North Carolina
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Attention:

Pediatric Service Providers

Childhood Blood Lead Testing, Reporting, and Follow-up Requirements for Point of Care (POC) Lead Analyzer (i.e., LeadCare) Laboratories

Reminder of Childhood Blood Lead Testing Requirements

All Medicaid-enrolled children are required to be tested at 12- and 24-months of age by a clinical laboratory that is licensed by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for blood lead analysis. Children between 36- and 72-months of age must be tested if they have not previously been tested. Capillary blood lead samples are adequate for the initial blood lead test. Venous blood lead samples should be collected **as soon as possible** for confirmation of all initial blood lead test results ≥ 5 micrograms per deciliter (µg/dL) and when a diagnostic or follow-up test result falls in a higher risk category. Capillary blood lead measurements may be used for initial testing purposes, but venous blood is appropriate for diagnostic evaluation using only a high complexity laboratory methodology and prior to initiating an environmental investigation or medical management.

Note: The need for confirmation testing is based on the rounded test result. For example, test results between 4.5 to 4.9 µg/dL should be rounded up to 5 µg/dL.

Use of Point of Care (POC) Lead Analyzers and Public Health Implications

POC blood lead analyzers have great public health potential providing the advantage of an immediate test result while the patient is still at the clinic. This is a distinct advantage in North Carolina because, under state law, two consecutive elevated test results are required in order to initiate follow-up services. The diagnostic blood lead sample can be collected during the same clinic visit, hence, eliminating the need to track down children for return testing, which often results in long delays before necessary follow-up services can be provided.

There are significant drawbacks to this technology as well. As with other CLIA-waived laboratory instruments, there is no requirement for documentation of employee training and competency, ongoing proficiency testing, or monitoring of quality control. Calibration of the LeadCare II instrument (the only waived POC analyzer on the market) is not electronically documented. In addition, this technology uses anodic stripping voltammetry, a technology abandoned for blood lead analysis by the State Laboratory of Public Health (State Lab) more than 20 years ago largely because of poor precision at lower blood lead levels.

Although state law requires laboratories to electronically submit all blood lead test results for children within five working days after test completion to the Division of Public Health (DPH), compliance and technical expertise of staff at the provider laboratories varies considerably. This has resulted in major issues with timely reporting and poor data quality. File submission from some POC laboratories is sporadic, and some just stop reporting altogether. Lack of reporting has resulted in missed identification of children in need of follow-up services. It also has a negative impact on data-driven, evidence-based decision-making and public health strategies.

POC Lead Analyzer Laboratory Requirements

Facilities using a POC lead analyzer need to be aware that CLIA designates them as a laboratory. Therefore, all POC laboratories must enroll in and meet requirements of CLIA, must follow all North Carolina Childhood Lead Poisoning Prevention Program (NC CLPPP) Testing and

Follow-up Recommendations, and must comply with North Carolina blood lead test reporting requirements (G.S. § 130A-131.5 to 131.8) below.

Note: Our state requirements go beyond the minimum requirements set forth by CLIA or the Commission on Office Laboratory Accreditation (COLA).

Diagnostic (i.e., Confirmation) Testing

While a useful screening tool, POC blood lead analyzers have a limit of detection of 3.3 µg/dL which is barely sufficient to identify children at the Centers for Disease Control and Prevention (CDC) reference value of 5 µg/dL. Because of limitations at lower blood lead levels, both the manufacturer and the CDC recommend against using POC analyzers for diagnostic testing. Therefore, the state requires 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 out.

Note: The State Lab will analyze blood lead specimens for all children less than 6 years of age (and refugee children through 16 years) at no charge to the Medicaid or N.C. Heath Choice (NCHC) beneficiary. Providers are encouraged to use the State Lab as it expedites test result reporting.

> * CLIA certified laboratory using an analytical method categorized by CLIA as a high complexity test.

Blood Lead Test Result Reporting Requirements

POC lead analyzer laboratories must comply with state mandated reporting requirements.

North Carolina General Statute § 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 6 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.

Additionally, POC lead analyzer laboratories must maintain documentation of instrument calibration and quality control testing, dates blood lead test result files are submitted to the state, and outside reference laboratory used for analysis of diagnostic tests.

Billing for POC Lead Analyzers and Follow-up Diagnostic Tests

Providers that use a POC lead analyzer may bill the usual and customary charge for the blood lead analysis using CPT code 83655. Diagnostic (confirmation) tests may be analyzed by the State Lab at no charge to the patient. Again, diagnostic tests should **not** be performed on the POC lead analyzer.

Additional Resources

For more information about blood lead testing guidelines and reporting requirements, providers can consult the following websites and documents:

- **NC General Statute for Lead Poisoning in Children G.S. § 130A-131.5 to 131.8 (See p.1-4)**
- **CDC Recommendations for Revised Blood Lead Testing Follow-up Schedule (2 pages)**
- **NC Childhood Lead Testing and Follow-up Manual**
- **NC Childhood Lead Poisoning Prevention Program Resources**
- **NC State Laboratory of Public Health**

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