Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2154847	05/01/2019
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
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 survey review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to follow its Competency Assessment (CA) procedures for five out of five TP from 10/2/18 to the date of the survey. The findings include: 1. The laboratory failed to use all the criteria in the CA procedure as follows: a. Four of five TP did not have assessment of test performance through testing Proficiency Samples or internal blind samples performed b. Three of five TP did not have direct observation of instrument maintenance or problem solving skills evaluated. c. One of five TP did not have any of the criteria used to assess CA. 2. The TP #3 listed on CMS form 209 confirmed on 5/1/19 at 12:30 pm the laboratory did not follow the CA procedure.
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 evaluate coded results obtained in the FH9-A 2019 Hematology Auto Differential event with the College of American

	Pathologists (CAP). The findings include: 1. The laboratory did not evaluate Code 27 (lack of participant or referee consensus) and Code 26 (educational challenge) obtained for Blood Cell Identification in the FH9-A 2019 event. 2. The TP #3 listed on CMS form 209 confirmed on 5/1/19 at 1:30 pm that the laboratory failed to evaluate coded results for PT events.
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 performed on the Sysmex XN-430 analyzer were adequate from October 2018 to the date of survey. The findings include: 1. The LD did not review and sign the Method Comparison (MC) results. 2. There were no documented evidence linearity was performed. 3. There was no work records to substantiate the reportable range study. 4, There was no documented evidence precision was reviewed by the LD. 5. There was no documented evidence the reference range was verified. 6. The TP #3 listed on CMS form 209 confirmed on 5/1/19 at 2:15 pm that PS records were not adequate.
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 lack of a Quality Assessment (QA) policy and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that a QA program was established from 10/2/08 to the date of survey. The TP #3 listed on CMS form 209 confirmed on 5/1/19 at 2:00 pm that the laboratory did not have a QA program.
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 the Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director failed to have appropriate training records for five out of six TP on file from 10/2/18 to the date of the survey. The TP #3 listed on CMS form 209 confirmed on 5/1/19 at 1:40 am all training records were not in the PF.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: a. Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personal (TP), the TP failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Sysmex XN-430 analyzer from 10/2/18 to the date of the survey. The TP #3 listed on CMS form 209 confirmed on 5/1/19 at 1:45 pm that trends and shifts were not reviewed. b. Based on surveyor review of the QC records and interview with the TP, the TP were not able to accurately identify problems that may affect test performance by not having the correct values to review and evaluate trends and/or shifts for tests programmed into the Sysmex XN-430 analyzer from 10/2/18 to the date of the survey. The finding includes: 1. A review of the QC Levy Jennings Charts in the instrument revealed that standard deviations from the mean were not calculated correctly. 2. The TP #3 listed on CMS form 209 confirmed on 5/1/19 at 1:45 pm that trends and shifts were not able to be reviewed accurately.