

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2136530	(X3) Date Survey Completed 08/04/2022
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to retain all QC records for tests performed on the Sysmex XN-L series analyzer from 10/15/19 to the date of survey. The finding includes: 1. The OM was unable to reveal current control values entered in the analyzer. 2. The OM confirmed on 8/4/2022 at 2:00 pm that all QC records could not be accessed.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>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 FH9-A and VPBS-A 2022. The findings include: 1. The laboratory did not evaluate Code 26 (educational challenge) for FH9-A 2022 Hematology Auto Differentials as below: a. IG %, samples FH9-1 thru FH9-5. b. IG % /Absolute, samples FH9-01 thru FH9-05. 2. The laboratory did not evaluate Code 26 (educational challenge) for VPBS-A 2022</p>

	<p>Peripheral Blood Smear as below: a. Red Blood Cell Morphology, samples VPBS-01, 7 , 13 b. Platelet estimate, samples VPBS-1, 7 ,13 c. Blood Cell Identification, samples VPBS-02-06, VPBS-08 -18 3. The OM confirmed on 8/4/22 at 1:30 pm that the laboratory failed to evaluate coded results for PT events. Note: This was previously cited 10/15/19</p>
<p>D5313</p>	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Accession Log (AL) and interview with the Office Manager (OM), the laboratory failed to ensure that the laboratory accurately recorded the date and time specimens were received on ten out of ten AL entries reviewed. The OM confirmed on 8/4/22 at 12:20 pm that the laboratory did not ensure that specimen date and time was documented accurately.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Operators Manual (OM) and interview with the Office Manager (OM) the laboratory failed to have a written procedure for Quality Control Verification (QCV) from 10/15/19 to the date of the survey. The OM confirmed on 8/4/22 at 1:30 pm that the laboratory did not have a written procedure for QVC.</p>
<p>D5469</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

	<p>Based on surveyor review of Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to verify commercial QC material with each new lot and/or shipment of QC used for Hematology tests performed on Sysmex XN-L series analyzer from 10/15/19 to the date of survey. The finding includes: 1. There was no documented evidence that QC was verified before being put into use. 2. The OM confirmed on 8/4/22 at 1:20 pm that the QC material was not verified before putting in use.</p>
<p>D5779</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual PM, Quality Control (QC) records, Patients Work Records (PWR) and interview with the Office Manager (OM) the laboratory failed to have available Corrective Action (CA) procedures for QC and flagged PWR from 10/15/19 to the date of survey. The OM confirmed on 8/4/22 at 2:00 pm that the laboratory failed have available Corrective Action (CA) procedures.</p>
<p>D5781</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Patient Work Records (PWR) records, Procedure Manual (PM), Operators Manual (OPM) and interview with the Office Manager (OM), the laboratory failed to take and document Corrective Action (CA) taken when Hematology WR run on the Sysmex XN-L series analyzer was unacceptable for 10/16/21 to the date of survey. The findings include: 1. There was no documented evidence of CA taken when the PWR had "*" flags on the differential on three out of ten PWR reviewed. 2. The OPM stated that "*" flag "indicates that the reliability of the data is low" "[*] has the highest priority". 3. The OM confirmed on 8/4/22 at 1:45 pm that CA was not taken for flagged PWR.</p>
<p>D5789</p>	<p>TEST RECORDS CFR(s): 493.1283(b)</p> <p>Records of patient testing including, if applicable, instrument printouts, must be retained.</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of Patient Work Records (PWR) and interview with the Office Manager (OM), the laboratory failed to retain WR for Hematology Tests performed on the Sysmex XN-L series analyzer from 10/15/19 to the date of survey. The finding includes: 1) A review of seven patients PWR revealed that two out of seven patients did not have a WR. 2) The OM confirmed on 8/4/22 at 2:30 pm that records for all patient testing were not retained.