Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0245017	10/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Fayetteville Children's Clinic, Pa	1606 Morganton Road, Fayetteville, 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
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 manufacturer's instructions, review of laboratory calibration records and technical consultant (TC) (laboratory director) interview 10/30/2018, the laboratory failed to accurately perform 6 month calibrations on the Coulter Act Diff 2 hematology analyzer since 01/28/17, a period of approximately 2 years. Review of manufacturer's instructions for calibration of the Coulter Act Diff 2 hematology analyzer revealed on page 5-17 the following: "IF NEEDED appears for any of the

	parameters, calibration adjustments are required. Touch the Save and Exit icon to automatically replace the NEEDED calibration factor with the new calibration factor. This automatically updates the instrument's calibration parameters." Review of laboratory calibration records for the Coulter Act Diff 2 hematology analyzer revealed the laboratory failed to replace "NEEDED" calibration factors with the new calibration factors for following calibrations: 1. Calibration performed on 01/28/17 revealed the Hemoglobin (HGB) parameter needed a calibration adjustment. The calibration adjustment of the HGB parameter was not performed. 2. Calibration performed on 07/12/17 revealed the HGB and Platelet (PLT) parameters needed calibration adjustments. The calibration adjustments of the HGB and PLT parameters were not performed. 3. Calibration performed on 01/17/18 revealed the HGB and PLT parameters needed calibration adjustments. The calibrations adjustments of the HGB and PLT parameters were not performed. 4. Calibration performed on 07/09/18 revealed the White Blood Count (WBC), Red Blood Count (RBC), HGB, Mean Cell Volume (MCV) and PLT parameters needed calibration adjustments. The calibration adjustments of the WBC, RBC, HGB, MCV, and PLT parameters were not performed. Interview with TC (laboratory director) at approximately 2:00 p.m. confirmed the calibration adjustments were not performed. She stated she was unaware that the calibration adjustments had not been updated after performing the calibrations on the Coulter Act Diff 2 analyzer.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Review of random patient test reports and technical consultant (TC) (laboratory director) interview 10/30/18 revealed patient test reports generated from the laboratory's computer system, Eclinical, failed to include reference ranges needed for test result interpretation. The laboratory scans test reports for Complete Blood Count (CBC) directly into the patient's chart. The test report for CBC includes reference ranges for test result interpretation. The laboratory enters waived testing results and urine culture results manually into the laboratory's computer system, Eclinical. Review of random patient test report for urine culture; Patient DOB 10/25/12, dated 10 /30/18, revealed the report contained no reference range for urine culture testing. In addition, random patient test report for waived testing "Rapid Strep; Patient DOB 02 /20/09, dated 10/30/18, revealed the report contained no reference range for "Rapid Strep" testing. Interview with TC (laboratory director) at approximately 2:00 p.m. confirmed the patient test reports generated from the laboratory's computer system, Eclinical, failed to include reference ranges for the testing performed. She stated it was a very difficult to get the customer support they needed to address problems the laboratory has with the Eclinical computer system. .