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Maine Health Alert Network (HAN) System

PUBLIC HEALTH ADVISORY

To: All HAN Recipients
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Subject: **Change to Guidelines for Specimen Collection Tubes for Venous Whole Blood Lead Analyses**
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Change to Guidelines for Specimen Collection Tubes for Venous Whole Blood Lead Analyses

The purpose of this advisory is to inform clinical laboratories and health care providers in Maine about changes to guidelines for submitting venous whole blood lead specimens to the Maine CDC's Health and Environmental Testing Laboratory (HETL). HETL is updating its guidelines given concerns, recently identified in Maine and nationally, that some lavender-top specimen collection tubes may be contaminated with lead, potentially producing falsely elevated results.

Guidelines for Laboratories Submitting Venous Whole Blood Lead Specimens to HETL

- 1) As of January 1, 2023, HETL will only accept venous whole blood lead specimens submitted in lead-free tan-top 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) As of November 14, 2022, for patients up to age 6 years, Maine CDC's Childhood Lead Poisoning Prevention Unit will initiate mandated services to identify and remove sources of lead exposure based on a blood lead level of 5 ug/dL or higher for venous samples collected in lead-free tan-top specimen collection tubes or trace element-free EDTA or sodium heparin royal blue-top specimen collection tubes.

Background

In late October 2022, Maine CDC conducted a review of HETL's venous blood lead specimen guidelines as well as venous blood lead test results for children up to age 6 years. Maine CDC initiated this review in response to notifications from another state public health agency and a national diagnostic laboratory that raised concerns about possible lead contamination in certain lots of lavender-top specimen collection tubes, potentially leading to elevated blood lead test results.

Maine CDC's investigation did not show an unusual occurrence of children with venous blood lead levels of 5 ug/dL or higher at either the state or county level. Maine CDC identified one health care provider practice group with a significant increase in the number of children with venous blood lead levels of 5 ug/dL or higher in August and September as compared to prior months and years and other practice groups for the same period. While Maine CDC was not able to determine whether the specimen collection tubes used by the practice group were contaminated, the increase occurred during the same period of time that a national diagnostic laboratory identified an unexpected increase in lead levels among specimens submitted in certain lavender-top specimen collection tubes.

Based on these findings, **submitting laboratories should collect venous whole blood lead specimens in lead-free or trace-element free specimen collection tubes as soon as practicable.** Effective January 1, 2023, HETL will only accept venous 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.

Because of concerns about specimen collection supply shortages, and to give submitters time to adjust to the change in guidelines, HETL will accept venous blood lead samples in lavender-top specimen collection tubes until December 31, 2022. Between November 14 and December 31, 2022, HETL will include a comment on results of 3.5 ug/dL or higher for samples submitted in lavender-top specimen collection tubes to indicate the provider should re-test the patient with a venous specimen in a lead-free or trace element-free specimen collection tube to confirm the result.

Additional Information and Resources

- Submitting laboratories unable to obtain lead-free or trace element-free specimen collection tubes should contact HETL to discuss options. Please contact Heather Grieser at Heather.Grieser@maine.gov or 207-287-5769.
- Maine CDC Frequently Asked Questions for Submitting Laboratories and Providers: <https://www.maine.gov/dhhs/mecdc/public-health-systems/health-and-environmental-testing/micro/download-forms.htm>
- U.S. Centers for Disease Control and Prevention (CDC) information about specimen collection tube shortages: <https://www.cdc.gov/nceh/lead/news/blood-lead-collection-tube-shortage.html>
- U.S. Food and Drug Administration information about specimen collection tube shortages: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/blood-specimen-collection-tube-shortage-frequently-asked-questions>
- Under Maine's Lead Poisoning Control Act (22 M.R.S. § 1319-D), all venous blood lead specimens collected for children up to age 6 years must be submitted to HETL for analysis.
- As of October 1, 2022, Maine CDC updated its Pediatric Blood Lead Testing Guidelines to align with U.S. CDC's Blood Lead Reference Value of 3.5 ug/dL. <https://www.maine.gov/dhhs/mecdc/environmental-health/eohp/lead/providers.shtml>