Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0303212	10/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Huntsville Pediatric Associates	2004 Airport Road, Huntsville, AL	

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 records for the Reichert Unistat Bilirubinometer and the Abbott I-Stat, and interviews with Testing Personnel #1, the laboratory failed to ensure calibration verification (C-V) was performed every six months as required by the manufacturer and laboratory procedure. The surveyor noted the laboratory failed to perform C-V on two of two Chemistry instruments since the previous survey on 12/16 /2020. The findings include: (I) Reichert Unistat Bilirubinometer (Neonatal Bilirubin)

	1. A review of records for the Reichert Unistat Bilirubinometer revealed the instrument was calibrated with water and the High-Level Check Cuvette (40.6 mg/dL [milligrams/ deciliter]) every six months. Analytes calibrated with less than three calibrators must have a calibration verification every six months, as per CLIA regulation. 2. A review of the operator's manual on page 14 under section "6.4 Calibration Verification" revealed, "Two assayed glass cuvettes are provided with the REICHERT UNISTAT Bilirubinometer: 1. ...Calibration cuvette (assay range from 19 to 23.9 mg/dL) ...[and the] 2. ...High-Level Check Cuvette (assay range approximately 40 mg/dL) ... ...[these] glass cuvettes may be used to check the bilirubinometer at the mid and high points of its 0-40 mg/dL measuring range. A sample cuvette ... filled with distilled water may be used to check zero. ...". 3. During an interview on 10/20 /2022 at 1:10 PM, Testing Personnel #1 stated she did not know about the above requirements in the operator's manual, and confirmed the laboratory had failed to follow the manufacturer's instructions to perform a three-point calibration verification which included the mid-range (21.4 mg/dL) cuvette. (II) Abbott I-Stat (Chem 8 + cartridges for the Basic Metabolic Profile) 1. A review of the Abbott I-Stat procedure revealed the instrument performed an internal calibration on each cartridge upon insertion. Analytes calibrated with less than three calibrators must have a calibration verification every six months, as per CLIA regulation. 2. A review of the Abbott i-Stat records revealed the last calibration verification was performed on 6/25/2020 using the I-Stat Tri-Control Calibration Verification kit. 3. During an interview on 10/20 /2022 at 3:30 PM, Testing Personnel #1 confirmed the laboratory had not performed calibration verification on the I-Stat since 6/25/2020. SURVEYOR ID #32558 Licensure and Certification Surveyor