

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D2022052	<b>(X3) Date Survey Completed</b> 03/02/2018
<b>Name of Provider or Supplier</b> Ascension St John Medical Center Emergency	<b>Street Address, City, State</b> 1923 S South Utica, Tulsa, OK	
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>D0000</b>	The findings were reviewed with the emergency department and point of care testing site manager, point of care technician, and point of care coordinator during an exit conference performed at the conclusion of the survey.
<b>D5215</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the point of care coordinator and point of care technician, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed 2016 and 2017 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Critical Care Aqueous Blood Gas (i) AQI - A 2017 Event (aa) 1 of 5 TCO2 - AQI -03 (ii) AQI -B 2017 Event (aa) 1 of 5 TCO2 - AQI-10 (iii) AQI - C 2017 Event (aa) 1 of 5 Creatinine - AQI-14 (2) Surveyor #2 further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) The surveyors asked the point of care coordinator and point of care technician if the results had been documented as evaluated. The point of care coordinator and point of care technician reviewed the records and stated the non-graded results had not been documented as reviewed.</p>
<b>D5791</b>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p>

(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. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the point of care coordinator, the laboratory failed to follow their policy for monitoring the effectiveness of their IQCP. Findings include: (1) At the beginning of the survey, the point of care coordinator stated the following to the surveyors: (a) The laboratory performed the following testing using the iSTAT 1 analyzer: (i) Sodium, Potassium, Chloride, BUN, Glucose, Creatinine, CO<sub>2</sub>, Ionized Calcium, Hematocrit, and Hemoglobin testing using the Chem 8+ cartridge and arterial, venous, and capillary specimens (making this a non-waived test system); (ii) pH, pO<sub>2</sub>, pCO<sub>2</sub> testing using the G3+ cartridge; (iii) pH, pC<sub>2</sub>, pCO<sub>2</sub>, and Lactate testing using the CG4+ cartridge; (iv) PT/INR (Prothrombin Time/International Normalized Ratio) testing using the PT/INR cartridge. (b) IQCP's (Individualized Quality Control Plans) had been developed for the test systems. (2) Surveyor #1 reviewed the IQCP (dated as effective 07/13/15 for the Chem 8+ cartridge and dated as effective 08/04/15 for the G3+, CG4+, and PT/INR cartridges). The QA (Quality Assessment) portion of the IQCP stated, "Monitoring of this plan will occur annually at minimum"; (3) Surveyor #1 then reviewed records for the testing. There was no evidence of QA reviews for the IQCP's as follows: (a) Chem 8+ - between the effective date of 07/13/15 and 03/02/17; (b) G3+, CG4+, and PT/INR - between the effective date of 08/04/15 and 03/02/17. (4) Surveyor #1 reviewed the records with the point of care coordinator and asked if annual QA reviews had been performed in 2016. The point of care coordinator stated annual QA reviews had not been performed in 2016.

**D5807**

TEST REPORT  
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on a review of a patient report and interview with the point of care coordinator and point of care technician, the laboratory failed to provide therapeutic reference intervals for INR test results. Findings include: (1) At the beginning of the survey, the point of care coordinator and point of care technician stated to the surveyors PT (Prothrombin Time) and INR (International Normalized Ratio) testing were performed using the Abbott iSTAT 1 analyzer; (2) Surveyor #2 reviewed one PT/INR report for a patient tested on 02/12/18. The report did not include a therapeutic range (range for treatment of venous thrombosis, treatment of pulmonary embolism, prevention of systemic embolism, etc); (3) The report was reviewed with the point of care coordinator and point of care technician, who stated that PT/INR reports did not include a therapeutic range.