Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2085975	(X3) Date Survey Completed 02/20/2024
Name of Provider or Supplier Ascension St John Urgent Care Claremore	**Street Address, City, State** 1910 South Falcon Ave, Claremore, 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 02/20/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #1, laboratory support, and manager physician practice operations during an exit conference performed at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with laboratory support, the laboratory failed to ensure a proficiency testing attestation statement had been signed by the laboratory director or designee for one of five Chemistry Core events reviewed from 2022 through 2023. Findings include: (1) A review of the second and third 2022; and first, second, and third 2023 Chemistry Core proficiency testing records identified the following for one of five events: (a) Second 2023 Event - The attestation statement had not been signed by the laboratory director or designee. (2) The findings were reviewed with laboratory support who stated on 02/20/2024 at 11:35 am, the attestation statement had not been signed by the laboratory director or designee.

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with laboratory support and technical consultant #1, the laboratory failed to follow their written policy for verifying the stated values of control materials prior to implementation for six of nine lot numbers used during the review period of June 2023 through the current date. Findings include: (1) On 02/20/2024 at 10:45 am, laboratory support stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XP-300 analyzer; (b) Three levels of EIGHTCHECK-3WP X-TRA QC (Quality Control) materials were tested each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of the policy titled, "Complete Blood Count (CBC) on the Sysmex XP 300 Automated Hematology Analyzer" under section E titled "Starting a New Lot of Controls" stated, "Parallel test new controls by analyzing the three levels of controls a minimum of twice a day for 5 days prior to the expiration of the previous lot"; (3) A review of records for nine control lot numbers used from June 2023 through the current date identified the laboratory had not followed their policy for six of nine lot numbers as follows: (a) Lot #31650710, 31650711, and 31650712 used from 06/29/2023 through 09/20/2023 - The laboratory had tested the controls three times on 06/27/2023 and three times on 06/28/2023; (b) Lot #32490710, 32490711, and 32490712 used from 09/21/2023 through 12/13/2023 - The laboratory had tested the controls one time on 09/11/2023, two times on 09/12/2023, one time on 09/13 /2023, one time on 09/14/2023, one time on 09/15/2023, one time on 09/16/2023, one time on 09/17/2023, and one time on 09/18/2023. (4) The findings were reviewed with technical consultant #1 who stated 01/04/2024 at 1:30 pm, the laboratory did not follow their written policy.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with laboratory support and physician practice operations manager, the laboratory failed to perform function checks every six months as defined by the manufacturer for the i-STAT 1 analyzer during the review period of May 2022 through the current date. Findings include: (1) On 02/20/2024 at 10:30 am, laboratory support and physician practice operations manager stated laboratory performed sodium, potassium, chloride, ionized calcium, TCO2, BUN (blood urea nitrogen), and creatinine testing using the Chem8+ cartridge and the i-STAT 1 analyzer; (2) A review of the i-STAT 1

	Operator's manual stated in chapter 14-1 (quality control),"Ensure the thermal probe check is performed every 6 months on each handheld reader"; (3) A review of records from 05/01/2022 through the current date identified no evidence the thermal probe checks had been performed prior to 04/24/2023; (4) The findings were reviewed with laboratory support and physician practice operations manager who stated on 02/20 /2024 at 11:55 am, the thermal probe checks had not been performed every six months.
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 laboratory support and physician practice operations manager, the laboratory failed to perform calibration verification procedures at least once every six months for the i-STAT 1 test system during the review period of May 2022 through the current date. Findings include: (1) On 02/20 /2024 at 10:30 am, laboratory support and physician practice operations manager stated laboratory performed sodium, potassium, chloride, ionized calcium, TCO2, BUN (blood urea nitrogen), and creatinine testing using the Chem8+ cartridge and the i-STAT 1 analyzer; (2) A review of records from 05/01/2022 through the current date identified no evidence the calibration verification procedures had been performed prior to 05/17/2023; (4) The records were reviewed with the laboratory support and physician practice operations manager who stated on 02/20/2024 at 11:55 am, the calibration verification procedures had not been performed every six months.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through

	493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with laboratory support and physician practice operations manager, the laboratory failed to perform QC (quality control) as stated in the IQCP (Individualized Quality Control Plans) for i-STAT 1 test system for one of 20 months reviewed. Findings include: (1) On 02/20/2024 at 10:30 am, laboratory support and physician practice operations manager stated the following: (a) The laboratory performed sodium, potassium, chloride, ionized calcium, TCO2, BUN (blood urea nitrogen), and creatinine testing using the Chem8+ cartridge and the i-STAT 1 analyzer; (b) Two levels of QC (quality control) materials were tested monthly according to the IQCP (Individualized Quality Control Plan). (2) A review of QC records from May 2022 through the current date identified no documentation to prove QC had been performed as stated in the QCP (Quality Control Plan) between 06 /01/2022 and 08/01/2022; (3) The records were reviewed with laboratory support and physician practice operations manager who stated on 02/20/2024 at 01:00 pm, QC had not been performed as shown above.