Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2172458	07/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Amg Ada Advanced Care Oncology &	333 Mount Hope Ave, Rockaway, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to retain all QC records for tests performed on the Sysmex XP-550 analyzer from 2/4/22 to the date of survey. The finding includes: 1. There was no record of QC past March 2022. 2. The TP confirmed on 7/27/2022 at 11:00 am that the all QC records were not retained.
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 at the date of survey. The findings include: 1) MPI for XN-L QC Lot 2154140 had CV as follows: a. Level 1: Mean Corpuscular Volume (MCV) 67.5-76.1 FL b. Level 2: Red Blood Cell (RBC) 4.22 - 4.57 106/uL,

	Mean Corpuscular Hemoglobin (MCH) 27.9 - 32.1 pg, Mean Corpuscular Hemoglobin Concentration (MCHC) 32.9 - 39.1 g/dL. c. Level 3: RBC count 5.11 - 5.53 106/uL, MCV 81 - 91.3 FL, Red blood cell Distribution Width-CV (RDW-CV) 14.0 -15.1 %. 2) CV in the Sysmex XN-550 Analyzer was as follows: a. Level l : MCV 68.7 - 74.9 FL b. Level 2: RBC 4.21 - 4.59 106/uL, MCH 28.7 - 31.3 pg, MCHC 32.6 - 39.1 g/dL c. Level 3: RBC 5.09 - 5.55 106/uL, MCV 82.7 - 89.7 FL, RDW-CV 13.8 - 15.2 % 3) The TP confirmed on 7/27/22 at 10:30 am the MPI was not followed.
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 every 6 months on the Sysmex XN-550 analyzer used for Hematology testing. The findings include: 1.There was no documentation of the number, type and concentration of the materials used for performing Calibration Verification (CV). 2. The COC did not provide lot numbers of calibration material used for CV. 3. The TP confirmed on 7/27/22 at 10:00 am that the laboratory failed to perform CV every 6 months.
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, and interview with the Testing Personnel (TP) the laboratory failed to have available Corrective Action (CA) procedures for QC from 1/26/20 to the date of survey. The TP confirmed on 7/27/22 at 11:00 am 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 review of Procedure Manual (PM), Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to establish written policies and procedures to monitor, assess and correct problems identified in the analytic system for Hemtology tests perfomed on the Sysmex XN-550 from 1/29/20 to the date of the survey. The findings include: 1. There was no evidence that QC verification was reviewed. 2. The PM procedure "C. Frequency of Control use and review" states "complete this section with your laboratory's policy for commercial and patient control analysis and review frequency". 3. The TP confirmed on 7/27/22 at 10: 40 am the laboratory did not have a procedure to monitor and assess problems for Hemtology tests perfomed on the Sysmex XN-550.
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 March 2021 to the date of survey. The finding includes: 1. The LD did not perform precision. 2. The LD did not provide a source for reference intervals/range (normal values) for the laboratory's patient population. 3. The TP confirmed on 7/27 /22 at 10:20 am that PS records were not adequate.
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 surveyor review of the Quality Control (QC) records, Procedure Manual (PM) and interview with the Testing personnel (TP), the Laboratory Director failed to ensure that the QC program was maintained for laboratory services provided from 1/29 /20 to the date of the survey. The findings include: 1. The QC plan in the PM was not completed 2. There was no documented corrective action when QC analytes were flagged and rerun. 3. The MP stated "Refer to the Sysmex XN-L Series Automated Hematology Systems Flagging interpretation Guide" but the laboratory had no such guild. 4. The TP confirmed on 7/27/22 at 11:30 am the LD did not ensure the QC plan was maintained. .
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a lack of a Quality Assurance (QA) plan and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a QA plan from 1/29/20 to the date of the survey. The TP confirmed on 7/27/22 at 11:30 am that a QA plan had not been established.