BD Granted FDA 510(k) Clearance for BD FACSLyric™ Flow Cytometer with Newly Integrated BD FACSDuet™ Sample Preparation System

BD FACSDuet™ Sample Preparation System, now available in the U.S., as the first fully automated sample-to-answer solution when integrated with the BD FACSLyric™ Flow Cytometer

FRANKLIN LAKES, N.J., Oct. 5, 2020 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the BD FACSLyric™ Flow Cytometer with the Integrated BD FACSDuet™ Sample Preparation System

The new integrated system enables clinical laboratories to fully automate the sample to answer process and improve their efficiency by reducing errors and limiting the manual user interactions required to run assays on the BD FACSLyric™ Flow Cytometer.

The BD FACSDuet™ Sample Preparation System builds new capabilities into the BD portfolio of clinical flow cytometry solutions offering a pre-analytical system, that combined with the BD FACSLyric™ Flow Cytometer is the first truly walkaway sample-to-answer solution for clinical labs.

Physical integration between the BD FACSDuet™ Sample Preparation System and the BD FACSLyric™ Flow Cytometer allows technicians to load samples and reagents onto the BD FACSDuet™ Sample Preparation System and obtain results once the samples are acquired and analyzed on the BD FACSLyric™ Flow Cytometer. Data integration using the BD FACSLink™ Middleware Solution offers bidirectional communication between the instruments and connectivity with laboratory information systems (LIS).

"Flow cytometry in the clinical lab is a complex process that involves multiple workflows and manual steps. There is therefore a need for lean and effective technologies to reduce lab costs, increase quality and limit error rates. The BD FACSDuet™ Sample Preparation System is the continuation of our 45-year history of making reliable flow cytometry solutions that are robust, easy to use and improve the clinical lab workflow," said Puneet Sarin, president of Biosciences at BD.

Automation solutions for flow cytometry such as the BD FACSDuet™ and BD FACSLyric™ Complete Sample-to-Answer Solution helps to improve accuracy and standardization from instrument-to-instrument and operator-to-operator, enhancing throughput and providing consistent results that clinicians depend on to inform patient care.

The BD FACSLyric™ Flow Cytometer with the integrated BD FACSDuet™ Sample Preparation System is now available as an in vitro diagnostic (IVD) system in the United States as well as countries recognizing the CE-IVD certification, which was achieved in March 2019.

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 health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect 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 health care. For more information on BD, please visit bd.com.

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