

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2108639	(X3) Date Survey Completed 10/13/2021
Name of Provider or Supplier Atlantic Ambulance Corporation	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Biannual Assessment (BA) records and interview with the General Supervisor (GS), the laboratory failed to ensure that all Testing Personnel (TP) who performed Lactate tests participated in the BA from 3/20/18 to the date of survey. The finding includes: 1. A review of all BA events revealed that only one out of one hundred fifty TP performed BA from 3/20/18 to the date of survey. 2. The GS confirmed on 10/13/21 at 2:00 pm that BA events were not rotated between TP.</p>
D5219	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Biannual Assessment (BA) records and interview with the General Supervisor (GS) the Laboratory Director (LD) failed to ensure that the laboratory participated in an accurate split sample assessment for Lactate tests. The findings include: 1. A review of the BA records revealed that the BA was not completed by blind testing of materials with known values. 2. TP performing BA</p>

knew the concentration values of BA material before performing and documenting BA. 3. The GS confirmed on 10/13/21 at 2:20 am that the LD did not ensure the laboratory participated in an accurate split sample assessment for Lactate tests.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on surveyor observation of the Statstrip Lactate Meter Quality Control Log Sheets (SLMQCLS), Manufacturers Package Insert (MPI) interview with the General Supervisor (GS), the laboratory failed to follow MPI for control values from 5/1/21 to 5/31/21. The findings include: 1) SLMQCLS had the Low Range Quality Control (LRQC) documented as 5.4-7.4 mmol/L the MPI had the LRQC as .3-.09 mmol/L. 2) SLMQCLS had the High Range Quality Control (HRQC) documented as .3-.09 mmol /L, the MPI had HRQC as 5.4-7.4 mmol/L 3) The GS confirmed on 10/13/21 at 1:30 pm the MPI was not followed.