BD Receives FDA 510(k) Clearance for New Flow Cytometer System with Leucocount Reagent Assay

BD FACSVia(TM) System for Clinical Simplicity in Cell Analysis and Enumeration

PR Newswire

FRANKLIN LAKES, N.J., April 6, 2017 <u>PRNewswire</u>/ -- 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 a flow cytometer system with a leucocount reagent assay used in residual white blood cell enumeration.

When used together with the BD Leucocount(TM) kit and BD Trucount(TM) tubes, the newBD FACSVia(TM) system provides a simple solution for identifying and counting rWBCs in leucoreduced blood products.

"The BD FACSVia system provides blood banks and clinical laboratories with an easy-to-use cell analysis solution to help determine and quantify the presence of residual white blood cells in their blood products," said John Ledek, president of Biosciences for BD. "The addition of the BD FACSVia system follows our larger strategy of making flow cytometry easier to use with improved efficiency, simplified sample analysis and high-quality diagnostic results."

With an intuitive user interface, the fully automated BD FACSVia system improves overall lab efficiency and simplifies workflow.

The BD FACSVia system offers the performance of a full-function clinical flow cytometer but in a compact design that easily fits on a benchtop or within a hood.

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 more than 40,000 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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SOURCE BD (Becton, Dickinson and Company)

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