

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2136530	(X3) Date Survey Completed 10/28/2025
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Laboratory Manager (LM), the laboratory lacked written procedures for performing Manual Differentials (MD) using the RAL Diff Quik stain for Hematology tests from 9/5/24 to 10/28/25. The findings include: 1. The PM lacked the following for performing MD with the RAL Diff Quik stain: a) Criteria for microscopic examination b) Step by step performance of the procedure including interpretation of results. c) Quality Control procedure for RAL Diff Quik stains. d) The laboratory's</p>

system for entering results in the patient record. e) Preparation of the stain. 2. The LM confirmed on 10/28/25 at 11:25 am, the PM lacked procedures for performing MD tests.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

This STANDARD is not met as evidenced by:

Based on the lack of Quality Control (QC) records and interview with the Laboratory Manager (LM), the laboratory failed to perform and document QC for Manual Differential (MD) tests using the RAL Diff Quik stain on each day of patient testing from 9/5/24 to 10/28/25. The finding includes: 1. There was no documented evidence laboratory personnel performed and documented QC for MD tests on each day of patient testing. 2. The LM confirmed on 10/28/25 at 11:35 am, the laboratory did not perform and document QC for MD tests.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control Verification Records (QCVR) and interview with the Laboratory Manager (LM), the laboratory failed to have complete QCVR for the Sysmex XN-L analyzer from 9/5/24 to 10/28/25. The findings include: 1. The " Establishing/ Verfiying Control Target Ranges" procedure stated "once a minimum of 10 data points are accumulated, print LJ chart." 2. The QCVR could not be differentiated from monthly levy jennings charts by the testing personnel. 3. The QCVR lacked the analyzer reports that were performed to verify the QC material. 4. The LM confirmed on 10/28/25, the QCVR were incomplete for the Sysmex XN-L analyzer.