Health Advisory

KITSAP PUBLIC HEALTH DISTRICT

May 18, 2017

Potential for Falsely Low Blood Lead Test Results from LeadCare® Analyzers

Actions Requested

- **Discontinue use of Magellan Diagnostics' LeadCare® analyzers with venous blood samples for children and adults, per the U.S. Food and Drug Administration (FDA) warning that these may cause falsely low test results.**
  - Note the safety alert does not apply to capillary blood lead test results collected by fingerstick or heelstick.
- **Re-test the following patients per the Centers for Disease Control and Prevention (CDC) recommendations:**
  - Children younger than 6 years (72 months) of age as of May 17, 2017, who had a venous blood lead test result of <10 µg/dL from a Magellan Diagnostics' LeadCare® analyzer;
  - Currently pregnant women or lactating women who had a venous blood lead test performed using one of Magellan's LeadCare® systems.
- **Read the complete health advisory from CDC and/or the safety warning from FDA if your office conducts or sends out any testing for blood lead levels.** *(See links below).*
- **Know that Washington State Department of Health (DOH) requires laboratories (including any facilities who use Point of Care Machines) to report all blood lead test results. Elevated levels must be reported to DOH within 2 days;** all other results are reportable within a month. Upon notification of an elevated level via DOH, the Kitsap Public Health District will follow up with the clinician and the patient or patient's family (if a minor) to attempt to help identify the source and advise upon mitigation.

For questions, please contact us at 360-728-2235.

Background

The U.S. Food and Drug Administration (FDA) issued a safety warning about the use of Magellan Diagnostics' LeadCare® testing systems (including LeadCare, LeadCare II, LeadCare Ultra and LeadCare Plus) with venous blood samples because they may underestimate blood lead levels (BLLs) and give inaccurate results. Falsely lower test results may lead to improper patient management and treatment for lead exposure or poisoning. Therefore, as of May 17, the FDA is advising that Magellan Diagnostics' LeadCare® analyzers should no longer be used with venous blood samples. The safety alert does not apply to capillary blood lead test results collected by fingerstick or heelstick.

We appreciate your cooperation in providing our case investigators any pertinent information about persons identified with elevated BLLs in a timely manner. Should you have a patient with an elevated BLL, you can expect to hear from us. We have created a new form to aid in gathering relevant clinical, laboratory, demographic, and exposure information necessary for our investigation. Please be sure to complete the form entirely and fax it back to us promptly.

Resources

- CDC Health Advisory regarding Magellan Diagnostics' LeadCare® analyzers (May 17, 2017): https://emergency.cdc.gov/han/han00403.asp
- FDA safety communication warning about Magellan Diagnostics' LeadCare® analyzers (May 17, 2017): https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm
- CDC's Lead Poisoning Prevention Program: https://www.cdc.gov/nceh/lead/
- Washington State Department of Health guidance on blood lead testing and reporting: http://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/ProfessionalResources/BloodLeadTestingandReporting