

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2133984	(X3) Date Survey Completed 09/30/2025
Name of Provider or Supplier Advanced Care Oncology &	Street Address, City, State 741 Northfield Ave, West Orange, 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	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Testing personnel (TP), the laboratory failed to document calibration on the Sysmex XN-550 analyzer from 4/23/2024 to 9/30/2025. The findings include: 1. The laboratory uses Sysmex BeyondCare Quality Monitor (BCQM). 2. The BCQM verifies calibration of the analyzer via the "Continuous Calibration" report. 3. There was no documented evidence that the "Continuous Calibration" report was generated and reviewed after 4/23/24. 4. The TP confirmed on 9/30/2025 at 11:15 am, the laboratory failed to generated and review the Continuous Calibration report.</p>