

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2030276	(X3) Date Survey Completed 09/02/2026
Name of Provider or Supplier Advanced Care Oncology &	Street Address, City, State 385 Morris Ave, Springfield, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. 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 follow the procedure "Viewing and printing the Levy-Jennings (LJ) Control Charts (Monthly)" from 7/23/24 to 9/2/26. The findings include: 1. The PM stated "6. The LJ chart for each level of quality control is reviewed monthly by the laboratory director and/or designee to ensure that the QC data falls within the ranges of the QC insert sheet". 2. There was no documented evidence that aforementioned procedure was followed. 3. The TP confirmed on 9/2/26 at 11:00 am that the aforementioned procedure was not performed.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control

materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:

Based on lack of of Quality Control Verification (QCV) records and interview with the Testing Personnel (TP), the laboratory failed to verify QC material before use for Sysmex XN-550 from 8/1/26 to 9/2/26. The findings include. 1) There was no documented evidenced that the QCV was performed on lot # 62061401 of XN-Check control material currently in use. 2) The TP confirmed 9/1/26 at 11:15 am that QC material was not verified before putting in use.