

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0679696	<b>(X3) Date Survey Completed</b>  02/15/2018
<b>Name of Provider or Supplier</b>  Longwood Pediatrics Llp	<b>Street Address, City, State</b>  319 Longwood Avenue 4th Floor, Boston, MA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A CLIA recertification survey was conducted for the Longwood Pediatric Office Laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, the laboratory failed to perform and document calibration verifications as appropriate as evidenced</p>

by the following: A review of Hematology calibration verification records for calendar years 2016 and 2017 revealed that calibration verifications of at least 3 points were not performed once every six months in 2017. The Laboratory Director confirmed through interview on 2/15/18 at 12:00 PM that Hematology calibration verifications of at least 3 points had not been performed at least once every six months in 2017.

**D5471**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on record review and interview, the laboratory failed to check each lot number and shipment of disks when opened for positive and negative reactivity as evidenced by the following: The laboratory performs throat culture screens for presumptive identification of Group A Streptococci (GAS) using Selective Strep Agar and Bacitracin disks. Interview with two testing persons revealed that the laboratory did not check each lot and each shipment of Bacitracin disks with positive and negative organisms. Interview with the laboratory director on 2/15/18 at 12:00 PM confirmed that the laboratory failed to check each lot and shipment of Bacitracin disks using GAS positive and negative organisms.

**D5477**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on record review and interview with the laboratory director, the laboratory failed to check each batch of media for sterility before or concurrent with initial use as evidenced by the following: A. Urine Culture Screen Uricult Media A review of bacteriology quality control records for 2016, 2017, and 2018 revealed that the laboratory failed to check and document each shipment and each lot of media for sterility. The laboratory performs 424 urine culture screens annually. B. Throat Culture Screen Selective Strep Agar (SSA) A review of bacteriology quality control records for 2016, 2017, and 2018 revealed that the laboratory failed to check and document each shipment and each lot of media for sterility. The laboratory director confirmed in an interview on 2/15/18 at 12:00 PM that the laboratory failed to check

and document each shipment and each lot of Uricult and SSA media for sterility. The laboratory performs 1040 throat cultures annually. This is a repeat deficiency.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on record review and interview with the laboratory director, the laboratory failed to ensure the test report indicated the test performed as evidenced by the following: The laboratory performs throat culture screens for presumptive identification of Group A Streptococci. On 2/15/18, the surveyor reviewed patient records from April 2017 through February 2018 in the laboratory's Electronic Medical Record (EMR), Epic. This review revealed the laboratory was resulting presumptive Group A streptococci cultures as "Positive." The laboratory director confirmed on 2/15/18 at 12:00 PM that the laboratory was resulting presumptive Group A streptococci results as "Positive" in their EMR. The laboratory performs 1040 throat cultures annually.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on the nature of the deficiencies cited herein, the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart as evidenced by the following: a) The laboratory director failed to ensure Hematology calibration verifications were performed once every 6 months. (Refer to D5439) b) The laboratory director failed to ensure each new lot and shipment of Bacitracin disks are checked with positive and negative controls. (Refer to D5471) c) The laboratory director failed to ensure each new lot and shipment of media are checked for sterility. This is a repeat deficiency. (Refer to D5477) d) The laboratory director failed to ensure Presumptive Group A Streptococci tests were reported accurately. (Refer to D5805)