30 Tuas Avenue 2
Singapore 639461
Registration No. 201114149N

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URGENT: MEDICAL DEVICE CORRECTION
Instructions for Use (IFU) Update

Date: April 23rd , 2018

For the Attention of: Medical Director, Chairman Medical Board, Risk Manager, Medical Device Safety Officer, Lab Manager, Relevant Head of Departments

Products Description	Material No	Lots and Batch No
BD Vacutainer EDTA Lavender Top Tubes	366643	All Lots and Batches within Expiry Dates
BD Vacutainer Lithium Heparin Green Top Tubes	367880	
	366667	
	366664	
	367884	
	367886	
	367683	
	368494	
BD Vacutainer EDTA Lavender Top Tubes	367525	
	368861	
BD Vacutainer EDTA K2E Lavender Top Tubes	368857	
	367864	
	367841	
	367856	
	367861	
	367863	
BD Vacutainer EDTA Pink Top Tubes	367899	
	367918	

Reason for this communication:

BD has recently determined that the curing agent thiuram, used in the processing of rubber stoppers since 1996, can lead to release of carbon disulfide (CS2) and carbonyl sulfide (COS) gases into the headspace of the tubes. These gases can dissolve into the blood sample to chelate lead, and therefore interfere with the accuracy of the Anodic Stripping Voltammetry (ASV) testing methodology. Although the thiuram has been used since at least 1996, the release of CS2 and COS gases into the headspace and their effect on ASV methodology was only recently observed. **ASV is the methodology used in Magellan Diagnostics' LeadCare® Testing Systems**.

BD has conducted studies using BD Vacutainer® EDTA tubes to evaluate the potential interference of thiuram on lead tests results. BD has also evaluated the impact of thiuram interference on tests for commonly used analytes, a variety of molecular structures and classes of analytes, and a variety of test instruments/methodologies (please see below for further information on the analytes tested).

Although BD has no evidence to suggest that any other BD Vacutainer® tube or blood test is adversely affected by the use of the thiuram, out of an abundance of caution, additional evaluations are being conducted on BD's blood collection tubes that contain thiuram (including red top tubes (serum tubes), grey top tubes (sodium fluoride tubes), black top tubes (seditainer tubes), light blue/black top tubes (CPT tubes), and green/red tubes (CPT tubes)). BD is communicating with FDA in our ongoing evaluation.

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Laboratories should follow FDA's May 17, 2017 safety communication[1] for testing lead levels, which recommends that no venous blood should be tested with Magellan's LeadCare test systems (regardless of the collection tube used).

Background to IFU Update:

On May 17, 2017, FDA issued a Safety Communication recommending laboratories and health care professionals discontinue use of Magellan Diagnostics Inc.'s (Magellan Diagnostics) LeadCare® Testing Systems with venous blood samples due to potential for suppression (underestimation) of lead levels in the blood specimen, potentially causing inaccurate diagnostic results.[1] Based on BD's extensive investigation, BD has added the following precaution for BD Vacutainer® Lavender, Tan, and Pink Top tubes and BD Vacutainer® Lithium Heparin Green Top tubes to its IFU. At this time, FDA recommends that no venous blood (regardless of the collection tube) should be used with the Magellan LeadCare test systems.

> *"Precaution: BD Vacutainer® EDTA tubes (Lavender, Tan, and Pink Top tubes) and BD Vacutainer® Lithium Heparin Green Top tubes are not recommended for use with Magellan Diagnostics LeadCare® assays, employing the Anodic Stripping Voltammetry (ASV) methodology, or any other assay employing ASV methodology."*

This precaution applies to BD Vacutainer® Lavender, Tan, and Pink Top EDTA tubes and BD Vacutainer® Lithium Heparin Green Top tubes used with assays employing Anodic Stripping Voltammetry (ASV) methodology. The precaution does not extend to use of BD Vacutainer® EDTA Lavender, Tan Top, Pink Top tubes or BD Vacutainer® Lithium Heparin Green Top tubes with other blood lead level test technologies such as GFAAS and ICP-MS. BD has no evidence to suggest the performance of the gold standard ICP methodology for lead testing is affected by the choice of venous blood collection tube.

[1]FDA Safety Communication dated May 17, 2017: https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm

Please Take the Following Actions:

1. Continue to follow FDA's safety communication[1] 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).

2. Determine the need to evaluate the tests performed in your facility for the potential of thiuram interference. BD evaluated tests that cover commonly used analytes, a variety of molecular structures and classes of analytes, and a variety of test instruments/methodologies: 44 chemistry tests and immunoassays, 4 immunology tests, and 1 hematology panel (i.e., complete blood count with differential). BD concluded there is no evidence that the tests listed in the tables below are impacted by the thiuram curing agent.

Chemistry tests and Immunoassays

Alanine aminotransferase (ALT)	Sodium	Creatine kinase (CK)	Progesterone
Aspartate aminotransferase (AST)	Potassium	Creatine kinase-MB isoenzyme (CK-MB)	Testosterone
Alkaline phosphatase	Chloride	Cholesterol	Follicle stimulating hormone (FSH)

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Gamma glutamyltransferase (GGT)	Calcium	Triglycerides	Beta-human chorionic gonadotropin (β-HCG)
Amylase	Phosphorous	High density lipoprotein (HDL)	Total prostate specific antigen (PSA)
Lipase	Magnesium	Low density lipoprotein (LDL)	Cortisol
Lactate dehydrogenase (LDH)	Glucose	Total triiodothyronine (T3)	Ferritin
Total protein	Carbon dioxide	Total thyroxine (T4)	Folate
Albumin	Blood urea nitrogen (BUN)	Free triiodothyronine (T3)	Iron
Total bilirubin (TBIL)	Creatinine	Free thyroxine (T4)	Vitamin B12
Direct bilirubin (DBIL)	Uric acid	TSH	Troponin

Hematology and Immunology tests

Complete blood count with differential	Immunoglobulin A (IgA)
Complement C3	Immunoglobulin G (IgG)
	Immunoglobulin M (IgM)

BD also continues to communicate with the FDA as we complete our investigation and perform additional tests to evaluate the potential for thiuram interference. BD and the FDA will ensure these tests are representative of commonly used tests in clinical laboratories. Additional tests being undertaken will evaluate assays of metals, cardiac markers, cancer markers, therapeutic drug monitoring tests, and toxicology tests. Upon completion of the testing, BD will promptly notify customers if any issues are identified, as appropriate. If you have any questions related to the use of these products with any specific assay please contact BD PAS using the Contact Information found below.

3. Share this Medical Device Correction Notice with all users of BD Vacutainer® EDTA Lavender, Tan, and Pink Top tubes and BD Vacutainer® Lithium Heparin Green Top tubes in your facility to ensure they are also aware of this IFU update.

   Note: This is a Medical Device Correction and there is no need to return or discard product. The product can continue to be used with other non-ASV blood lead level test technologies such as GFAAS and ICP-MS and all assays which do not employ ASV methodology.

4. Complete the attached Customer Response Form and return to the BD contact noted on the form whether or not you have any of the covered product so that BD may acknowledge your receipt of this notification.

5. Report any adverse health consequences experienced with the use of this product to BD.

6. Additional information and updates on this issue can be found on FDA's website https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/LabTest/ucm566188.htm

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Actions Taken by BD:

BD has updated the IFU for BD Vacutainer® EDTA and BD Vacutainer® Lithium Heparin Tubes to include the noted precaution for use of Lavender, Tan, Pink, and Green Top tubes on Magellan Diagnostics LeadCare® assays as well as other assays using ASV methodology. A copy of the IFU is included with this Medical Device Correction Notification and can also be located at the following web address: www.bd.com/vacutainer/referencematerial.

Customers receiving paper copies of the IFU will receive the updated insert in future product orders.

Contact Information

If you require further assistance, please contact your BD Representative.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with the highest quality products.

Sincerely,

[redacted]

Joyce Tan
Associate Director, Regulatory Affairs
Greater Asia

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Customer Response Form
Medical Device Correction Notice
BD Vacutainer® EDTA Tubes –Lavender, Tan, K2 Plus, Pink Top Tubes, BD Vacutainer® Lithium Heparin Green Top Tubes IFU Update

Facility: _____

Please use full, current facility name. Do not use initials.

Street Address: _____

City:_____ **State**: _____ **Zip**: _____

Contact Person: _____

Telephone No.: _____**Email Address**: _____

Fax No.: _____

☐ I have read and understood the attached notice.

☐ I confirm that our facility does not use the Maghellan Diagnostics Leadcare Testing System.

Name:	
Title:	
Signature/Date:	