Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0681418	11/30/2022
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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to document corrective action on unsatisfactory scores for PT for one of five events in 2021 and 2022. The findings include: 1. A review of the MLE PT records revealed no corrective action documented for the unsatisfactory score of zero percent on Cell Identification for Event M1 in 2022 2. During an interview on November 30, 2022, at 10:30 AM, Testing Personnel #1 confirmed the above findings.
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 records, the manufacturer's user manual, and an interview with Testing Personnel #1, the Laboratory failed to perform calibrations every six months on the Medonic M-series Hematology analyzer as per the manufacturer's instructions. The laboratory failed to perform one of six calibrations due in 2021 and 2022. The findings include: 1. A review of the Hematology calibration records revealed the Medonic was calibrated on 2/12/2021, 5/21/2021, 6/22/2021, 4/18/2022, 8/19/2022, and 11/22/2022. There was a 10 month gap in between calibrations for June 2021 and April 2022. Based on Medonic calibration instructions, there should have been a calibration performed in December of 2021. 2. A further review of the Medonic user manual revealed in Chapter 7, "It is recommended to calibrate the instrument every 6 months." 3. During an interview on November 30, 2022, at 11:39 AM, Testing Personnel #1 confirmed the calibration due in December 2021 was not performed.