

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2064348	(X3) Date Survey Completed 05/02/2018
Name of Provider or Supplier Ascension St John Medical Center Picu	Street Address, City, State 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 findings were reviewed with the point of care coordinator/technical consultant and the point of care technician at the conclusion of the survey.
D5413	<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 a review of records, manufacturer's instructions, and interview with the point of care coordinator/technical consultant, the laboratory failed to ensure analyzers were stored as required by the manufacturer. Findings include: (1) At the beginning of the survey, the point of care coordinator/technical consultant stated the following to the surveyor: (a) Sodium, Potassium, Ionized Calcium, Glucose, Total CO₂, Hematocrit, Hemoglobin, pH, PCO₂, PO₂ were performed on the Abbott iSTAT analyzer. (2) Later during the survey, the surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer's required the operating temperature be maintained as follows: (a) Abbott iSTAT must be within the range of 18-30 degrees Celsius (3) The surveyor reviewed laboratory temperature records from December 2016 through April 2018 and identified the following for 2 of 17 months: (a) August 2016 - 4 of 31 temperature readings were not documented (days 14,16,18,19); (b) November 2016 - 2 of 30 temperature readings</p>

were not documented (days 25,27). (4) The surveyor reviewed the records with the point of care coordinator/technical consultant who stated the temperatures of the laboratory had not been documented as indicated above.