URGENT: FIELD SAFETY NOTICE – PAS-17-1019

BD Vacutainer® EDTA & BD Vacutainer® Lithium Heparin Tubes
When used for Lead Testing or other assay with ASV methodology

9th April 2018

Attention: End Users utilising BD Vacutainer® EDTA and BD Vacutainer® Lithium Heparin tubes for Lead testing using Magellan Diagnostics LeadCare® systems or other assays employing ASV methodology; Medical Device Safety Officers; Laboratory Directors, Laboratory Managers and Pathologists.

This letter contains important information which requires your **immediate** attention.

Details of affected devices and description of the problem:

BD has become aware that thiuram, a material found in the rubber stoppers of the BD Vacutainer® EDTA and the BD Vacutainer® Lithium Heparin blood collection tubes, is not compatible with Anodic Stripping Voltammetry (ASV) methodology. This methodology is known to be used within the Magellan LeadCare® testing systems. The thiruam can sometimes release sulphur (sulfur)-containing gases, which may dissolve into the blood sample and bind the lead particles. This chemical reaction makes it difficult for the Magellan lead tests to detect the correct amount of lead in a sample.

As a result, BD is informing all users who use the BD Vacutainer® EDTA and BD Vacutainer® Lithium Heparin tubes for the purposes of lead testing that these 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. A list of impacted BD Vacutainer® EDTA and Lithium Heparin catalogue codes can be found in Appendix 1.

Revised instructions for use will be made available for users to download from www.bd.com/IFU by the 8th May 2018, which will include a specific precaution statement that BD Vacutainer® EDTA and BD Vacutainer® Lithium Heparin 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.

BD Vacutainer® EDTA and BD Vacutainer® Lithium Heparin tubes, when used in combination with 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. Further, BD recommends the use of BD Vacutainer® Trace Element K_2EDTA tube (368380) for lead testing.

There is no requirement for customers to return any BD Vacutainer® EDTA or Lithium Heparin tubes to BD. These products can continue to be used in accordance with the guidance in this safety notice & the updated Instructions for Use.

Table 1 – Affected product details

Catalogue Number	Product Description	Lot number	Expiry Date
See Appendix 1	BD Vacutainer® EDTA Blood Collection Tubes	All lot numbers	All tubes within expiry date
See Appendix 1	BD Vacutainer® Lithium Heparin Blood Collection Tubes	All lot numbers	All tubes within expiry date

This Field Safety Notice only affects the catalogue numbers in Appendix 1.

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 (refer to Appendix 2 for further details) and has concluded there is no evidence that the tests listed in the table in Appendix 2 are impacted by the presence of thiuram in the stopper.

BD continues to perform additional tests to evaluate the potential for thiuram interference. 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 notify customers if any issues are identified, as appropriate.

Advice on action to be taken:

- Inform appropriate personnel in your organisation of the content of this Field Safety Notice.
- The Laboratory Director/Pathologist should identify the methodology used for Lead testing in your organisation:
    - BD recommends that you discontinue lead testing if using Magellan LeadCare® instrumentation or any other assay employing ASV methodology in combination with BD Vacutainer® EDTA and Lithium Heparin tubes.
    - **BD recommends to review previous lead test results which were performed using Magellan LeadCare® instrumentation or any other assay employing ASV methodology.**
    - For Magellan Diagnostics LeadCare® instrumentation users BD recommends that you contact Magellan for the sample type that can be used with their assays.
    - If using BD Vacutainer® EDTA and BD Vacutainer® Lithium Heparin tubes in combination with other lead testing systems, such as graphite furnace atomic absorption spectroscopy (GFAAS) and inductively coupled plasma mass spectrometry (ICP-MS), no further action is required.

- Complete and return the acknowledgement form (page 4) as soon as possible and **no later than the 27th of April 2018**. **Please return the acknowledgement form even if your organisation does not use Magellan LeadCare® instrumentation or any other assay employing ASV methodology for regulatory authority reconciliation purposes.**

Transmission of this Field Safety Notice

Please maintain awareness of this notice in your organisation for an appropriate period to ensure effectiveness of the corrective action.

Contact Reference Person

If you have any questions about the product please contact your local BD representative or the BD office on **<<insert tel. no.>>** or **<<insert email>>**.

BD Life Sciences – Preanalytical Systems is committed to providing quality products to our customers. We apologise for the inconvenience this situation may cause.

We confirm that the appropriate regulatory agencies have been informed of these actions.

Yours sincerely,

Lorna Darrock

EMEA Regulatory Affairs and Compliance Manager
BD - Preanalytical Systems

Field Safety Notice Acknowledgement Form

BD Vacutainer® EDTA & Lithium Heparin Plus Blood Collection Tubes

Please read in conjunction with Field Safety Notice PAS-17-1019 and return form to **<<insert email>>** as soon as possible and **no later than the 27th of April 2018**.

An acknowledgement form is required even if your organisation does not utilise BD Vacutainer® EDTA and Lithium Heparin tubes in combination with Magellan LeadCare® instrumentation or any other ASV methodology for regulatory authority reconciliation purposes.

- **YES**, I have:
  - Read and understood the Field Safety Notice
  - Informed appropriate personnel of this Field Safety Notice
  - Identified the methodology used for Lead testing
  - And if required, reviewed previous lead test results that were performed using Magellan LeadCare® instrumentation or any other assay employing ASV methodology.

Organisation / Hospital / Clinic :	
Department *(if applicable)* **:**	
Address :	
Postcode :	**City :**
Contact Name :	
Job Title :	
Contact Telephone Number :	**Contact E-mail Address :**
Signature :	**Date :**

This form must be returned to BD PAS before this action can be considered closed for your account.

Appendix 1: List of Catalogue Numbers

Catalogue Number	Product Description	Catalogue Number	Product Description
367862	BD Vacutainer® Plus EDTA tube	368841	BD Vacutainer® Plus EDTA tube
362089		368856	
364661		368857	
364662		368860	
364663		368861	
364664		362072	
365300		362084	
365312		362088	
365900		365329	
366547		366164	
367525		367924	
367836		367941	
367838		367978	
367839		368267	
367858		368834	
367864		362073	
367873		362085	
368270		362086	
368274		367386	
368499		367950	
365331		362083	
365330		362087	
368843		361017	BD Vacutainer® Glass EDTA Aprotinin tube
365308	BD Vacutainer® Plus Lithium Heparin tube	368495	BD Vacutainer® Plus Lithium Heparin tube
367526		368496	
367883		368884	
367885		368886	
368272		368889	
368494			

Appendix 2: Tests Not Impacted by Presence of Thiuram

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 concludes that there is no evidence that the tests listed in the tables below are impacted by presence of thiuram in the stopper.

Chemistry tests and Immunoassays

Alanine aminotransferase (ALT)	Sodium	Creatine kinase (CK)
Aspartate aminotransferase (AST)	Potassium	Creatine kinase-MB isoenzyme (CK-MB)
Alkaline phosphatase	Chloride	Cholesterol
Gamma glutamyltransferase (GGT)	Calcium	Triglycerides
Amylase	Phosphorous	High density lipoprotein (HDL)
Lipase	Magnesium	Low density lipoprotein (LDL)
Lactate dehydrogenase (LDH)	Glucose	Total triiodothyronine (T3)
Total protein	Carbon dioxide	Total thyroxine (T4)
Albumin	Blood urea nitrogen (BUN)	Free triiodothyronine (T3)
Total bilirubin (TBIL)	Creatinine	Free thyroxine (T4)
Direct bilirubin (DBIL)	Uric acid	TSH
Progesterone	Testosterone	Follicle stimulating hormone (FSH)
Beta-human chorionic gonadotropin (β-HCG)	Total prostate specific antigen (PSA)	Cortisol
Ferritin	Folate	Iron
Vitamin B12	Troponin	

Hematology and Immunology tests

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

BD is continuing to perform additional tests to evaluate the potential for thiuram interference on 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.