Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0106272	09/24/2024
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. 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 maintain the Attestation Statements (AS) signed by the analyst and laboratory director for Hematology Cell Identification performed with the College of American Pathologists in the calendar year 2023 and first and second events for 2024. The findings include: 1. The laboratory did not document handling, processing and each step in the testing and reporting of PT samples for events below: a. Hematology Blood Cell ID, photographs- Event 1 ,2 and 3 for 2023 (TP) failed to sign the attestation statements b. Hematology Blood Cell ID, photographs- Event 1, and 2 (TP) failed to sign the attestation statements 2. The TP confirmed on 9/24/24 at 10:35 am that the laboratory did not maintain all records for PT.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Testing Personnel (TP), the laboratory failed to maintain the patient raw data from the Sysmex XN-430 used for hematology testing from 4/19/24 to the date of survey. The TP confirmed on 9/24/24 at 10:00 am that raw data containing results and data alarm flags were not maintained
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 coded results for Hematology Testing performed with the College of American Pathologists (CAP) in the first and second events of 2024. The findings include:. The finding include: 1. The laboratory received a coded result (Code 26 -Educational Challenge) for Blood Cell ID ungraded for event BCP-A, adn BCP-B 2024 and . 2. There was no documented evidence that coded PT results were reviewed. 3. The TP confirmed on 9/24/24 at 10: 15 am 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 the surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a complete Quality Control (QC) plan from 4/19/23 to the date of the survey. The findings include: 1) The QC procedure did not define the frequency on when to review and generated levy Jennings charts. 2) The QC procedure did not define the which Sysmex BeyondCare Quality Monitor (BCQM) reports to be generated and reviewed. 3) The QC procedure did not define the frequency in which to review BCQM reports. 4) The QC procedure did not define parameters for acceptable QC results. 5) The QC procedure did not specify who will review QC. 6) The TP confirmed on 9/24/24 at 11:00 am that the LD failed to establish a complete QC program.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control Verification (QCV) records and interview with the Testing Peronnel (TP), the laboratory failed to verify QC material before use for Hematology tests run on the Sysmex XN-430 analyzer on the date of survey. The finding include. 1) There was no documented evidenced that the QCV was performed on XN-check controls lot # 41801400. 2) The TP confirmed 9/24/24 at 11:15 am that QC material was not verified before putting in use.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyors observation of Quality Control (QC) material in use and interview with the Testing Personnel (TP), the laboratory failed to follow Manufacturers Specifications (MS) for controls from 4/19/23 to the date of survey. The finding includes: 1. Controls in use did not have open or expiration dates documented as per MS. 2. The MS states "XN-L Check is stored at 2-8C before and after opening. The period of use is 12 weeks per lot, with an open vial stability of 15 days if stored at 2 - 8 C. The volume is 3.0 mL per vial." 2. The TP confirmed on 9/24/24 at 11:20 am that MS were not followed.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. 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 have available Corrective Action (CA) procedures to maintain the laboratory's operation for testing patient specimens in a

	manner that ensures accurate and reliable patient test results and reports from 4/19/23 to the date of survey. The finding includes: 1) There were no CA procedures for Failed Quality Control (QC) results. 2) The TP confirmed on 9/24/24 at 12:00 pm that the laboratory failed to have available CA procedures.
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 a lack of a Quality Assessment (QA) plan, review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a QA program to assure the quality of laboratory services provided from 4/19 /23 to the date of the survey. The TP confirmed on 9/24/24 at 11:00 am that the LD failed to establish a QA program.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records, Procedure Manual (PM) and interview with the Testing Personnel (TP) the Laboratory Director (LD) failed to have established written procedures for assessing the competency of TP from 4/19/23 to the date of survey. The findings include: 1. There was no written procedure or policy for how to assess the competency of new employees and the annual competency of TP. 2. The TP confirmed on 9/24/24 at 10:30 am the LD failed to establish written policies and procedures for CA.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files, Competency Assessment (CA) records and interview with the Testing Personnel (TP), the Technical Consultant (TC) failed to perform CA from 4/19/23 to the date of survey. The findings include: 1. TP performing CA did not meet federal regulator requirements for Techincal Consultant. 2. The CA was not performed by qualified personnel. 3. The TP confirmed on 9/24/24 at 10:15 am that the CA was not performed by TC.