

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2108639	<b>(X3) Date Survey Completed</b> 03/20/2018
<b>Name of Provider or Supplier</b> Atlantic Ambulance Corporation	<b>Street Address, City, State</b> 25 B Vreeland Rd, Florham Park, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Temperature Records (TR) and interview with the Quality Manager (QM) the laboratory failed to monitor and record the Temperature (T) and Humidity (H) where Nova Stat Strip Lactate Meters were stored in each unit in January (Jan) and February (Feb) 2018. The findings include: 1. T and H were not monitored or out of range as follows: a. Unit 7 - 16 out of 31 days in Jan and 4 out of 28 days in Feb. T was out of range 4 out of 15 days in Jan. b. Unit M8 - 3 out of 31 days and T was out of range 5 out of 28 days in Jan. c. Unit 11 - 9 days out of 31 in Jan and 9 out of 28 days in Feb. d. Unit 902 - 14 days out of 28 in Feb. 2. The QM confirmed on 3/20/18 at 1:45 pm that T and H were not monitored and recorded.</p>
<b>D5447</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:  
Based on survey review of Quality Control (QC) records and interview with the Quality Manager (QM), the laboratory failed to perform and document controls each day of patient testing for Lactate Tests performed on the Nova Stat Strip analyzer in January (Jan) and February (Feb) 2018. The findings include: 1. A review of the QC record revealed controls were not run as follows: a. Unit 7 - Jan 5 and 8. b. Unit M8 - Jan 11. c. Unit 11 - Jan 1, 5, 7 and Feb 26. 2. Approximately 1 to 2 patients were run per unit each day control was not run. 3. The QM confirmed on 3/20/18 at 1:25 pm that QC was not done on each day of patient testing.

**D5783**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Quality Control (QC) records and interview with the Quality Manager (QM) the laboratory failed to take corrective action when one out of two levels of control was out of range for Lactate test performed on the Nova Stat Strip analyzer in January (Jan) and February (Feb) 2018. The findings include: 1. Lactate Control Solution Level 2 Lot number 2716336302 was out of range as follows: a. Unit 7 - Jan 1, 2, 4, 6, 7, 9, 11, 13, 14, 16, 17, 22, 23, 26, 28, 30 and Feb 15, 16 and 18. b. Unit M8 - Jan 2, 3, 4, 6, 14, 15, 16, 18, 21, 22, 24, 25, 26, 27, 28, 29 and 30. c. Unit 11 - Jan 2, 4, 6, and 10. d. Unit 902 - Jan 1, 2, 3, 7, 8, 23 and Feb 5-14. 2. Approximately 1 to 2 patients were run per unit each day control was out of range. 3. The QM confirmed on 3/20/18 at 1:30 pm that corrective action on QC failures was not performed.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Quality Control (QC) records and interview with the Quality Manager (QM), the Laboratory Director failed to ensure that the established QC program was maintained for laboratory services provided in January (Jan) and February (Feb) 2018. The finding includes: 1. There was no review of the Lactate QC

Log Sheet in Jan and Feb. 2. The QM confirmed 3/20/18 at 1:50 pm the LD did not ensure the QC plan was maintained.