Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2170513	02/14/2024
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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to authorize PT data for Hematology events performed with the American Proficiency Institute (API) to be released to the Centers for Medicare and Medicaid Services (CMS) in calendar years 2022 and 2023. The findings include: 1. The Hematology PT records from API state "CLIA ID indicates results available to CMS." 2. All Hematology PT records performed with API in calendar years 2022 and 2023 stated the CLIA Number was "Not on file". 3. TP #2 as listed on the CMS-209 form confirmed the PT results performed with API were not being released to CMS.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview

	with the Testing Personnel (TP), the laboratory failed to follow its policies and procedures for assessing the competency of Testing Personnel (TP) in calendar years 2022 and 2023. The findings include: 1. The laboratory CA policy stated: "Competency must be assessed: at least semiannually(first assessment within seven months from initiation of testing and second assessment no later than 12 months for the start of testing during the first year and individual tests patient specimen (new employee)." " At least annually after an individual has performed assigned duties for one year." 2. TP #6 as listed on the CMS-209 form, had a competency assessment form that did not have any competency areas marked as met or not met. The form was signed by the evaluator and employee and the employee was marked as competent. 3. Three out of Six TP did not have a semiannual CA performed after initial their training. 4. Two of of Six TP did not have a CA performed in 2023. 5. TP #2 as listed on the CMS-209 form confirmed on 2/14/24 at 11:00 am, the laboratory failed to follow its policies and procedures for assessing the competency of TP.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with Testing Personnel (TP), the laboratory failed to document the evaluation of all unacceptable scores and corrective action taken for Hematology events performed with the American Proficiency Institute (API) for the 2nd and 3rd events of 2022. The findings include: 1. The following samples were graded as unacceptable for the 2nd Hematology event of 2022. a) Sample XE-06 for Mean Corpuscular Hemoglobin Concentration (MCHC) b) Sample XE-06 for Mean Corpuscular Volume (MCV) c) Sample XE-06 for Mean Platelet Volume (MPV) d) Sample XE-06 for Platelet Count e) Sample XE-06 for Red Cell Distribution Width (RDW-CV) 2. Sample XE-12 for MPV was graded as unacceptable for the 3rd Hematology event of 2023. 3. There was no documented evidence for evaluation or corrective action performed for the aforementioned PT events. 4. The TP#2 as listed on the CMS-209 form confirmed on 2/14/24 at 12:20 pm, the laboratory failed to evaluate and perform corrective action for the failed analytes for Hematology PT events in calendar years 2022 and 2023.
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), Beyond Care Quality Monitor (BCQM) procedures and reports and interview with the Testing Personnel (TP), the laboratory failed to have all applicable procedures for Hematology Tests performed on the Sysmex XN 550 analyzer from 7/14/22 to 2/14/24. The findings include: 1. The laboratory failed to have corrective action procedures when calibration or control results fail to meet the laboratory's criteria for acceptability on reports provided by the Sysmex Beyondcare Quality Montior for Hematology tests. 2. The TP #2 as listed on the CMS-209 form confirmed on 2/14/24 at 12:00 pm that the PM failed to have all applicable procedures for the Sysmex XN 550 analyzer.
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: A. Based on surveyor review of the Insight Quality Control Report (IQCR) for the Sysmex XN analyzer and interview with the Testing Personnel (TP), the laboratory failed to perform and document corrective action from 1/23/22 to 2/14/24. The findings include: 1. The IQCR states "if your Coefficient of Variation (CV) is 1.5 times greater than the group CV, your result is presented in bold and an investigation is warranted." 2. Mono % Level 3 was in bold in the IQCR for Lot 1351 Period 2 from 1/23/22 to 2/24/22. 3. There was no documented evidence for corrective action for the above analyte and control lot number. 4. TP #2 as listed on the CMS-209 form, confirmed on 2/14/24 at 11:45 am, the laboratory failed to perform and document all corrective action. B. Based on surveyor review of the Continuous Calibration Verification Report (CCVR) for the Sysmex XN analyzer and interview with the TP, the laboratory failed to perform and document corrective action from 2/15/23 to 2/14 /24. The findings include: 1. The CCVR states "Your Calibration Verification (CV) will be bolded along with a 1 appearing in notes column if your CV exceeds the CV% limit." The Report interpretation guide states P1 means " Parameter passed accuracy check, but failed precision check." 2. The following analytes in the CCVR were bold and had a P1 appearing in the notes column for Lot 3041 from 2/15/23 to 5/23/23: a) RDW-CV % Level 3 b) Lymph % Level 3 c) Lymph # Level 3 3. There was no documented evidence for corrective action for the above mentioned analytes and control lot number. 4. TP #2 as listed on the CMS-209 form, confirmed on 2/14/24 at 11:55 am, the laboratory failed to perform and document all corrective action.
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 the lack of a Quality Assessment (QA) records, review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to maintain the QA program to assure the quality of laboratory services provided from 7/14/22 to 2/14/24. The findings include: 1. The quality management plan in the PM states " the quality management plan is reviewed and approved by the LD on an annual basis." 2. There was no documented evidence the quality management policy was followed. 3. TP #2 as listed on the CMS-209 form, confirmed on 2/14/24 at 12:30 pm, the LD failed to maintain the QA program.