Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0106272	03/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Amg Hematology & Oncology	99 Beauvoir Avenue, Overlook Med Ctr, Summit, 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: 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. Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow the Competency Assessment (CA) procedure to assess competency of three of twelve TP from 05/30/18 to the date of survey. The finding includes: 1. Three of the twelve TP were not assessed on " test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples" as required in the Competency Assessment procedure. 2. The TP # 2 listed on CMS form 209 confirmed on 3/11/21 at 1:00 pm that the laboratory did not follow the CA procedure.
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: All proficiency testing evaluation and verification activities must be documented. Based on surveyor review of Proficiency Testing (PT) results and interview with the

	Testing Personnel (TP), the laboratory failed to review coded results for Hematology Testing performed with the College of American Pathologists (CAP) in 2020. The findings include: 1. The laboratory received a coded result (Code 26 -Educational Challenge) for Immature Granulocytes (IG) Percentage and Absolute Number in event FH9-B and C for samples FH 9 (5-10) and (11- 15) respectively. 2. There was no documented evidence that coded PT results were reviewed. 3. The TP #2 listed on CMS form 209 confirmed on 3/11/21 at 1:15 pm that the laboratory did not review coded PT results. .
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) and interview with the Testing Personnel (TP), the laboratory failed to follow the procedure for reviewing results with flags obtained on the Sysmex XNL 430 analyzer used for Hematology testing from 5/30/18 to the date of the survey. The findings include: 1. The PM stated "What to do if indicators appear." "Send specimen to main hospital lab" * Review smear according to office" "+/- Criteria. Many labs out of range" 2. A review of ten patient results with indicators (*, +, -) revealed ten of ten had no documented evidence smears were made or any samples were sent to the hospital. 3. The TP # 2 listed on CMS form 209 confirmed on 3/11/21 at 1:40 pm that the laboratory did not follow the procedure for flag review.
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:

	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. a. Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to have a procedure to report Panic Values for Hematology Tests performed on the Sysmex XN-L 430 from 5/30/18 to the time of the survey. The TP #2 listed on CMS form 209 confirmed on 3/11/21 at 1: 25 pm that the PM did not have the above procedure. b. Based on surveyor review of the PM and interview with the TP, the laboratory failed to have a procedure to to stain Manual Differential slides for Hematology Tests from 5/30/18 to the time of the survey. The TP #2 listed on CMS form 209 confirmed on 3/11/21 at 1:30 pm that the PM did not have the above procedure.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR), Procedure Manual (PM), Performance Specification Records (PSR) and interview with the Testing (TP), the laboratory failed to report patient test results accurately when test results were above or below the assay detectable limit for Hematology Tests performed on the Sysmex XN 430 from 5/30/18 to the date of survey. The findings include: 1. The laboratory had no documentation in the PM, PSR, or in the room with the Sysmex XN 430 analyzer which indicated the linearity of Hematology parameters reported on the FR. 2. The TP #2 listed on CMS form 209 confirmed on 3/11/21 at 2:50 pm that the laboratory did not have linearity limits.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to identify problems on the FR for Hematology tests performed on the Sysmex XN 430 from 5/30/18 to the date of the survey. The findings include: 1. Three of ten FR had exclamation mark (!) and a "W" next to results but there was no explanation on the FR as to what they meant. 2. Asterisks (*) found on five of ten Sysmex work records which indicated low reliability of date were missing from the FR. 3. The TP #2 listed on CMS form 209 confirmed on 3/11/21 at 2: 30 pm that the laboratory did not identify problems on the FR.
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 review of the Personnel Files (PF) and interview with Testing Personnel (TP), the Laboratory Director (LD) failed to have foreign education evaluated for one out of twelveTesting Personnel (TP) performing nonwaived tests from 5/18/21 to the date of the survey. The finding includes: 1. The laboratory did not have a foreign education evaluation for one out of twelve TP. 2. The TP #2 listed on CMS form 209 confirmed on 3/11/21 at 1:30 pm that the LD did not have foreign education evaluated.
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:

	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. Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to specify in writing the duties and responsibilities of each Testing Personnel (TP) engaged in the performance of preanalytic, analytic and post analytic phases of testing. The TP # 2 listed on CMS form 209 confirmed during the survey on 3/11/2021 at 1:30 pm that the LD did not specify the job description.