Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2170513	02/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Amg Ada Advanced Care Oncology And	657 Willow Grove Street Suite 305, Hackettstown, 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 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: a. Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow the procedure to verify new lot numbers of Quality Control (QC) used in Hematology tests at the time of the survey. The finding includes: 1. The PM stated new lots of QC will be run "once before using" use but there was no documented evidence any QC lots were run before use. 2. The TP #1 listed on CMS form 209 confirmed 2/4/20 at 11:30 am that the laboratory did not follow the PM. b. Based on surveyor review of the PM, patient Work Records (WR) and interview with the TP, the laboratory failed to follow the PM for "Abnormal, WBC abn Scattergram" for Hematology tests run on the Sysmex XN550 from June 2019 to the time of survey. The finding includes: 1. The laboratory did not have a its own policy to review flags but used the PM. 2. The PM stated " * Verify WBC differential and PLT results according to your laboratory policy" but a review of patient WR revealed instrument flags as below: a. Hgb critical: Repeat b. WBC critical: Repeat c. Comment "FLAG in LIS" d. Reflex to low WBC mode e. PLT IP Message 3. There was no documented evidence samples were repeated, scanned or run in "low WBC mode" for ten of ten samples with flags reviewed. 4. The TP #1 confirmed on 2/4/20 at 11:05 am the above mentioned procedures were not followed.
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 a Critical Value (CV) procedure for Hematology Tests from June 2019 to the time of the survey. The TP #1 listed on CMS form 209 confirmed on 2/4/20 at 11:20 am that the PM did not have all applicable procedures.
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 at the time of the survey. The TP #1 listed on CMS from 209 confirmed on 2/4/20 at 12:00 pm that a QA plan had not been established.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical

	phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements at the time of the survey. The TP #1 listed on CMS form 209 confirmed on 2/4/20 at 10:30 am that a CA procedure was not established.