Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2064348	10/29/2020
Name of Provider or Supplier	**Street Address, City, State**	
Ascension St John Medical Center Picu	1923 S 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 on 10/29/2020. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the point of care lead at the conclusion of the survey.
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 a review of records, procedure manual, and interview with the point of care lead, the laboratory failed to ensure the demonstrated reportable ranges were utilized for a new test method. Findings include: (1) On 10/29/2020 at 10:00 am, the point of care lead stated the following to the surveyor: (a) The laboratory performed pH, pCO2, pO2, Sodium, Potassium, Glucose, Ionized Calcium, Hemoglobin, and Hematocrit testing using the CG8+ cartridge and the iSTAT 1 analyzer; (b) A new iSTAT 1 handheld analyzer (serial number 335887) was put into use on 04/05/2019. (2) The surveyor reviewed the performance specification records for the new analyzer and identified the following for the reportable ranges for pO2 and Potassium: (a) pO2 - The laboratory had demonstrated a reportable range of 13-401 mm Hg; (b) Potassium - The laboratory had demonstrated a reportable range of 2.3-7.7 mmol/L. (3) The surveyor then requested documentation to verify the reportable ranges that were being utilized by the laboratory. The following was identified: (a) pO2 - The laboratory was using a reportable range of 15-426 mm Hg; (b) Potassium - The

	laboratory was using a reportable range of 2.0-8.2 mmol/L. (4) The surveyor reviewed the findings with the point of care lead, who stated on 10/29/2020 at 12:30 pm, the laboratory was not using the reportable ranges for pO2 and Potassium that had been demonstrated by the laboratory.