Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0665218	05/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Perry Medical Clinic Pc	401 Northwood Drive, Centre, 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, a review of the Beckman Coulter AcT Diff 2 user manual, and an interview with the TC (Technical Consultant), the Laboratory failed to follow manufacturers instructions when performing calibrations on the AcT Diff 2 Hematology analyzer. This was noted for one of two calibrations reviewed in 2023. The findings include: 1. A review of the Hematology calibration records revealed the AcT Diff 2 was calibrated on 7/5/2023, however the WBC (White Blood Cell) failed the calibration and PLT (Platelet) failed the carry-over. There was no evidence of acceptable calibration documentation to review for 2023. The previous acceptable calibration was performed on 12/30/2023 and then one year later a new Beckman Coulter DxH 520 Hematology analyzer was implemented and calibrated on 1/8/2024. 2. A further review of the user manual pg. 52 under "CALIBRATION / REPRODUCIBILITY" revealed "Verify PASSED for all parameters." 3. During an interview on 5/15/2024, at 11:03 AM, the TC confirmed the acceptable calibration documentation for 2023 could not be located.