Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0944420	10/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Oncology & Hematology Specialists Pa	100 Madison Avenue Suite C3402, Morristown, NJ	

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 surveyor review of the Calibration records, Procedure Manual (PM), Beckman Coulter Act Diff 2 User Manual (UM) and interview with the Laboratory Manager (LM), the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Beckman Coulter Act Diff 2 analyzer from 9/21/24 to 10/17/24. The findings include: 1. A review of calibration records revealed that the laboratory last performed calibration of the analyzer on 3/21/24. Calibration on the instrument was due in September 2024. 2. The PM and UM states "Calibrate the Act diff 2 Series Analyzer at least every 6 months." 3. The LM confirmed on 10/17/24 at 12:15 pm, the laboratory failed to perform and document calibration of the analyzer at least every six months.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory

	performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the surveyor review of the Final Reports (FR), Procedure Manual (PM),Test Records (TR) from the analyzer and interview with the Laboratory Manager (LM), the laboratory failed to have accurate Reference Intervals (RI) for Hematology tests from 7/7/23 to 10/17/24. The findings include: 1. The PM had two separate RI for both male and females that were verified. 2. Review of Patient FR and TR from the Beckman Coulter Act Diff 2 analyzer revealed that only the male RI were being used for both male and female patients test results. 3. The LM confirmed on 10/17/24 at 11: 00 am, the laboratory did not implement separate RI for both male and female patients.