Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2133984	08/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Care Oncology &	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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the PT records and interview with the Testing Personnel (TP), the laboratory failed to maintain Attestation Statements (AS) for Hematology testing performed with the American Proficiency Institute (API) in the Third event for 2021 and first event for 2022.. The TP #1 listed on CMS form 209 confirmed on 8/18 /22 at 1:45 am that the AS was not maintained.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to retain graded results for Hematology

	/coagulation PT event 3-2021 and 1-2022 performed with the American Proficiency Institute. The TP confirmed on 8/18/22 at 11:45 am that all PT graded results were not retained.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor review of Manufactures Instructions (MI), Procedure Manual (PM), Quality Control (QC) Records, the lack of Calibration Records (CR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that quality systems for the pre-analytic, and analytic phases of Hematology testing were monitored on the date of survey. 1. The laboratory failed to maintain Attestation Statements. Cross refer 2015 2.. The laboratory failed to maintain Proficiency Testing (PT) records. Cross refer to D3037. 3. The laboratory failed to have all applicable procedures for Hematology Tests. Cross refer D5403 4. The laboratory failed to follow Manufacturer Package insert for control values. Cross refer D5411. 5. The laboratory failed to ensure that all Performance Specifications records were adequate. Cross refer D5421. 6. The laboratory failed to perform Calibration Verification. Cross refer D5439 7. The laboratory failed to verify commercial Quality Control material. Cross refer D5469 8. The laboratory failed to have available Corrective Action (CA) procedures. Cross refer D5779
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 8/18/22 at 11: 50 am that the PM did not have all applicable procedures for all test procedures.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor observation of the Sysmex Hematology Control for Sysmex XN-L Analyzers Manufacturers Package Insert (MPI) and Control Values (CV) in the Sysmex XN-550 Analyzer interview with the Testing Personnel (TP), the laboratory failed to follow MPI for control values on the date of survey. The findings include: 1) MPI for XN-L QC Lot 2154140 had CV as follows: a. Level 1 Hemoglobin (HGB) 5.4 - 5.9 g/dL b. Level 2 Red Blood Cell (RBC) 4.22-4.57 10^6/u/L c. Level 3 RBC 5.11-5.53 10^6/u/L 2) CV in the Sysmex XN-550 Analyzer was as follows: a. Level 1 HGB 5.3-5.9 g/dL b. Level 2 RBC 4.21-4.59 10^6/u/L c. Level 3 RBC 5.09-5.55 10^6 /u/L 3) The TP confirmed on 8/1//22 at 11:30 am the MPI was not followed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of Complete Blood Cell (CBC) and automated differential Performance Specification (PS) records and interview with the Testing Personnel (TP), the laboratory failed to ensure that all PS records were adequate for all analytes run on the Sysmex XN-550 Analyzer on the date of survey. The findings include: 1. There was no source cited for Normal Patient Range. 2. There was no documented evidence that the Laboratory Information System (LIS) was verified. 3. The TP confirmed on 8/18/22 at 11:30 am that the laboratory failed to ensure that all PS records were adequate.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of the Sysmex Certificate of Calibrations (COC) and interview with the Testing Personnel (TP), the laboratory failed to perform Calibration Verification (CV) every 6 months on the Sysmex XN-550 analyzer used for Hematology testing. The findings include: 1. There was no documentation evidence that CV was performed. 2. The TP confirmed on 8/18/22 at 12:00 pm that the laboratory did not have documented evidence that CV was performed.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify commercial QC material with each new lot and/or shipment of QC used for Hematology tests performed on Sysmex XN-L 550 analyzer on the date of survey. The finding includes: 1. There was no documented evidence that QC was verified before being put into use. 2. The TP

	confirmed on 8/18/22 at 12:20 pm that the QC material was not verified before putting in use.
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 surveyor review of the Procedure Manual 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 on the date of survey. The OM confirmed on 8/18/22 at 12:00 pm that the laboratory failed have available Corrective Action (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 on 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 8/18 /22 at 11:45 am that 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.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of the Laboratory records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory from 6/12/19 to the date of survey. The findings include: 1. The LD failed to ensure that Performance Specification procedures

	performed on the Sysmex XN-550 analyzer were adequate. Cross refer D6013 2. The LD failed to ensure that all Proficiency Test results received were reviewed by the appropriate staff . Cross refer D6018 .
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 on 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 8/18/22 at 11:20 am that PS records were not adequate.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD), failed to ensure that all PT results received were reviewed by the appropriate staff to identify any problems that require corrective action for Hematology performed with the American Proficiency Institute (API) in the third event of 2021 and the first event of 2022. The TP confirmed on 8/18/22 at 11:45 am that the PT results were not reviewed.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that the QC program was established and maintained for laboratory services provided on the date of the survey. The TP confirmed on 8/18/22 at 11:30 am the LD did not ensure a QC plan was established and maintained. .
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on the lack of Calibration Verification Records, Quality Control Records and interview with the Testing Personnel (TP), the TP failed to document calibration and maintain Quality Control (QC) records for the Sysmex XN-L 550 analyzer on the date of survey. The findings include: 1. The TP provided 3 months of QC levy Jennings graphs. 2. There was no documented evidence that CV was performed. 3. The TP confirmed on 8/18/22 at 11:50 am that the laboratory did not document all Calibration and QC activities and .
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.