Ed Norman, Program Manager, 919-707-5951, 919-218-6511 (cell), ed.norman@dhhs.nc.gov
Children's Environmental Health (Childhood Lead & Child Care/School Sanitation)
& Health Hazards Control Units (Asbestos & Lead-Based Paint)

Reporting Requirements: § 130A-131.8. Laboratory reports. (a) All laboratories doing business in this State shall report to the Department all environmental lead test results and blood lead test results for children less than six years of age and for individuals whose ages are unknown at the time of testing. Reports shall be made by electronic submission within five working days after test completion. (b) Reports of blood lead test results shall contain all of the following: (1) The child's full name, date of birth, sex, race, ethnicity, address, and Medicaid number, if any. (2) The name, address, and telephone number of the requesting health care provider. (3) The name, address, and telephone number of the testing laboratory. (4) The laboratory results, whether the specimen type is venous or capillary; the laboratory sample number, and the dates the sample was collected and analyzed.

Point of care (POC) (i.e., LeadCare) blood lead analyzers:

- Facilities using a POC analyzer need to be aware that the Clinical Laboratory Improvement Amendments of 1988 (CLIA) designates them as a laboratory.
- The advantage of using the POC analyzer is the immediate test result while the patient is still at the clinic - so that the diagnostic specimen can be collected during the same visit.
- For initial results ≥ 5 µg/dL – state guidelines call for the immediate collection of a diagnostic specimen for analysis by an outside reference laboratory – without any repeat analysis using the POC analyzer before sending the diagnostic specimen.

Issues: Lack of/gaps in reporting and using the POC analyzer instead of sending diagnostic specimens to an outside lab.
Primary Contact: Tena Hand-Schafale; (919) 815-0141 cell; tena.hand@dhhs.nc.gov
Secondary Contacts: Melanie Napier, Samantha Sites & Jeff Smedley

LeadCare® Blood Test Kits RECALL

- Magellan and the FDA has issued a recall for LeadCare® Blood Test Kits distributed between 10/27/20 and 6/15/21 due to a *significant risk of falsely low blood lead level results*.
- A list of the recalled test kits can be found at https://www.fda.gov/medical-devices/medical-device-recalls/magellan-diagnostics-recalls-leadcare-ii-leadcare-plus-and-leadcare-ultra-blood-lead-tests-due-risk
- Customers with questions about the recall should contact Magellan's LeadCare® Product Support Team at 1-800-275-0102.

CDC & NC recommendations for retesting:

1) Retest children who were tested with a recalled LeadCare test kit

- All children who were tested with a recalled LeadCare test kit and had a result less than 5 µg/dL should be retested.
- All children who were previously tested with a LeadCare test kit if the lot number of the initial test kit is unknown and the test was done on or after October 27, 2020.
    - Blood lead specimens should be sent to an outside reference laboratory for analysis.
    - Capillary specimens are accepted provided they are analyzed by an outside reference laboratory that uses a high complexity test (e.g., the State Lab and most commercial laboratories).

2) While LeadCare test kits are unavailable:

- Do not stop testing children or require families to come back later just because a health care provider is out of LeadCare test kits
- Children should continue to receive blood lead testing per NC guidelines. This includes testing of **all** children participating in Health Check (Medicaid), Health Choice or the Special Nutrition Program for Women, Infants and Children (WIC) at **12 and 24 months of age.**
- The **NC State Laboratory of Public Health** (State Lab) offers analysis of blood specimens for all children less than six years of age at no charge. Providers are encouraged to use the State Lab as this expedites test result reporting.
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For analysis of blood lead specimens by the State Lab, please call **(919) 733- 3937** or contact:
Kate Koehler, Hemachemistry Manager,NC State Laboratory of Public Health
919-807-8878 (office); 919-602-2481 (cell); kate.koehler@dhhs.nc.gov