BD Launches Molecular Test For Detecting Tuberculosis And Multi-Drug Resistant TB

BD MAX(TM) MDR-TB Panel Obtains CE-IVD Status in Europe

PR Newswire

FRANKLIN LAKES, N.J., Oct. 16, 2018 /<u>PRNewswire</u>/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced the availability of the BD MAX(TM) MDR-TB panel in Europe. Clinicians can use the test to simultaneously detect bacteria that cause tuberculosis (TB) and determine if the bacteria contain mutations associated with resistance to two important first line drugs, isoniazid (INH) and rifampicin (RIF), enhancing the information available to direct the optimal treatment for their patients.

Every year, about 10 million people develop TB disease and close to 2 million die from the disease, making it the leading cause of death from a single infectious agent. With proper detection and treatment, TB is curable. Multidrug-resistant TB (MDR-TB), defined as resistance to both INH and RIF, remains a critical hurdle in the fight to eradicate TB as patients with resistance to therapy will not benefit from those medicines and could spread the resistant forms of the disease to others.(1)

The BD MAX(TM) MDR-TB panel is an in vitro diagnostic with CE mark now available in Europe. The single PCRbased molecular diagnostic test is an integrated diagnostic test intended to help in the detection and diagnosis of TB, and INH- and RIF- resistance.

BD has a long history in TB diagnostics having launched the first automated liquid culture system, the BD BACTEC(TM) MGIT(TM) system for comprehensive testing for drug susceptibility and resistance. The new BD MAX(TM) MDR-TB assay complements this technology enabling clinicians to rapidly test for TB and multidrug resistance as a first line test and then use the BD BACTEC(TM) MGIT(TM) system for broader drug susceptibility testing and patient monitoring.

"We continue to focus on improving the diagnosis of TB so that we can provide clinicians with the best tools for identifying effective treatments for their patients," said Nikos Pavlidis, vice president and general manager of Molecular Diagnostics & Women's Health for BD Diagnostic Systems. "This new test is a big step forward for clinical practice as antimicrobial resistance has made this identification more complex. With the BD MAX(TM) MDR-TB panel and BD BACTEC(TM) MGIT(TM) products, BD is able to offer laboratories a suite of tools for effective and accurate patient diagnosis and management."

Preliminary results from an international clinical study of the BD MAX(TM) MDR-TB assay will be presented followed by an expert panel discussion on the value of a multi-pronged approach to fighting TB at the 49(th) Union World Conference on Lung Health (TB Union) at The Hague in The Netherlands on Thursday, October 25 at 6:00 p.m.

"As antimicrobial resistance becomes a greater problem in TB, understanding the drug resistance profile has become an increasingly important tool for successful treatment of individual patients," said Charles Cooper, MD, vice president of medical affairs for BD Diagnostic Systems. "Our global clinical trial of the BD MAX(TM) MDR-TB assay demonstrated that the assay can reliably detect both INH- and RIF-resistance. In addition, this assay can rapidly provide clinicians with valuable information necessary to manage patients with TB infections."

BD will be displaying the BD MAX(TM) system and presenting on the BD MAX(TM) MDR-TB panel at the TB Union conference. For more information, stop by booth #52-53 or visit: <u>www.bd.com/Europe/ds</u>.

About BD MAX(TM) SYSTEM

The BD MAX(TM) system is a fully-integrated, automated molecular diagnostics platform that performs nucleic acid extraction and real-time PCR. The system can multiplex up to 24 samples across multiple test applications and provide test results for most assays in less than three hours. Using BD MAX(TM) products, laboratories can test for a range of conditions including women's health and sexually transmitted infections, enteric conditions, and health care associated infections.

About BD

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of healthcare by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for healthcare providers. BD and its 65,000 employees have a passion and commitment to help improve patient outcomes, improve the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to better diagnose disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to healthcare. In 2017, BD welcomed C. R. Bard and its products into the BD family. For more information on BD, please visit <u>bd.com</u>.

(1) World Health Organization. Global Tuberculosis Report 2018. Geneva: WHO, 2018.

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