

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2117092	(X3) Date Survey Completed 02/07/2024
Name of Provider or Supplier Ascension St John Bartlesville	Street Address, City, State 3550 Se Frank Phillips Blvd, Bartlesville, 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 02/08/2024. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with technical consultant #2, the lab support person and the nurse manager at the conclusion of the survey.
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the</p>

laboratory failed to perform calibration verification procedures at least once every six months for the iSTAT test system during the review period of January 2022 through 05/15/2023. Findings include: (1) On 02/07/2024 at 02:00 pm, technical consultant #2 stated the following testing was performed using the iSTAT 1 analyzer (Serial Number 401690): (a) Sodium, Potassium, Chloride, CO2, Ionized Calcium, Glucose, BUN, and Creatinine testing using the Chem 8+ cartridge. (2) A review of records from January 2022 through the current date identified no evidence calibration verification had been performed at least once every six months as follows: (a) Chem 8+ Cartridge - Not performed between 01/01/2022 and the current date. (3) The records were reviewed with technical consultant #2 who stated on 02/07/2024 at 02:00 pm, calibration verification procedures had not been performed every six months as shown above.