Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0693984	(X3) Date Survey Completed 12/11/2019
Name of Provider or Supplier Carolina Kids Pediatric Associates	**Street Address, City, State** 2605 Blue Ridge Road , Suite 100, Raleigh, NC	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of 2018 and 2019 College of American Pathologists (CAP) proficiency testing (PT) records and interview with testing personal (TP) 12/11/19, the laboratory failed to ensure all attestation statements were signed by the laboratory director (LD). Findings: Review of 2018 and 2019 CAP PT records revealed 6 of 6 PT event attestation statements were not signed by the LD. Interview with TP #2 at approximately 11:00 a.m. confirmed the attestation statements were not signed by the LD. She stated she thought his review was all that needed to be signed by the LD.
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 review of laboratory procedure, review of calibration records and interview with testing personal (TP) 12/11/19, the laboratory failed to perform calibration of the Coulter Act Diff hematology analyzer every 6 months. Findings: Review of laboratory procedure "IQCP Procedure Coulter Act Diff Calibration" revealed "Procedure Indications: Perform calibration every 6-months. Review of calibration records for the Coulter Act Diff hematology analyzer revealed calibration was performed on 7/31/18. The next calibration was due on 1/31/19. Calibration was not performed until 5/1/19, a period of approximately 3 months in which patient testing occurred and calibration had not been performed. Interview with TP # 13 at approximately 1:30 p.m. confirmed the laboratory had not performed calibration when required and continued testing patients from 1/31/19 until 5/1/19.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, review of hematology calibration records and review of quality assessment (QA) records 12/11/19, the laboratory director (LD) failed to ensure the quality assessment programs established were able to identify failures found at time of survey. Findings: Review of PT records revealed the laboratory failed to ensure all attestation statements were signed by the LD. See D2009. Review of hematology calibration records revealed calibration was not performed every 6 months as required. See D5439. Review of 2018 and 2019 QA records revealed the quality assessments were completed quarterly as per laboratory policy. The quality assessments failed to identify PT attestation statements were not signed as required and failed to identify calibration of the Coulter Act Diff hematology analyzer was not performed every 6 months as required.