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Bruker announces US FDA clearance of expanded 3rd claim for MALDI Biotyper

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Singapore – Bruker, a US based manufacturing company of scientific instruments announced 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.

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. "