



NEWS RELEASE

Bruker Introduces MBT Sepsityper® Kit US IVD for Rapid and Affordable Identification of over 400 Microorganisms from Positive Blood Cultures

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- MBT Sepsityper Kit US IVD enables rapid, specific detection of many cases of bacteremia-induced sepsis to assist infectious disease specialists in potentially life-saving decisions
- Used for MALDI Biotyper® (MBT) identification directly from Positive Blood Cultures (PBC) with short time-to-result (TTR) of less than 30 minutes
- US FDA clearance received in late December for diagnostic use on MALDI Biotyper CA System with library of 425 organisms, covering gram-positive and gram-negative bacteria, as well as yeasts, e.g. *Candida auris*

BILLERICA, Mass.--(BUSINESS WIRE)--

Bruker Corporation (Nasdaq: BRKR) today announce US FDA clearance and the US launch of the **MBT Sepsityper Kit US IVD** for rapid microbial identification of more than 425 microorganisms from positive blood cultures on the **MALDI BiotyperCASystem**.

This press release features multimedia. View the full release here:

<https://www.businesswire.com/news/home/20210104005112/en/>

Figure 1: Ike Northern, Director of Infectious Disease Testing and Immunology, CompuNet Clinical Laboratory (Photo: Business Wire)

Dr. Wolfgang Pusch, Executive Vice President Microbiology & Diagnostics at Bruker Daltonics, stated: "This represents an order of magnitude increase in the number of microorganisms that can be identified rapidly from positive blood cultures in suspected bacterial or fungal sepsis cases

compared to targeted PCR detection. This could make the **MBT Sepsityper Kit US IVD** a nearly universal, rapid sepsis identification solution for clinical microbiology. We expect this affordable fast assay to benefit large numbers of patients, as it comes at a fraction of the cost of expensive syndromic panels with limited species coverage. Faster

identification can assist infectious disease physicians and pharmacists in switching sepsis patients to appropriate antibiotics or antifungals for local or hospital infection patterns, which reduces costs, length of ICU stays and could save lives.”

The **MBT Sepsityper Kit US IVD** enables the rapid identification of many microorganisms from positive blood culture bottles. Harvested microorganisms are processed, and then identified using the FDA-cleared **MALDI Biotyper CASystem**, with a reference library that covers 425 different gram-negative and gram-positive bacterial species and groups, as well as yeasts, including *Candida auris*, an emerging pathogen for hospital-acquired candidiasis.

The **MBT Sepsityper Kit US IVD** workflow typically takes less than 30 minutes from a positive blood culture bottle alert to identification. It can save up to 24 hours in time-to-result (TTR) for many identifications, versus additional agar plate culturing, and a further 8–12 hours for biochemical identification after agar plate culturing. The **MBT Sepsityper Kit US IVD** workflow does not test for resistance or antibiotic susceptibility. It rapidly identifies the microbial species once the blood culture system has detected microbial growth.

Mr. Ike Northern, Director of Infectious Disease Testing and Immunology at the CompuNet Clinical Laboratory in Dayton, Ohio, explained: “I think a lot of laboratories are realizing that they need to use MALDI-TOF MS technology for microbial identification. Many are now making this investment when they recognize the long-term patient and cost benefits. The **MBT Sepsityper Kit US IVD** will be the next step for a lot of clinical microbiology laboratories. Many are currently using multiplex PCR tests, but once you have the **MALDI Biotyper** instrument, it is more cost-effective to use the **MBT Sepsityper Kit US IVD** for fast identification than PCR syndromic panels.” (*)

Rapid testing from positive blood cultures is gaining increasing interest in the clinical microbiology community due to high mortality and morbidity rates in sepsis and septic shock. Sepsis impacts an estimated 30 million patients worldwide every year, many of whom die or suffer permanent health issues. Survival rates can be increased by rapid initiation of an appropriate antibiotic therapy (<http://www.worldsepsisday.org>). Developed for use with Bruker's U.S. FDA-cleared **MALDI Biotyper CA System**, the **MBT Sepsityper Kit US IVD** is intended to simplify and speed up identification of microorganisms directly from positive blood cultures of sepsis patients.

Dr. Elisabeth C. Shearon, the Medical Director at Alverno Laboratories in Hammond, Indiana, commented: “Rapid (MBT) **Sepsityper** identification has become instrumental in terms of our patient care. Especially in critically ill patients, the improved turn-around-time allows disease specific treatment which conserves health-care resources and, most importantly, improves patient outcomes.” (*)

Currently, guidelines call for physicians to treat septic patients quickly with broad-spectrum antibiotics with the goal of switching to a more targeted therapy once the infecting organisms have been identified and/or any antibiotic resistances have been determined. The **MBT Sepsityper Kit US IVD** can improve this process by providing rapid microbial identifications to help clinical microbiologists, treating physicians, and patients alike.

Dr. Steven D. Burdette, the Chief of Infectious Diseases at the Miami Valley Hospital in Dayton, Ohio added: “The **MBT Sepsityper** kit data has allowed us to adjust antibiotic therapy according to our local antibiogram. This, at times, has allowed us to narrow or stop certain antibiotic treatments while in other cases, it has allowed us to escalate antibiotic coverage pending sensitivity data. It has become a crucial tool for our Antimicrobial Stewardship team.” (*)

* All quoted early adopters have self-validated the research-use-only (RUO) version of the **MBT Sepsityper** kit prior to FDA-clearance of the **MBT Sepsityper Kit US IVD**.

About the Bruker MALDI Biotyper® (MBT) Platform

The MALDI Biotyper® enables molecular identification of 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, as well as the 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 software allow selected, high-value antimicrobial resistance tests. The CE-IVD MBTSTAR®-Cepha kit now allows rapid, functional antibiotic resistance testing against Cephalosporins, and the CE-

IVD MBT STAR-Carba kit is for fast Carbapenem-resistance testing.

About Bruker Corporation (Nasdaq: BRKR)

Bruker is enabling 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, improved productivity and customer success in life science molecular research, in applied and pharma applications, in microscopy and nanoanalysis, and in industrial applications, as well as in cell biology, preclinical imaging, clinical phenomics and proteomics research and clinical microbiology. For more information, please visit: www.bruker.com.

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