Change to Guidelines for Specimen Collection Tubes for Venous Whole Blood Lead Samples Submitted to Maine's Health and Environmental Testing Laboratory (HETL)

FAQs for Submitting Laboratories and Health Care Providers
Updated 11/10/2022

1. **What are the new guidelines for submitting <u>venous</u> whole blood lead specimens to HETL?**
   As of January 1, 2023, HETL will only accept <u>venous</u> whole blood lead specimens submitted in lead-free tan-top specimen collection tubes or trace element-free EDTA or sodium heparin royal blue-top specimen collection tubes. To allow submitters time to adjust to this change, from November 14, 2022, through December 31, 2022, HETL will accept venous blood lead samples in lavender-top specimen collection tubes. During this interim period, providers should re-test patients with results from a specimen collected in a lavender-top specimen collection tube that are 3.5 ug/dL or higher. The re-test should be a venous specimen collected in a lead-free tan-top specimen collection tube or trace element-free EDTA or sodium heparin royal blue-top specimen collection tube.

2. **Do the new guidelines apply to capillary specimens submitted in lavender-top microtainer tubes?** (Added 11/10/2022)
   No. The guidelines only apply to venous specimens. Capillary testing is <u>not</u> affected by these changes.

3. **What should we do if our laboratory is not able to obtain lead-free or trace element-free specimen collection tubes?**
   Please contact Heather Grieser from HETL to discuss options. She can be reached at Heather.Grieser@maine.gov or 207-287-5769.

4. **Why is it necessary to re-test children with venous blood lead levels of 3.5 ug/dL or higher if the specimen is submitted in a lavender-top specimen collection tube?**
   Lavender-top specimen collection tubes may not be certified by the manufacturer to be lead free and may contain trace amounts of lead which could cause falsely elevated blood lead levels. Re-testing in a lead-free or trace element-free specimen collection tube is necessary to confirm the blood lead level.

5. **Will HETL or the Maine CDC Childhood Lead Poisoning Prevention Unit notify patients if they need to be re-tested?**
   No. Patient notification is the responsibility of the ordering provider or submitting laboratory.

6. **Should I re-test children with a venous blood lead level of 3.5 ug/dL or higher from a specimen collected in a lavender-top specimen collection tube before this guidance was issued?**
   You should follow Maine CDC's latest guidance for follow-up testing and repeat patients' blood lead levels according to the schedule. Refer to: https://www.maine.gov/dhhs/mecdc/environmental-health/eohp/lead/providers.shtml

   If you suspect a child's result may be falsely elevated due to a lack of risk factors or other information about the patient, you may want to consider re-testing the patient. You may consult Maine CDC's Childhood Lead Poisoning Prevention Public Health Physician if you have questions about re-testing a patient (see response to Question 7 below for contact information).

7. **What is the guidance from U.S. Food and Drug Administration (FDA) and U.S. Centers for Disease Control and Prevention (CDC) regarding blood lead specimen collection tubes during the current specimen collection tube shortage?**
   Please refer to the following web pages for federal guidance.
   - U.S. FDA: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/blood-specimen-collection-tube-shortage-frequently-asked-questions
   - U.S. CDC: https://www.cdc.gov/nceh/lead/news/blood-lead-collection-tube-shortage.html

8. **Who should I call if I have questions?**
   For questions about submitting venous whole blood samples to HETL, contact Heather Grieser from HETL at Heather.Grieser@maine.gov or 207-287-5769.

   For questions about re-testing patients or Maine CDC Childhood Lead Poisoning Prevention Unit interventions contact Dr. Maggie Bordeau, Public Health Physician, at Margaret.bordeau@maine.gov or 207-592-2432.