FDA/CDC Health Advisory regarding Magellan LeadCare Analyzers

Information for Local Health Departments (LHDs)

May 18, 2017

• The New Jersey Department of Health (NJDOH) has received notification from the U.S Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) of a safety warning related to lead test kits manufactured by Magellan Diagnostics.
• The safety warning focuses on the use of Magellan Diagnostics’ LeadCare analyzers (LeadCare, LeadCare II, LeadCare Ultra and LeadCare Plus) when used for venous blood samples, due to the potential for falsely low test results.
• Not all blood lead tests are affected:
  o The safety alert only applies to venous blood lead tests conducted using Magellan Diagnostics’ LeadCare analyzers;
  o The safety alert does not apply to capillary blood test results collected by finger stick or heel stick using Magellan Diagnostics’ LeadCare analyzers; and
  o The safety alert does not apply to blood tests performed using non-Magellan equipment.
• Nearly all LHDs that use the Magellan Diagnostics’ LeadCare analyzers for blood lead testing are not impacted by this safety warning; most LHDs use the capillary method, where blood tests results are collected using a finger stick or heel stick.
• However, a limited number of LHDs use venous testing with a Magellan Diagnostics’ LeadCare analyzer and will be advised to retest children who meet the CDC criteria for retesting*.
• In addition, some hospitals and healthcare providers use venous testing with a Magellan Diagnostics’ LeadCare analyzer and will be advised to retest children who meet the CDC criteria for retesting*.
• LHDs may receive inquiries on this matter, from residents or healthcare providers.
• LHDs with current capacity to perform blood lead testing may be asked to assist with retesting children.
• The NJDOH is working to characterize the number and location of potentially affected children, and will be providing additional guidance to LHDs as soon as possible.
• Questions from LHDs should be directed to the NJ Department of Health, Child and Adolescent Health Program during routine business hours at 609-292-5666.

*CDC Criteria for Retesting
• The CDC recommends that healthcare providers and LHDs retest patients who:
  o Are younger than 6 years (72 months) of age at the time of the alert (May 17, 2017), and
  o Had a venous blood lead test result of less than 10 micrograms per deciliter analyzed using a Magellan Diagnostics’ LeadCare analyzer.