



NEWS RELEASE

Bruker Announces US FDA Clearance of Expanded 3rd Claim for MALDI Biotyper

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- Expanded US FDA claim with 144 additional microbial species, for a total of 424 species now
- Disposable MBT Biotargets™ with 96-spot AnchorChip™ functionality for high sensitivity
- Available on standard microflex™ and high-end 200 Hz microflex smart MALDI-TOF systems
- Workflow automation and productivity enhancements by MBT Pilot™ and MBT Galaxy™

BILLERICA, Mass., July 31, 2017 /PRNewswire/ -- Bruker today announces that it has received US Food & Drug Administration (FDA) clearance for its third, further expanded claim for the market-leading **MALDI Biotyper-CA** (MBT-CA) system for fast, accurate and cost-effective microbial identification. The new claim includes a significant expansion of the microbial reference library for clinical microbiology, by adding 144 new species covering anaerobes, gram-positive and gram-negative bacteria, as well as yeasts. The library coverage of the **MALDI Biotyper-CA** now includes 424 microbial species in 333 different groups that are FDA-cleared for the US clinical microbiology market. This further significantly increases the clinical utility of the MBT.

The third claim now also includes the new disposable **MBT Biotargets 96 US IVD**, disposable targets based on Bruker's proprietary **AnchorChip™** technology, which provides superior sample concentration. The barcoded 96-spot **MBT Biotargets** are cost-efficient as there is no wastage of spots, and they allow a convenient workflow without target plate cleaning and the corresponding validation requirements.

The new expanded claim 3 library is now available in the US on two different versions of Bruker's **MALDI Biotyper CA** system, either based on the standard **microflex** MALDI-TOF mass spectrometer, or on the high-end **microflex smart**, which uses Bruker's proprietary **smartbeam™** laser. Under typical microbial identification conditions, the 200 Hz **smartbeam** is a 'lifetime laser' for microbial identification, decreases time-to-result and increases throughput. The **MBT smart** is the platform of choice for laboratories requiring high sample

throughput, and for potential future assays 'beyond identification', which are presently for research use only in the United States. Both MBT systems are compact, bench-top instruments requiring only 110V, operate in **Whispermode™** and require no special HVAC infrastructure.

Finally, the **MALDI Biotyper-CA** now offers additional workflow tools for US clinical microbiology customers: the **MBT Pilot™** is a unique, optically guided target preparation assistance tool designed to reduce specimen transfer human errors. The **MBT Galaxy™** automates reagent additions, reduces repetitive motions associated with target preparation, and improves productivity and standardization.

Dr. Christopher Doern, Associate Director of Microbiology at the VCU Medical Center in Richmond, Virginia, commented: "Implementation of the **MBT Pilot** and **MBT Galaxy** will be for the workflow of the **MALDI Biotyper**, what implementation of MALDI-TOF MS has been for the identification of microorganisms in clinical microbiology, game changing! The **MBT Pilot** system virtually eliminates the possibility of transcription error, while also greatly improving efficiency. Similarly, the **MBT Galaxy** system automates the time consuming and previously manual process of repeatedly pipetting small volumes of liquids. Not only do these workflow tools improve the quality and consistency of results, but they free up precious technologist time and automate the repeated motions required for MALDI-TOF target preparation."

George Goedesky, the Bruker Daltonics Vice President for Microbiology - Americas, added: "We are very pleased with the collaboration with our clinical trial partners that has resulted in this major library expansion for the **MALDI Biotyper CA** system. Our latest FDA claim 3 submission showed an impressive 99.8% correlation to sequencing methods, which demonstrates the extremely high quality of the fast, affordable and broad-based microbial identification with the **MALDI Biotyper-CA**. "

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, as well as typically much faster time-to-result (TTR).

Applications of the MALDI Biotyper include clinical microbial identification, environmental and pharmaceutical analysis, taxonomical research, food and consumer product safety and quality control, as well as marine microbiology. In many laboratories, the MALDI Biotyper has replaced biochemical testing for bacterial identification 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 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 in accordance with the 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, nanoanalysis 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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