



NEWS RELEASE

Bruker Announces Improved Assay for Tuberculosis Diagnostics in Novel Liquid Array™ Format for Improved Multiplexing

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- Expanded FluoroType™ MTBDR 2.0 Liquid Array molecular assay with CE-IVD mark provides highly differentiated tuberculosis (TB) detection and antibiotic resistance testing

- Novel FluoroCycler™ XT PCR system with CE-IVD mark enables new Liquid Array format

NEHREN, Germany, March 22, 2019 /PRNewswire/ -- In time for the World Tuberculosis (TB) Day 2019 on Sunday, March 24th (www.who.int/campaigns/world-tb-day/world-tb-day-2019), Bruker today announced the launch of an important further innovation in the field of tuberculosis diagnostics.

According to the World Health Organization (WHO), TB is among the most dangerous infectious diseases worldwide, ranking alongside HIV/AIDS (<https://www.who.int/tb/en/>) as a cause for death. One of the targets of the United Nations' Sustainable Development Goals for 2030 is to end the tuberculosis epidemic (<https://www.un.org/pga/73/event/fight-to-end-tuberculosis/>), which demands a global effort to tackle the rise of multi-drug-resistant TB (MDR-TB) and extensively-drug-resistant TB (XDR-TB). MDR-TB is resistant to the first-line drugs isoniazid (INH) and rifampicin (RIF), and XDR-TB in addition has developed resistance to fluoroquinolone and the injectable compounds used. The rapid diagnosis and appropriate treatment of both MDR-TB and XDR-TB is therefore essential to prevent significant morbidity, mortality and further transmission of the disease.

In recent years an increased spectrum of anti-mycobacterial resistance, and therefore an increased number of MDR and XDR cases has been observed. Conventional antibiotic susceptibility testing (AST) methods for TB can take an extremely long time to yield results, require significant laboratory infrastructure and training, and are potentially biohazardous. As a result, there is still under-diagnosis and a gap between acute TB cases and TB notifications.

The new PCR-based **FluoroType MTBDR 2.0** assay identifies tuberculosis pathogens, as well as several

important antibiotic resistance characteristics in only three hours. The novel assay detects TB pathogens directly from patient samples, without the need for any culture. In addition, it can be used to detect MDR-TB, i.e. resistance against rifampicin and isoniazid, the two most important first line TB drugs. This novel TB test relies on the innovative Bruker-Hain Liquid Array technology to analyze a multitude of mutations in the associated TB resistance genes.

The new **FluoroCycler XT** is a novel, high-performance thermal cycler and optical reader that enables the Liquid Array assay technology. The **FluoroType MTBDR 2.0** assay can detect more than 60 mutations in the TB genes, leading up to 522 resistance patterns with relevant information to guide therapy. This level of genetic specificity normally can only be achieved with sequencing.

Dr. Jaime Esteban from the Depto. Microbiología Clínica at the Universidad Autónoma de Madrid stated: "We will implement the new high-resolution **FluoroType MTBDR 2.0** test together with the newly developed, high-performance optical **FluoroCycler XT** to improve our ability to diagnose acute TB with greater specificity and as quickly as possible."

The **FluoroCycler XT** PCR system and the **FluoroType MTBDR 2.0** assay were CE-IVD registered in January 2019. With their combined launch, the fight against TB has a new tool for advanced testing to provide superior diagnostic information.

David Hain, Managing Director of Bruker-Hain Diagnostics, said: "With introduction of the **FluoroType MTBDR 2.0** Liquid Array assay for in-depth tuberculosis testing on our innovative **FluoroCycler XT** platform, Bruker supports the multinational healthcare objective to improve diagnosis for improved personalized therapy of acute tuberculosis."

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.

About Bruker-Hain Diagnostics

Bruker-Hain Diagnostics was formed after the recent acquisition of a majority share of the Hain Lifescience GmbH as a Business Unit for Molecular Diagnostics (MDx) products in Bruker's Microbiology & Diagnostics business. Hain Lifescience GmbH is the legal manufacturer of the **FluoroCycler XT** and the **MTBDR 2.0** assay. For more information, please visit, www.hain-lifescience.de.

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