Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2030276	09/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Care Oncology &	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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT), interview with Testing Personnel (TP), the laboratory failed to ensure that all TP who routinely perform Hematology testing participated in the American Proficiency Institute (API) PT in the calendar years 2019, 2020, 2021 and first and second events of 2022. The findings include: 1. A review of PT attestation records showed that two out of seven TP performed PT in the aforementioned time frame. 2. The TP confirmed on 9/13/22 at 2: 30 pm that PT events were not rotated between TP.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in

	the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. 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 have all applicable procedures for Hematology Tests performed on the Sysmex XNL 550 on the date of the survey. The findings include: 1. The laboratory did not have procedures for: a. Resolving flags on test results. b. Reporting panic or alert values. d. Calibration and calibration verification procedures. e. Corrective actions to be taken when calibrations or controls fail. f. Description of the course of action to take if a test system becomes inoperable. g. Quality Assurance h. Verification of new lots of reagents and controls. i. Proficiency testing. j. Analyzer Maintenance. 2. The TP confirmed on 9/13/22 at 1:50 pm that the PM did not have all applicable procedures for all test procedures.
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 the lack of Calibration (CAL) records, lack of a Procedure Manual (PM) and interview with the Testing personnel (TP), the laboratory failed to document Calibration procedures for Hematology Tests performed on the Sysmex XP-550 analyzer in the from October 2019 to the date of survey. The findings include: 1. Continuous Calibration Verification Certificates (CCVC) were not available at the time of survey. 2. There was no evidence that (CCVC) were reviewed. 3. The TP confirmed on 9/13/22 at 1:32 pm that the laboratory failed to document CAL.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by:

	Based on the lack of a Procedure Manual PM (PM), Quality Control (QC) records, Patients Work Records (PWR) and interview with the Testing Personnel (TP) the laboratory failed to have available Corrective Action (CA) procedures for QC and flagged PWR from October 2019 to the date of survey. The TP confirmed on 9/13/22 at 2:00 pm that the laboratory failed have available CA procedures.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with Testing Personnel (TP) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from October 2019 to the date of survey. The findings include: 1. The laboratory did not have a policy with criteria on when to repeat a patient test. 2. The laboratory failed to have a procedure to verify new lots of controls before they were put in use. 3. The Laboratory failed to have a procedure on how Quality Control is reviewed, monitored and maintained. 4. The TP confirmed on 9/13/22 at 1:45 pm that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PS procedures performed on the Sysmex XL-550 analyzer were adequate from October 2019 to the date of survey. The finding includes: 1. The LD did not provide a source for reference intervals/range (normal values) for the laboratory's patient population. 2. The LD did not approve and sign the PS. 3. The TP confirmed on 9/13/22 at 1:20 pm that PS records were not adequate.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual (PM) and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that an approved procedure manual was available for Hematology testing from October 2019 to the date of survey. The TP confirmed on 9/13/22 at 2:00 pm that an approved PM was not available.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to specify in detail the duties and responsibilities for One out of One Clinical Consultant (CC) and LD engaged in the performance of preanalytical, analytic and post analytic phases for Hematology tests from October 2019 to the date of survey. The TP confirmed on 9/13/19 at 1:15 pm that the LD did not specify the duties and responsibilities of the LD and CC.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with the testing Personnel (TP), the LD failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Sysmex XN-L 550 series analyzer from on the date of survey. The TP confirmed on 8/18/22 at 12:35 pm that trends and shifts were not reviewed.