Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0306320	09/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Of Auburn	2901 Corporate Park Drive, Opelika, 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) (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 American Proficiency Institute (API) Proficiency Test (PT) records, the CMS 209 Personnel document, and an interview with Testing Personnel #1 (TP1), the Laboratory failed to rotate all Testing Personnel in Proficiency Testing. This was noted for one of six Testing Personnel performing all eight PT events in 2023 through 2025. The findings include: 1. A review of the API PT records revealed TP1 performed all eight Hematology PT events in 2023 through 2025. 2. A further review of the CMS 209 Personnel document revealed five other qualified Testing Personnel performing moderate complexity testing in Hematology. 3. During an interview on 9-9-2025 at 10:30 AM, TP1 confirmed she was the only TP performing PT.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(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 (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well

	as acceptable limits for and the frequency of calibration; and (a)(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 a review of the Hematology records, the Quality Systems Assessment log, and an interview with Testing Personnel #1, the Laboratory failed to perform calibrations on the Abbott Emerald Cell Dyn Hematology analyzer every six months as per the QA policy. The laboratory failed to perform one of two calibrations due in 2023. The findings include: 1. A review of the Hematology calibration records revealed the Cell Dyn was calibrated 3/7/2023 and then almost twelve months later on 4/1/2024. There was no documentation of a calibration the second half of 2023. 2. A further review of the Quality Systems Assessment review revealed "...calibrations performed at least every six months." 3. During an interview on 9-9-2025, at 11:25 AM, Testing Personnel #1 confirmed the calibration due the second half of 2023 was not performed.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the 2023 Hematology quality control (QC) records for the Abbott Emerald Cell Dyn, the patient results log, and an interview with Testing Personnel #1, the laboratory failed to ensure at least two levels of quality control were run, acceptable and documented, prior to analyzing patient specimens and reporting the results. This was noted one day out of three months reviewed in 2023. The findings include: 1. A review of the QC records for the Emerald Cell Dyn Hematology analyzer revealed on 12/04/2023, there was no evidence of documented QC performed. 2. A review of the cumulative patient log printed from the instrument revealed two patient CBCs (Complete Blood Count) were performed on 12/4/2023. 3. During an interview on 9-9-2025 at 12:18 PM, Testing Personnel #1 confirmed QC documentation could not be located.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on a review of the refrigerator temperature records and an interview with Testing Personnel #1, the Laboratory failed to document corrective actions when refrigerator temperatures were outside the manufacturers' storage parameters for items therein. The surveyor noted refrigerator temperatures were outside of acceptable ranges for 21 days of 21 months reviewed in 2023 and 2024 with no documentation of corrective action. The findings include: 1. A review of environmental records revealed refrigerator temperatures were outside the manufacturers' storage parameters for the Hematology Quality Controls stored therein with no evidence of corrective action. This was noted for the following dates: a. 2023: May (1), June (1), July (1). b. 2024: February (2), March (3), April (2), May (1), June (4), July (3), August (2), and September (1). 2. During an interview on 9-9-2025, at 12:45 PM, Testing Personnel #1 confirmed the above findings.