Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2009504	08/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pediatrics Plus, Pc	3312 Henry Road, Anniston, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the 2018-2021 API (American Proficiency Institute) proficiency testing (PT) records, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to ensure proficiency testing was rotated between all personnel who performed patient testing. This was noted on nine of nine Hematology surveys reviewed. The findings include: 1. A review of API PT attestation statements revealed Testing Personnel #1 had performed all the testing on nine of nine of the 2018-2021 (2018 Event #3 through 2021 Event #2) Hematology PT surveys. No surveys were performed by the other eight testing personnel (#2 through #9). 2. During an interview and review of the PT records on 8/5/2021 at 11:00 AM, Testing Personnel #1 confirmed the above noted findings. .
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on reviews of personnel files and an interview with Testing Personnel (TP) #1, the laboratory failed to implement policies specifying required timeframes for semi-

	annual and annual competency evaluations for laboratory testing personnel. This was noted on two of five new testing personnel listed on the Form CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of the Form CMS-209 (Laboratory Personnel Report) provided during the entrance tour revealed five TP (#5, #6, #7, #8, and #9) were employed since the previous survey. 2. A review of the employee files revealed the following: A) TP #5: The "semi-annual" competency evaluation was dated the same day as the training on 2/1/2019; the "annual" evaluations were dated 8/2/2019 and 9/27/2020. B) TP #6: The "semi-annual" competency evaluation was dated the same day as the training on 10/25/2019; the "annual" evaluations was dated 10/23/2020. 3. During an interview on 8/5/2021 at 10: 05 AM, the surveyor reviewed the semi-annual competency dates for TP #5 and #6, and explained the semi-annual evaluation should not be performed immediately after training. CLIA required the Technical Consultant to evaluate and document performance evaluations several months after the training and annually thereafter. [Note: Timing of competency evaluations was explained during the previous survey on 11/15/2018, however the facility failed to implement policies defining the required time frames.] .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on reviews of the Abbott Emerald Cell Dyn Hematology analyzer calibration and quality control records, the manufacturer's calibration instructions, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to follow the manufacturer's instructions to verify calibrations by running the calibrator or perform quality controls (QC) before resuming patient testing. This was noted on one out of ten calibrations performed in 2019-2021. The findings include: 1. A review of calibration records for the Abbott Emerald Cell Dyn Hematology analyzer revealed the analyzer was calibrated on 1/24/2020 at 2:52 PM. A review of patient records revealed one patient CBC (Complete Blood Count) was performed at 3:22 PM. 2. A review of the Emerald Cell Dyn Calibration Procedure (Page 6-9) revealed, "...18. Verify Calibration [using the calibrator] as directed in the Calibration Verification procedure below...". There was no documentation the testing personnel had verified the calibration using the Calibration Verification procedure, or run QC as an alternate method to ensure the calibration was valid. 3. During an interview on 8/5/2021 at 12: 40 PM, TP #1 confirmed she had not performed the Calibration Verification procedure and had not verified the calibration by running QC before she resumed patient testing. SURVEYOR ID #32558 Licensure and Certification Surveyor