



NEWS RELEASE

Bruker Launches MALDI Biotyper Sirius at ASM Microbe Conference

6/20/2019

- Introduction of new MALDI Biotyper sirius™ system with additional negative-ion mode to support MALDI research and RUO validation studies, e.g. for colistin-resistance testing

- US introduction of Micronaut™ products for true minimum inhibitory concentration (MIC) antibiotic susceptibility testing (AST) in veterinary medicine

- US introduction of RUO versions of MALDI Biotyper-based rapid Selective-Testing of Antibiotic Resistance (MBT-STAR™) assays for validation studies on carbapenem resistance and cephalosporine resistance

SAN FRANCISCO, June 20, 2019 /PRNewswire/ -- At the ASM Microbe Conference 2019 (www.asm.org), Bruker launches the new MALDI Biotyper sirius system for all previously FDA-cleared, and for all research-use-only (RUO) MALDI Biotyper (MBT) reference libraries, which are used for near-universal, fast and cost-effective microbial identification from cultures in microbiology. The MALDI Biotyper sirius for the first time now also supports novel negative-ion mode assay research and clinical studies in fast antibiotic-resistance testing. This new high-end system complements the standard MALDI Biotyper and the high-throughput MALDI Biotyper smart.

The global spreading of antibiotic resistances is a growing healthcare problem, and the development and implementation of new, fast and cost-efficient resistance tests are important for advancing antibiotic stewardship. For gram-negative bacteria, the resistance-problem is so serious in many countries that antibiotics like colistin, with the risk of nephrotoxic side effects, increasingly must be used as an 'antibiotic of last resort'. Antibiotic stewardship aims to de-escalate the therapy in such cases early, if possible, or switch patients to other therapeutic options, if resistance is detected.

New, fast assays to detect colistin resistance in gram-negative bacteria can now be further developed and validated on the MALDI Biotyper Sirius, in addition to all routine clinical FDA-cleared identification assays, on the same

instrument. The new RUO colistin-resistance assay uses lipid analysis in negative-ion mode, and has been developed at Imperial College London, UK (Larrouy-Maumus et al., presented at ECCMID 2019, submitted for publication).

The new **MALDI Biotyper sirius** uses the proprietary **smartbeam™** solid-state laser with a 200 Hz repetition rate, and a lifetime of 500 million shots. This essentially makes the **smartbeam** a 'lifetime laser' in typical microbiology laboratories. The high-performance vacuum system allows for an even faster exchange of target plates in laboratory workflows, where multiple technicians prepare targets independently. Moreover, the high-performance vacuum system reduces downtime after service or preventive maintenance, which typically can be completed on the same day. The **MBT sirius** features new electronics, and LED strips indicate the system status. In the RUO **MBT sirius**, polarity switching to negative-ion mode is software-controlled and just takes a minute.

Dr. Gerald Larrouy-Maumus, Group Leader at the MRC-Centre for Molecular Bacteriology & Infection at Imperial College London, UK, commented. "The **MALDI Biotyper sirius** is a versatile MALDI-TOF MS system, which is not only able to perform near-universal bacterial identification very rapidly, but with its additional negative-ion mode also has allowed us to develop a fast and robust assay to detect colistin-resistant bacteria as an important, potential future routine assay after regulatory approvals. As my students say, the new **MALDI Biotyper sirius** is just 'Wow!'"

In addition, Bruker introduces the **MBT-STAR** assays for Selective-Testing of Antibiotic Resistance for carbapenems and for cephalosporins as research-use-only (RUO) assays to support US research and validation studies for the fast detection of antibiotic resistance. The functional **MBT-STAR** assays monitor molecular mass shifts due to the enzymatic metabolization that occurs in the case of bacterial resistance against the beta-lactam class of antibiotics.

Time-to-result (TTR) for both **MBT-STAR** assays is only about 60 minutes after positive culture. Unlike gene-targeted molecular resistance tests, the **MBT-STAR** assays are functional tests that can detect not only known resistance mechanisms, but also new, emerging resistances.

Dr. Wolfgang Pusch, Executive Vice President for Microbiology & Diagnostics at Bruker Daltonics, said: "Bruker has been driving the broad implementation of near-universal, fast and cost-effective MALDI identification in microbiology for many years. We are committed to enable important new workflows, and with the **MBT-STAR** RUO assays, our US customers now have access to research and validation studies for fast, functional assays of important beta-lactamase resistances. We are excited that the new **MALDI Biotyper sirius** is designed for further research on fast colistin-resistance testing in gram-negative bacteria, which is likely to become an important future clinical MBT assay, once it is fully validated and has regulatory approvals."

Moreover, Bruker introduces the **Micronaut™** portfolio of veterinary antibiotic susceptibility tests (AST) to the US market (not for human diagnostic use). The **Micronaut** products for veterinary medicine can assist in selecting targeted treatments of microbial infections in companion animals, livestock and horses. The **Micronaut** plates analyze true minimum inhibitory concentrations (MIC) by broth microdilution.

True MIC testing is increasingly becoming the 'gold standard' in veterinary testing. With the growing prevalence of resistant bacteria in veterinary medicine, the **Micronaut** AST plates help to guide veterinarians with the appropriate selection of antibiotic therapy. **Micronaut VET Com** assays support the analysis of bacteria isolated from companion animals, while **Micronaut VET CSH** plates can be used for bacteria isolated from live-stock animals and horses. **Micronaut VET Mas** enables the analysis of antibiotic resistance in bacteria that are causing bovine mastitis in the dairy industry.

About the Bruker MALDI Biotyper (MBT) Platform

The MALDI Biotyper enables molecular identification of bacteria, yeasts and fungi from cultures. 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 and veterinary 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 its accuracy, speed, extensive species coverage, ease of use and cost effectiveness. Traditional biochemical techniques detect different metabolic properties of microorganisms, can take many hours or even days, and 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 many other countries.

RUO versions of the MALDI Biotyper software allow selected, high-value antimicrobial resistance tests. The CE-IVD MBTSTAR®-Cepha kit 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.

Investor Contact:

Pamela Clark

Investor Relations

Bruker Corporation

T: +1 (978) 663-3660, ext. 1479

E: pamela.clark@bruker.com

Contact for Media and Customers:

Philip Perry

Bruker Daltonics

T: +49-172-313-7216

E: Philip.Perry@bruker.com

View original content to download multimedia: <http://www.prnewswire.com/news-releases/bruker-launches-maldi-biotyper-sirius-at-asm-microbe-conference-300871836.html>

SOURCE Bruker Corporation