



Health Advisory Alert: Potential for Falsely Low Blood Lead Test Results from LeadCare® Analyzers

June 6th, 2017

Dear State Refugee Health Coordinator,

On May 17, 2017, the U.S. Food and Drug Administration (FDA) issued [a safety communication](#) warning regarding the use of Magellan Diagnostics LeadCare® Testing Systems (all versions). These LeadCare® analyzers should **no longer be used to test venous blood samples**, due to the potential for falsely low test results. This safety alert does not apply to capillary blood lead test results collected from a finger or heel stick.

CDC recommends that healthcare providers re-test certain patient subgroups who are at the highest risk for negative consequences of lead exposure:

1. Patients who are <6 years of age at the time of the alert (May 17, 2017) OR currently pregnant or lactating, AND
2. Who had a **venous** blood lead test result of <10 micrograms per deciliter ($\mu\text{g}/\text{dL}$) analyzed using a Magellan Diagnostics LeadCare® analyzer at an onsite (e.g., healthcare facility) or at an offsite laboratory.

Re-tests are not recommended if the provider is certain that analyzers other than those described by this Health Advisory were used to analyze the venous blood samples.

If the healthcare provider is unsure of the laboratory method used, re-testing is recommended for children <6 years of age who had a venous blood lead test results of <10 $\mu\text{g}/\text{dL}$, as well as for pregnant or lactating women. Further information and a testing algorithm can be found at <https://emergency.cdc.gov/han/han00403.asp> and https://emergency.cdc.gov/coca/calls/2017/callinfo_052417.asp under the “Call Materials” tab.

As some refugee groups are at increased risk for lead exposure, healthcare providers who are conducting lead screening on recently resettled refugees should be aware of the laboratory testing method that is used at their onsite or at an offsite laboratory. Further, providers in facilities that are medical homes for recently resettled refugees should be aware of these recommendations and re-test refugees who meet the above criteria and who are still seeking care at that healthcare facility.

Newly arrived refugees should continue to be screened in accordance with CDC’s domestic screening guidelines (<https://www.cdc.gov/immigrantrefugeehealth/guidelines/lead-guidelines.html>), provided **venous** blood samples are tested using a method other than LeadCare® analyzers. CDC will continue to follow the investigation, and will provide additional details and recommendations, as necessary.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

Sincerely,

A handwritten signature in black ink that reads "Emily Jentes".

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