Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2136530	(X3) Date Survey Completed 10/15/2019
Name of Provider or Supplier Amg Dba Atlantic Hematology/	**Street Address, City, State** 100 Madison Ave, Morristown, 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 Office Manager (OM), the laboratory failed to review and evaluate coded PT results obtained with the College of American Pathologists (CAP) in 3-2018, 1-2019 and 2-2019 for Immature Granulocyte (IG). The findings include: 1. The laboratory did not evaluate Code 26 (educational challenge) as below: a. IG % /Absolute Number - A - 2018 event. Samples FH9-11 thru FH9-15. b. IG % /Absolute Number - A - 2019 event. Samples FH9-01 thru FH9-05. c. IG % /Absolute Number - B - 2019 event. Samples FH9-06 thru FH9-10. 2. The OM confirmed on 10/15/19 at 10:30 am that the laboratory failed to evaluate coded results for PT events.
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 Office Manager (OM), the laboratory failed to evaluate results when they received an unacceptable score in Hematology tests performed with the the College of American Pathologists (CAP) in event 3-2018. The findings include: 1. The laboratory received an "Unacceptable" result on sample FH9-11 Eosinophils % and sample FH9-14 Hemoglobin and Hematocrit. 2. There was no documented evidence

	that the laboratory investigated the failures. 3. The OM confirmed on 10/15/19 at 10: 10 am that the laboratory did not perform and document an evaluation of unacceptable PT results.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of Calibration Verification (CV) records and interview with the Office Manager (OM), the laboratory failed to perform and document CV procedures at least once every six months for Hematology Testing on the Sysmex XN550 analyzer in the calendar year 2019. The findings include: 1. The laboratory did not perform CV between 8/16/18 and 5/22/19. 2. The Certificate of Calibration issued from Sysmex stated Calibration Expiration date was 2/14/19 for the calibration performed on 8/6/18. 3. The laboratory performed approximately 50 Complete Blood Counts (CBC) per day from 2/14/19 to 5/22/19. 4. The OM confirmed on 10/15/19 at 11:30 am CV was not performed every six months.
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 Procedure Manual and interview with the Office Manager (OM), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements for Hematology tests from 5/23/18 to the date of the survey. The OM confirmed on 10/15/19 at 10:40 am that a CA procedure was not established.