Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 44D1103237	**(X3) Date Survey Completed** 10/10/2022
Name of Provider or Supplier Pediatric Consultants Of Lenoir City	**Street Address, City, State** 303 Medical Park Dr, Lenoir City, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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. This STANDARD is not met as evidenced by: ========== Based on a review of the Laboratory's Procedure, Calibration Verification records for the Hematology analyzer and upon interview with the Lead Testing Personnel and Laboratory Director determined the laboratory failed to ensure calibration verification was performed at six month intervals for 2021 and 2022. The findings include: 1. A review of the Laboratory's Procedure titled, "CBC Machine" stated calibration to be done every six

	months. 2. A review of Calibration Verification records for the hematology analyzer revealed calibration verification performed on 09.09.2021 and 05.04.2022, therefore the laboratory failed to perform calibration verification at six month intervals. 2. An interview with the Lead Testing Personnel and Laboratory Director at 11:30 a.m. on October 10, 2022 confirmed calibration verification was not performed on the hematology analyzer at six month intervals for 2021 and 2022. ==========