Appendix C: Recent Memoranda

Prelude to Medicaid Special Bulletin Re: Point of Care Lead Analyzers

Page 2 of the Medicaid Special Bulletin contains outdated policy language to round the blood lead test result to the next whole number. As of July 1, 2017, the need for confirmation testing is based on the *truncated* test result, not the rounded one.

An update is provided on the page, stating:

UPDATE: Confirmation is now based on the *truncated* test result. Test results ≥4.0 and <5.0µg/dL should be *truncated* to 4.0µg/dL.

Due to the fact that the bulletin was published in 2015, links throughout may no longer be active.

Prelude to Memo re: Point of Care Lead Analyzers

The 2015 Memo from Kim Gaetz references outdated contact/phone information as Kim Gaetz no longer works for NC CLPPP.

The contact name and phone number to call to make arrangements for reporting of blood lead test results have changed.

Please call Tena Hand at (919) 707-5933. We will work with you to help you meet these reporting requirements.

North Carolina
Medicaid Special Bulletin

An Information Service of the
Division of Medical Assistance

Visit DMA on the Web at http://www.ncdhhs.gov/dma

September 2015

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. **UPDATE: Confirmation is now based on the *truncated* test result. Test results ≥4.0 and <5.0µg/dL should be *truncated* to 4 µg/dL.**

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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September 22, 2015

MEMORANDUM

TO: Blood Lead Laboratories

FROM: Kim Gaetz, Public Health Epidemiologist
Children's Environmental Health Program

SUBJECT: Point-of-care lead analyzers

The Clinical Laboratory Improvements Amendments (CLIA) designates facilities that use point-of-care (POC) lead analyzers (i.e. LeadCare II) as laboratories. Blood lead test results, even if determined in a clinical setting, are required to be reported.

All blood lead test results are required to be reported by electronic submission within five working days after test completion for children less than six years of age and for individuals whose ages are unknown at the time of testing (please see below). Examples of approved electronic formats are datafiles such as .xml format (LeadCare report format), Excel file formats, or Access file formats.

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 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.

To make arrangements for reporting of blood lead test results, please call (919) 707-5953. We will work with you to help you meet these reporting requirements.

UPDATE: Please call (919) 707-5933 to arrange blood lead test result reporting.

www.ncdhhs.gov • www.publichealth.nc.gov
Tel 919-707-5950 • Fax 919-870-4808
Location: 5505 Six Forks Road • Raleigh, NC 27609
Mailing Address: 1912 Mail Service Center • Raleigh, NC 27699-1912
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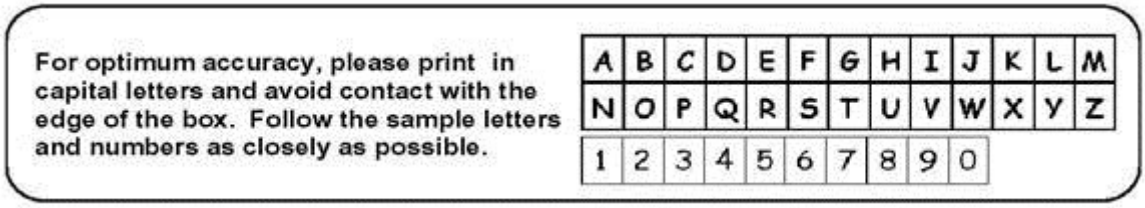
Scott J. Zimmerman, DrPH, MPH, HCLD (ABB)
Laboratory Director

Memorandum

Blood Lead teleform implementation at the North Carolina State Laboratory of Public Health

Beginning November 12, 2014 the Blood Lead Unit of the Hemachemistry Lab at the North Carolina State Laboratory of Public Health (NCSLPH) will begin using a new form to increase productivity and reduce errors in reports. This new form will be available on the NCSLPH website at: http://slph.ncpublichealth.com/forms.asp#specimen. **Form DHHS-3707.**

This form is designed to be scanned. A NCSLPH data entry person will manually verify any letters or numbers that the computer cannot interpret. Please help us to save time and improve accuracy by writing carefully and following the instructions below. Please use X instead of √ for check boxes.



Patient Information: Print the information if the standard label/HSIS Laboratory Label is not attached. Do not attach any other label format. The standard label format is available from the **Hemachemistry office**. Please align the label in the box on the top right of the form. The label must fit within the box, not touch the lines on the edge of the box, and the printed information must be parallel to the top of the box. Labels placed at an angle will not be read accurately.

Please Note: If you need additional copies of the submission form, please do NOT photo copy. Instead, print them from the original PDF found on the State Lab's website ON WHITE PAPER only. Colored paper will not be able to be scanned. Or you may call the Hemachemistry office at 919-807-8878 to have an electronic copy emailed to you.