Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2172458	02/27/2024
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to ensure that all Testing Personnel (TP) who perform Hematology testing participated in the American Proficiency Institute (API) PT events for the 1st and 2nd events in the calendar year of 2022. The findings include: 1. The PM states "Analyze the survey specimen in the same manner as routine patients specimens. Testing should be performed by all qualified laboratory personnel and not restricted to individuals." 2. A review of PT attestation records showed that one TP performed the 1st and 2nd Hematology PT events of 2022. 3. TP#1 as listed on the CMS-209 form confirmed on 2/27/24 at 11:45 am that the laboratory failed to rotate all TP to participate for Hematology API PT events in 2022.
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:

	Based on surveyor review of the Procedure Manual (PM), New lot reagent logs and interview with the Testing Personnel (TP), the laboratory failed to follow the procedure for "Reagent Replacement" from 10/10/22 to 2/27/24. The findings include: 1. The PM states " New lots of reagents must be verified against the old reagent using Quality Control (QC) material and at least one patient run on the previous lot of the reagent." 2. There was no documented evidence the procedure was performed for all new lot reagents for the Sysmex XN 550 analyzer used in Hematology testing in the aforementioned timeframe. 3. TP #1 as listed on the CMS-209 form confirmed on 2/27 /24 at 12:00 pm, the laboratory failed to follow the PM.
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 Continuous Calibration Verification Report (CCVR) for the Sysmex XN 550 analyzer and interview with the TP, the laboratory failed to perform and document corrective action from 11/22/22 to 2/27/24. 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 4012 from 1/17/24 to 4/23/24: a) Neut % L3 b) Lymph % L1 c) Mono% L1 d) IG % L2 e) Mono # L1 f) EO # L3 g) IG # L2 3. The following analytes in the CCVR were bold and had a P1 appearing in the notes column for Lot 2322 from 11/22/22 to 2/28/23: a) RBC L1, L2 and L3 b) MCH L1, L2 and L3 4. There was no documented evidence for corrective action for the above mentioned analytes and control lot numbers. 5. TP #1 as listed on the CMS-209 form, confirmed on 2/27/24 at 11:55 am, the laboratory failed to perform and document all corrective action.