

# Becton Dickinson (BD) and Company Recalls Vacutainer® EDTA Blood Collection Tubes Due to Chemical Interference with Certain Tests

*The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.*

- Recalled Product:
  - BD Vacutainer® EDTA Lavender, Tan, and Pink Top Tubes
  - BD Vacutainer® Lithium Heparin Green Top Tube
- Product Lot Numbers: All
- Distribution Dates: May 5, 2016 to present
- Manufacturing Dates: March 29, 2016 to present
- Devices Recalled in the U.S.: 982,743,603 nationwide

## Device Use

BD Vacutainer® EDTA Blood Collection Tubes are used to collect blood samples from a vein (venous). The tubes are used to transport and process the blood samples for testing in clinical laboratories.

## Reason for Recall

BD is recalling their Vacutainer® EDTA Blood Collection Tubes with lavender, tan, pink and green rubber tube stoppers due to a chemical in the rubber tube stopper that interferes with the accuracy of the Anodic Stripping Voltammetry (ASV) testing methodology. **The tubes can continue to be used with other non-ASV blood lead level test technologies such as Graphite furnace atomic absorption spectroscopy (GFAAS) and Inductively Coupled Plasma Mass Spectrometry (ICP-MS) and other assays (non-lead) which do not use ASV methodology.**

ASV is the methodology used in Magellan Diagnostics' LeadCare Testing Systems. The tube stoppers contain a substance called thiuram that can sometimes release 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 the sample and may cause falsely lower test results. Falsely lower test results may lead to improper patient management and treatment for lead exposure or poisoning. The use of affected product may cause serious adverse health consequences.

## Who May be Affected

- Patients being tested with assays using ASV methodology (i.e. Magellan LeadCare Diagnostics' Testing Systems) whose blood is drawn in the affected BD blood collection tubes.