Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0681418	11/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Anniston Pediatrics Inc	1001 Leighton Avenue, 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
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 a review of the Hematology calibration records and an interview with the Practice Manager (PM), the laboratory failed to perform calibration on the Medonic M-Series Hematology analyzer at least every six months as per manufacturer's specifications. This was noted for one of the four calibrations from 2023 through 2024. The findings include: 1. A review of the Hematology calibration records revealed the Medonic M-Series analyzer was calibrated 10-20-2023 and the next calibration was performed eight months later on 06-26-2024. 2. A further review of Medonic M-Series service reports revealed a preventive maintenance was performed on 05-10-2024 without calibration documentation. 2. In an email the PM sent to the surveyor on 12-03-2024 at 1:28 PM, she confirmed the calibration was not performed during the annual preventive maintenance.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)

	(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Complete Blood Count (CBC) Quality Control (QC) records for the Medonic M-Series Hematology analyzer, and an interview with the Practice Manager (PM), the surveyor determined the laboratory failed to implement mechanisms to track for shifts and trends over time from the previous survey date of 11-30-2022 through the current survey date of 11-26-2024. The findings include: 1. A review of the CBC QC records for the Medonic M-Series Hematology analyzer revealed the laboratory had no mechanism to track for shifts and trends over time in their QC testing. The laboratory had retained records of the daily QC testing. 2. PM confirmed the above findings during the exit conference on 11-26-2024 at 2:00 PM.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the Practice Manager (PM), the technical consultant failed to ensure five of the five testing personnel performing moderate complexity testing had competency assessments that included the six minimal regulatory requirements from 2022 through 2024. The surveyor noted five of the six requirements were missing on annual and semi-annual competencies. The findings include: 1. A review of the personnel records revealed annual and semi-annual Hematology competency assessments were completed without the documentation of the five minimal requirements for assessment of competency. Missing requirements are as follows; 1. Monitoring the recording and reporting of test results. 2. Review of intermediate test results of worksheets, quality control records, proficiency testing results, and preventive maintenance results. 3. Direct observation of performance of instrument maintenance and function checks. 4. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 5. Assessment of problem solving skills. 2. PM confirmed the above findings during the exit conference on 11-26-2024 at 2:00 PM.