BD Unveils Platelet Quality Control Media to Help Reduce the Incidence of Sepsis in Patients Requiring Platelet Transfusion

BD BACTEC™ Platelet Quality Control Media is cleared by the U.S. Food and Drug Administration and CE-IVD marked for platelet testing

FRANKLIN LAKES, N.J., April 8, 2019 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced the global availability of BD BACTEC™ platelet quality control media, which allows microbiology laboratories, blood banks and transfusion services to identify contaminated platelet units.



An estimated 12 million apheresis platelet donations are collected each year. Platelets are associated with a higher risk of sepsis and related fatality than any other transfusable blood component. The World Health Organization (WHO), U.S. Food and Drug Administration (FDA) and American Association of Blood Banks (AABB) have introduced guidelines and protocols for the detection of bacterial contamination in platelet donations, helping to reduce septic transfusion reactions and related fatalities by an estimated 50 to 70 percent. 3,4,5

"The availability of the BD BACTEC platelet quality control media allows clinicians the opportunity to identify potentially contaminated platelet donations by using a culture-based methodology, helping to reduce the risk of sepsis," said Gerald Denys, Ph.D., senior research professor of pathology and laboratory medicine at Indiana University School of Medicine.

BD BACTEC[™] platelet quality control media is part of a comprehensive solution leveraging the automated <u>BD BACTEC[™] FX technology</u> and <u>BD Synapsys[™] microbiology informatics solution</u> to help laboratories meet culture-based platelet testing requirements. The recent FDA 510(k) clearance of BD BACTEC[™] platelet quality control media adheres to FDA guidelines for culture-based methods and meets requirements of the CE-IVD directive. The

product can be used for quality control testing of leukocyte reduced apheresis platelet (LRAP) units, both leukocyte reduced single and a pool of up to six units of leukocyte reduced whole blood platelet concentrates (LRWBPC).

"The addition of BD BACTEC platelet quality control media builds on our legacy of offering accurate and cost-effective solutions through our BD BACTEC portfolio," said Steve Conly, vice president, general manager of microbiology for BD. "By offering this FDA cleared product, we hope to help our customers better serve some of their most vulnerable patients while minimizing the health and financial burdens associated with sepsis."

BD BACTEC™ platelet quality control media is now available globally. Visit https://go.bd.com/Platelet-media.html for more information.

About BD BACTEC™ Solutions

BD BACTEC™ blood culture system, offering a scalable footprint, helps clinicians diagnose bloodstream infections with a range of blood culture media and instrumentation. Coupled with a wide variety of culture media formulations, BD provides screening for microorganisms present in blood and blood components. BD BACTEC™ FX instruments powered by BD Synapsys™ microbiology informatics solution may enhance laboratory's ability to track samples and report results with an intuitive, browser-based interface.

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 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 healthcare. In 2017, BD welcomed C. R. Bard and its products into the BD family. For more information on BD, please visit bd.com.

- 1. Global Status Report on Blood Safety and Availability Report, World Health Organization, 2016.
- 2. Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion, March, 2016.
- 3. Blood Products Advisory Committee Meeting FDA White Oak Campus, Silver Spring, MD July 18, 2018.
- 4. Fuller AK, Uglik KM, Savage WJ, Ness PM, King KE. Bacterial culture reduces but does not eliminate the risk of septic transfusion reactions to single-donor platelets. Transfusion. 2009;49(12):2588-2593.
- 5. Eder AF, Kennedy JM, Dy BA, et al. Bacterial screening of apheresis platelets and the residual risk of septic transfusion reactions: the American Red Cross experience (2004-2006). Transfusion. 2007;47(7):1134-1142.

Contacts:

Gwen Gordon BD Public Relations 858.812.3724 Monique N. Dolecki BD Investor Relations 201.847.5378

gwen.gordon@bd.com monique dolecki@bd.com

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