Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2161401	10/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Atlantic Advanced Urgent Care	333 Route 46, Mountain Lakes, 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
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: a) Based on surveyor review of the Procedure Manual (PM), Operators Manual (OM) and interview with the Testing Personnel (TP), the laboratory failed to follow the PM for performing a precision check before calibration on the Sysmex Automated Hematology XN-550 analyzer from December 2019 to the date of the survey. The findings include: 1. The PM stated "before calibration, ensure that routine cleaning has been performed and precision check is within acceptable limits". 2. The laboratory did not perform the aforementioned procedure when calibrating the Sysmex Automated Hematology XN-550 analyzer. 3. The PM stated " manually analyze the same calibrator eleven times, and check the repeatability and accuracy of the analysis parameters" 4. The laboratory repeated the calibrator ten times. 5. The TP #1 as listed on CMS form 209 confirmed on 10/20/21 at 10:30 am that the laboratory did not follow the PM.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii)

	Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of Performance Specification (PS) records and interview with the Testing Perrsonel (TP), the laboratory failed to ensure that all PS procedures were adequate for all analytes run on the Symex XN-550, Cobas C311 and i-Stat analyzers from December 2019 to the date of survey. The finding includes: 1. There was no criteria for Precision and Accuracy run on the Symex XN-550 before starting patient testing. 2. There was no evidence that Linearity was perfomed on the Symex XN-550 before starting patient testing. 3. There was no evidence that Accuracy was performed on the Cobas C311 and i-Stat analyzers before starting patient testing. 4. The TP#1 listed on CMS form 209 confirmed at 10:10 am on 10/20/21 the laboratory failed to ensure that all PS procedures were adequate before starting patient testing
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: a) Based on surveyor review of Calibration Verification (CV) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Sysmex Automated Hematology XN-550 analyzer from December 2020 to the date of the survey. The finding includes: 1. There was no documented evidence CV was performed after December 2020. 2. There was no documented evidence QC was performed after CV on 7/23/19, 1/7/20 and 12/31/20. 3. The TP #1 lsited on CMS form 209 confirmed on 10/20/21 at 10:30 am that the laboratory failed to perform and document CV.
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 (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of QC used for Coagulatrion tests performed on the Cobas C311 analyzer from December 2019 to the date of the survey. The finding includes: 1. Cobas D-dimer controls had no documented evidence that QC verification was performed. 2. The TP #1 listed on CMAS from 209 confirmed on 10/20/21 at 11:00 am that assayed QC material was not verified before putting in use.