungi in the microbiological lab. This is yet another milestone for the broad introduction of MALDI-TOF technology into clinical routine microbiology."

Moreover, Bruker introduces two novel CE-IVD marked, real-time PCR assays from its recently established Glasgow molecular testing branch:

- The new Fungiplex® Aspergillus multiplex, real-time PCR assay in less than 2 hours from extraction identifies the most common pathogens associated with invasive aspergillosis, providing rapid results with high sensitivity and specificity, and without the need for any culture. For this assay, DNA can be extracted from whole blood, serum, plasma and bronchoalveolar lavage (BAL), so that the Fungiplex Aspergillus assay can support clinicians in providing an earlier diagnosis of invasive aspergillosis in order to improve patient outcomes, or alternatively reduce the cost of unnecessary anti-fungal drugs.
- The new Carbaplex® assay is a multiplex, real-time PCR assay that detects and differentiates the most important carbapenemase gene families, namely KPC, NDM, VIM, IMP and OXA-48-like, in less than 3 hours from extraction. The assay is validated against DNA extracted from rectal swabs with no need for any culture. The test can also be used to identify these genes from isolates as a confirmatory test. The Carbaplex assay offers the potential to rapidly identify colonization and improve patient management decisions.

Dr. Lewis White, Principal Clinical Scientist at NPHS Microbiology Cardiff, commented on the new **Fungiplex Aspergillus** assay: "Fungal diseases such as Invasive Aspergillosis pose an extremely serious healthcare risk to immunocompromised patients, especially in the haemato-oncology cohort. 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, prevents the overuse of unnecessary antifungals and allows the targeted use of antifungal drugs. Bruker's **Fungiplex Aspergillus** real-time PCR assay, when combined with international recommendations on DNA extraction, provides a standardised approach that displays excellent clinical sensitivity and specificity, providing a commercial solution with the potential to improve the diagnosis and treatment of at-risk patients."

Dr. Wolfgang Pusch, Executive Vice President for Clinical MALDI at Bruker Daltonics, added: "We are pleased with the innovation that Bruker's microbiology business has generated and its further organizational evolution. With the **MBT STAR-Carba IVD** as the first commercial diagnostic kit for MALDI-based rapid, functional resistance testing, plus further significant improvements of our successful **MALDI Biotyper** platform, we have underlined our passion for innovation in routine clinical microbiology. Our parallel introductions of the **Fungiplex Aspergillus** and **Carbaplex** multiplex PCR assays, with 2-3 hours of time to result, are expected to offer significant patient benefits at affordable cost, and further strengthen our microbiology portfolio."

## 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:

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### MBT STAR®-Carba IVD kit

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