Perez, Victor@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Friday, May 26, 2017 9:35 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Medical Device Safety and Recalls: Magellan Diagnostics Inc. Recalls LeadCare Plus and Ultra Testing Systems Due to Inaccurate Test Results

Magellan Diagnostics is recalling the LeadCare Plus and the LeadCare Ultra Testing Systems because they may underestimate the blood lead levels (BLL) and give inaccurate results when processing venous blood samples. 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.

This recall accompanies FDA's safety communication from May 17, 2017. Magellan's LeadCare Plus and Ultra Testing Systems are two of four blood lead testing systems affected by the recommendations in FDA's safety communication.

The FDA is unable to identify the root cause for the inaccurate results, based on data provided by Magellan. We are conducting studies with the Center for Disease Control and Prevention (CDC) to identify the cause and better characterize the extent of the problem.