Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2022052	(X3) Date Survey Completed 01/08/2020
Name of Provider or Supplier Ascension St John Medical Center Emergency	**Street Address, City, State** 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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed 01/08/2020. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the technical consultant and the point of care technician at the conclusion of the survey.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and the point of care technician, the laboratory failed to review and evaluate proficiency testing results. Findings include: BIASES (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory used 3 i-STAT 1 analyzers and performed the following tests on arterial, venous, and capillary whole blood samples: (a) ABG's (Arterial Blood Gases)(i.e. pH, pO2, pCO2) using the G3+ cartridge (b) Sodium, Potassium, Chloride, Glucose, BUN (Blood Urea Nitrogen), Creatinine, Total CO2, Ionized Calcium, and Hematocrit using the Chem8+ cartridge (2) The surveyor reviewed the 2018 and 2019 Critical Care Aqueous Blood Gas proficiency testing records. The surveyor identified in the Third 2018 Event, the laboratory's results obtained biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program), as follows: (a) pCO2: A Negative bias (the results were below the proficiency testing program's assigned means) was obtained for 2 of the laboratory's 5 results: (i) AQI-13: SDI value of -2.6 (ii) AQI-15: SDI value of -3.9 (b) BUN: A Negative bias was obtained for 1 of the laboratory's 5 results: (i) AQI-12: SDI value of -9.4 (3) The surveyor could not locate documentation that the laboratory identified and investigated the biases for the analytes listed above; (4) The surveyor reviewed the findings with the technical

consultant and the point of care technician, who stated to the surveyor the laboratory failed to identify and investigate the biases obtained for the proficiency testing results listed above. FAILURES (1) At the beginning of the survey, the technical consultant stated to the surveyor, the laboratory performed PT/INR (Prothrombin Time /International Normalized Ratio) testing using the PT/INR cartridge with the i-STAT 1 analyzers; (2) The surveyor reviewed proficiency testing records for 2018 and 2019. The surveyor identified the following: (a) Third 2018 WB Prothrombin Time/INR, I-STAT Event: (i) The laboratory failed the result for 1 of the 5 samples (WP3-15) and obtained a score of 80%; (ii) There was no documentation in the records the laboratory identified the failure and took corrective action (i.e. reviewed quality control, temperature records, calibration, etc.). (3) The surveyor asked the technical consultant if corrective action had been taken for the failure listed above. The technical consultant and the point of care technician reviewed the records and stated to the surveyor the laboratory had not identified the failure and had not taken corrective action for the failed result.