

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2172458	<b>(X3) Date Survey Completed</b>  01/29/2020
<b>Name of Provider or Supplier</b>  Amg Ada Advanced Care Oncology &	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Patient work records and interview with the Testing Personnel (TP), the laboratory failed to follow their PM policy for "Act Diff #2 Flags and Codes" for Hematology tests ran on the Beckman Coulter AcT diff 2 from September 2019 to the date of survey. The finding includes: 1) The PM stated "X flag indicates that one of the multiple Alert criteria was not met. 1. Thoroughly mix and rerun the sample. 2. If the flag does not repeat report result. 3. If flag repeats, clean the aperture as instructed in zapping the aperture. 4. if after cleaning, problem persists contact your Beckman Coulter Representative". a) Patient number 0821 run on 11/20/19 with "X" flagged results was not rerun. 2) The PM stated "- - - flag indicates Total Voteout. Replaces result when: Two of the three count periods did not agree. or For WBC and RBC, the first count period. 1. Thoroughly mix and rerun the sample. 2. If the voteout repeats, zap apertures 3. Thoroughly mix and rerun the sample. 4. If the voteout repeats, run a previously run sample with known values. 5. If the voteout repeats, clean the baths according to Cleaning (Bleaching) the Baths in this chapter. 6. Thoroughly mix and rerun the sample. 7. If the voteout repeats, call your Beckman Coulter Representative. ". b) Patient numbers 6708 run on 1/2/20, and 4570 run on 1/8/20 with "- - -" flagged results were not rerun. 2) The TP #1 confirmed on 1/29/20 at 11:05 am the above mentioned procedures were not followed.</p>
<b>D5403</b>	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 procedures needed for Hematology tests run on the Beckman Coulter Act Diff 2 analyzer from September 2019 to the date of the survey. The finding includes: 1. The laboratory failed to have a procedure for verification of new lots of controls before they were put in use. 2. The TP #1 listed on CMS form 209 confirmed on 1/29/20 at 11:50 am that the laboratory did not have the above procedure.

**D5783**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to take corrective action when controls were out of range for Hematology Testing on the Beckman Coulter Act diff 2 from September 2019 to the date of survey. The findings include: 1. A review of the QC records revealed: a. On 9/18/19 Hemoglobin (HGB), Mean Corpuscular Hemoglobin (MCH), and Mean Corpuscular Hemoglobin Concentration (MCHC) were out of range on all three levels of controls. b. On 9/25/19 & 10/23/19 HGB was out of range on Normal and Low levels of controls. c. On 1/2/20 HGB and MCHC were out of

range on Normal and Low levels of controls 2. Approximately 25 patients were run and reported each day of testing. 3. The TP #1 listed on CMS form 209 confirmed on 1/29/20 at 12:00 pm that corrective action on failure of QC was not performed.

**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 for Hematology tests performed on the Beckman Coulter Act Diff2 analyzer were adequate from September 2019 to the date of survey. The findings include: 1. There was no evidence documented that accuracy or precision was performed. 2. There was no documented evidence that the LD approved the PS. 3. The TP #1 listed on CMS form 209 confirmed on 1/29/20 at 10:00 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 American Proficiency Institute in the calendar year 2019. The TP #1 listed on CMS form 209 confirmed on 1/29/20 at 10:40 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 surveyor review of the Procedure Manual (PM), Quality Control (QC) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure the Quality Control (QC) program was maintained for Hematology Testing from September 2019 to the date of survey. The finding includes: 1. There was no documented evidence of QC review from September 2019 to the date of survey. 2. The TP #1 listed on CMS form 209 confirmed on 1/29/20 at 12:00 pm that a QC program was not maintained.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on surveyor review of Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to have education documented for three out of five TP from September 2019 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 1/29/20 at 10:30 am that all education records were 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 Records (PR) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to specify in detail the duties and responsibilities for five out of five TP engaged in the performance of Hematology testing from September 2019 to the date of survey. The TP #1 listed on

CMS form 209 confirmed on 1/29/20 at 11:15 am that the LD did not specify the duties and responsibilities of TP.