Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1077103	02/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ascension St John Clinic Urgent Care-Sand Springs	402 W Morrow Road, Sand Springs, 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 02/09/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the Nurse Manager, technical consultant #2, and the lab support person during an exit conference performed at the conclusion of the survey.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instruction manual, and interview with the technical consultant and nurse manager, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Sysmex XP-300 analyzer during the review period of July 2023 through December 2023. Findings include: (1) On 02/09/2024 at 11:15 am, the technical consultant stated CBC (Complete Blood Count) testing was performed using the Sysmex XP-300 analyzer; (2) A review of the "Sysmex XP-300 Maintenance Checklist" on section 14.8 Appendix of the manufacturer's instructions manual required the following weekly maintenance procedure, "Clean SRV tray". (3) A review of maintenance logs from July 2023 through December 2023 identified maintenance had not been documented as performed for the following: (a) Between 10 /06/2023 and 10/16/2023; (b) Between 09/16/2023 and 09/25/2023; (c) Between 07/18 /2023 and 08/01/2023. (4) The records were reviewed with the technical consultant and nurse manager who stated on 02/09/2024 at 11:15 am, maintenance procedures had not been documented as performed as stated above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

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.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the technical consultant, the 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 the current date. Findings include: (1) On 02/09/2024 at 11:00 am, 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 02/09/2024 at 11:00 am, calibration verification procedures had not been performed every six months as shown above.