

BD Receives FDA 510(k) Clearance for New Immunological Diagnostic System

BD FACSLyric(TM) Flow Cytometer System with BD Multitest(TM) Assays Offers Reliability and Consistency

PR Newswire

FRANKLIN LAKES, N.J., July 19, 2017 [PRNewswire/](#) -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the BD FACSLyric(TM) flow cytometer system, an easy-to-use in vitro diagnostic (IVD) system, for use with BD Multitest(TM) assays for immunological assessment of individuals and patients having or suspected of having immune deficiency.

The BD FACSLyric system strengthens BD's portfolio of clinical flow cytometry solutions available in the U.S. The system was CE marked to the EU IVD Directive last year.

The new flow cytometer system combines a benchtop-sized instrument with software, reagents and services to provide clinicians and scientists with accurate, reliable and repeatable results.

"The FDA clearance of the BD FACSLyric system continues BD's drive to increase access to new innovations in clinical flow cytometry technology to more labs around the world," said John Ledek, president of Biosciences for BD. "BD recognizes that products for the clinical market require ease of use and standardization from instrument to instrument to ensure consistent results that ultimately inform patient care."

BD FACSLyric supports the BD Multitest(TM) 4-Color assays and the BD Multitest(TM) 6-Color TBNK assay, which are some of the most used flow-based IVD assays. These tests determine the percentages and absolute counts of T, B and natural killer (NK) cells, as well as the CD4 and CD8 subsets of T cells. Together, these metrics can be used in the immunological assessment of individuals and patients having, or suspected of having, immune deficiency. The BD FACSLyric cell analyzer is available in four configurations to provide laboratories with the flexibility to adapt to changing clinical needs. More IVD assays will be added to the BD FACSLyric solution as they become available.

The BD FACSLyric system is available as an IVD instrument in the U.S., Europe and other geographies. For more information, visit bdbiosciences.com.

About BD

BD is a global medical technology company that is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. BD leads in patient and health care worker safety and the technologies that enable medical research and clinical laboratories. The company provides innovative solutions that help advance medical research and genomics, enhance the diagnosis of infectious disease and cancer, improve medication management, promote infection prevention, equip surgical and interventional procedures, and support the management of diabetes. The company partners with organizations around the world to address some of the most challenging global health issues. BD has nearly 50,000 associates across 50 countries who work in close collaboration with customers and partners to help enhance outcomes, lower health care delivery costs, increase efficiencies, improve health care safety and expand access to health. For more information on BD, please visit bd.com.

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