BD Updates Instructions for Use for Certain BD Vacutainer® Blood Collection Tubes

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FRANKLIN LAKES, N.J., March 22, 2018 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced it is updating the instructions for use of certain BD Vacutainer(®) tubes as part of its quality process to ensure that customers understand the appropriate uses of these products.

Since BD became aware of the concerns about inaccurate lead test results from Magellan Diagnostics LeadCare(®) Testing Systems, the company has been cooperating fully with the U.S. Food and Drug Administration (FDA). BD launched an internal investigation and determined that Anodic Stripping Voltammetry (ASV) technology, which is used in Magellan LeadCare testing systems, is not compatible with thiuram, a material found in the rubber stoppers of the BD Vacutainer(®) EDTA Lavender, Pink and Tan top tubes and BD Vacutainer(®) Lithium Heparin Green top tubes. Thiuram has been in these rubber stoppers since 1996, however, the effect of thiuram on lead testing when used with ASV technology was only recently observed through the course of this investigation. As a result, BD is updating the instructions for use of its BD Vacutainer(®) Lavender, Pink and Tan top tubes and BD Vacutainer(®) Lithium Heparin Green top tubes to include a precaution that these products are not recommended for lead testing when using Magellan Diagnostics LeadCare(®) assays employing the ASV methodology, or any other assay employing ASV methodology. Other lead testing systems, such as graphite furnace atomic absorption spectroscopy (GFAAS) and inductively coupled plasma mass spectrometry (ICP-MS) are not affected by this update. In addition, BD is not aware of any other instrumentation that uses ASV technology. BD Vacutainer(®) tubes have been on the market for more than 60 years and continue to have a track record of safe and effective use.

Instructions to Customers

Please refer to the customer letter for specific information atbd.com/ en-us/support/alerts-and-notices/bd-edta-tubes-and-litium-heparin-tubes-ifu-update.

There is no need for customers to return any products to BD, and these products can continue to be used in accordance with the updated instructions for use.

Customers should continue to follow FDA's safety communication for testing lead levels, which currently recommends that no venous blood should be tested with Magellan's LeadCare test systems (regardless of the collection tube used).

Customers with inquiries related to this action may contact BD at 1-888-237-2762 (select Option #3 and then Option #4), Monday through Friday between 8 a.m. and 5 p.m. CDT.

Customers should report any adverse health consequences experienced with the use of these products to BD at the number above. Events may also be reported to the FDA's MedWatch Adverse Event Reporting program:

- Web: Medwatch website at www.fda.gov/medwatch
- Phone: 1-800-FDA-1088 (1-800-332-1088)
- Mail: MedWatch, HF-2, FDA 5600 Fisher's Lane, Rockville, MD 20853-9787

BD believes that every member of the industry -- from instrument manufacturers, to tube manufacturers to laboratory staff -- plays a role in the validation of testing methods and tools used in the diagnostic process. BD remains committed to providing high-quality products and expertise to support accurate diagnostic testing, good specimen integrity and quality, and a safe environment for patients and health care workers.

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

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