

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2136530	(X3) Date Survey Completed 05/23/2018
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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Coordinator (CO), the laboratory failed to verify the accuracy of Hematology PT results obtained in event FH9 - C 2017 Comprehensive Hematology with Auto Differential from the College of American Pathologists (CAP). The findings include: 1. There was no evidence of the laboratory verified the accuracy of Hematology analytes when the laboratory received an exception code of 20 (no appropriate target /response cannot be graded on specimens FH9- 11-15 for: a. White Blood Cells (WBC) b. Red Blood Cells (RBC) c. Hematocrit d. Hemoglobin e. Platelets f. Lymphocytes, Monocytes, Eosinophils, Basophils - Absolute (#) and Percent (%) g. Absolute Neutrophil/Granulocyte - Absolute Count h. Mean Corpuscular Volume (MCV) i. Mean Corpuscular Hemoglobin (MCH) j. Mean Corpuscular Hemoglobin Concentration (MCHC) 2. There was no evidence of review when the laboratory received and exception code of 26 (educational challenge) for Immature Granulocytes # and % on samples FH9-11 thru FH9-15. 3. The CO confirmed on 5/23 /18 at 10:40 am the accuracy of PT results were not verified</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the</p>

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), Quality Control Records (QC) and interview with the Coordinator (CO), the laboratory failed to follow their PM for Hematology Testing performed on the Sysmex XNL 550 from September 2017 to the date of the survey. The findings include: 1. The laboratory did not follow the PM as stated below: a. Sysmex calibration verification was required every six months but there was no documented evidence calibration was performed after 8/15 /17. b. New QC lots were to be verified against the old lot before using but there was no documented evidence QC lots were verified prior to use. c. There was no documented evidence QC was reviewed. d. There was no documented evidence QC was evaluated for shifts and trends monthly. e. Temperature charts were not reviewed monthly from October 2017 to the date of the survey. 2. The CO confirmed on 5/23 /18 at 11:40 am that the PM was not followed.

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:

Based on surveyor review of the Procedure Manual (PM) and interview with the Coordinator (CO) the laboratory failed to have all applicable procedures for Hematology Tests performed on the Sysmex XNL 550 from September 2017 to the date of the survey. The findings include: 1. The laboratory did not have procedures for: a. Resolving flags on test results b. Reporting panic or alert values c. Corrective actions to be taken when calibrations or controls fail 2. The CO confirmed on 5/23/18 at 11:50 am that the PM did not have all applicable procedures for all test procedures.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Final Report (FR) and interview with the Coordinator (CO), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR from September 2017 to the date of survey. The CO confirmed on 5/23/18 at 12:30 pm that the TRD was not on the FR.

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 Reports (FR) and interview with the Coordinator (CO), the laboratory failed to correct problems in the postanalytic system when the test results were flagged from September 2017 to the date of the survey. The finding includes: 1. A review of FR with a plus or minus sign indicating the result was above or below the Reference Value (RV) revealed that some results were within the RV. a. Patient ID HNE642131936 - Platelets, Neutrophils and Red Blood Cell Distribution Width (RDW) had a + flag but results were within normal range. b. Patient ID HNE2081406541 - Lymphocytes had a - flag and RDW and Basophils had a + flag but results were within normal range. 2. The CO confirmed on 5/26/18 at 2:00 pm that the laboratory failed to ensure results were flagged correctly.

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 Coordinator (CO), the Laboratory Director (LD) failed to ensure that PS procedures performed on the Sysmex XNL 550 analyzer were adequate from September 2017 to the date of survey. The findings include: 1. The LD did not review

and sign the PS records. 2. The laboratory staff were not involved in performing PS only the manufacturer personnel did it. 3. The CO confirmed on 5/23/18 at 11:15 am that PS records were not reviewed.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on surveyor review of Proficiency Testing (PT) records and interview with the Coordinator (CO), the Laboratory Director (LD) failed to ensure that all PT results received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for Hematology testing performed with the American College of Pathologists (CAP) in event C - 2017. The CO confirmed on 4/5/18 at 10:30 am that the CAP PT results were not reviewed.

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 Coordinator (CO), the Laboratory Director failed to have education documented for five out of five Testing Personnel (TP) and training records for one out of three TP from September 2017 to the date of the survey. The CO confirmed on 5/23/18 at 10:10 am that all TP did not have education and training records.