Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2154847	07/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
Amg Hematology & Oncology	1000 Galloping Hill Road, Union, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. 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 review and evaluate PT results obtained from the College of American Pathologists (CAP) for Hematology tests from 9/1/23 to 7/23/25. The findings include: 1. There was no documented evidence that PT results obtained from CAP for Hematology events FH9-C-23, FH9-B-24, BCP-B-24, FH9-C-24 and BCP-C-24 were reviewed and evaluated. 2. The CAP PT results for FH9-C-23, FH9-B-24, BCP-B-23, FH9-C-24 and BCP-C-24 were printed on site during the survey by the TP. 3. Code 26 (educational challenge) results for Immature Granulocytes (IG) % and IG Absolute for PT event FH9-A-25 were not reviewed or evaluated. 4. TP #1 as listed on the CMS 209 form confirmed on 7/23/25 at 12:10 pm, the laboratory did not review and evaluate all PT results obtained from CAP.
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 the Testing Personnel (TP), the laboratory failed to review all unsatisfactory scores and document corrective action taken for PT results obtained from the College of American Pathologists (CAP) for Hematology tests from 9/1/23 to 7/23/25. The

	findings include: 1. The laboratory received unacceptable results for the analyte Mean Corpuscular Hemoglobin Concentration (MCHC) for three out of five PT samples in event FH9-C-23. 2. The laboratory received unacceptable results for the analyte Neut /Gran Absolute for PT sample FH9-12 in event FH9-C-24. 3. TP #1 as listed on the CMS 209 form confirmed on 7/23/25 at 12:15 pm, the laboratory did not review all unsatisfactory scores and document any corrective action taken.
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. 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 PM lacked a Quality Control Verification (QCV) procedure for new lots of Quality Control (QC) used for Hematology tests from 5/3 /23 to 7/23/25. The findings include: 1. The laboratory did not establish a detailed procedure for performing QCV on new lots of QC material that included frequency and acceptability criteria. 2. The laboratory performed QCV on new lots of QC, but did not have a detailed procedure to refer to. 3. TP #1 as listed on the CMS 209 form confirmed on 7/23/25 at 12:05 pm, the laboratory did not establish a QCV procedure to refer to.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the surveyor review of the Electronic Medical Record Test Reports (EMRTR), Sysmex Test Records (STR), Procedure Manual (PM), and interview with the Testing Personnel (TP), the laboratory failed to have accurate Reference Intervals (RI) for Hematology tests performed on the Sysmex XN 430 analyzer from 5/3/23 to 7 /23/25. The findings include: 1. Surveyor review of EMRTR, PM and STR revealed that the PM and STR had the same RI, but the EMRTR had different RI for five out of five patients. 2. The follwing analytes did not have RI that matched on both the STR and the EMRTR: Red Blood Cell, Hemoglobin, Hematocrit, Mean Corpuscular Volume, Mean Corpuscular Hemoglobin, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Neutrophils Absolute, Lymphocytes Absolute, Monocytes Absolute, Eosinphils Absolute, Basophils Absolute and Mean Platelet Volume. 3. TP #1 as listed on the CMS 209 form confirmed on 7/23/25 at 12:20 pm, the laboratory did not have accurate RI.