Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1062273	05/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ascension St John Urgent Care - Utica	1717 A South Utica Ave, 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 05/11/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, technical consultant #1, technical consultant #2, nurse supervisor, Utica team lead, and the clinical educator 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 technical consultant #1, the laboratory failed to ensure a proficiency testing attestation statement had been maintained for one of ten events reviewed during 2021, 2022, and to date in 2023. Findings include: (1) A review of 2021, 2022, and 2023 proficiency testing records identified the following for one of ten events: (a) First 2022 Chemistry Core Event - The attestation statement had not been maintained. (2) The findings were reviewed with technical consultant #1 who stated on 05/11/2023 at 11:30 am, the attestation statement had not been maintained as stated above.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with technical consultant #1, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the laboratory on 05/11/2023 at 09:15 am, identified the following expired collection supplies that appeared to be available for use: (a) BD Affirm VPIII Ambient Temperature Transport System - Nine of lot #B01C3 with an expiration date of 04/30/2022 and ten of lot #B01D096M with an expiration date of 07/31/2022; (b) Holigic Aptima Unisex Swab Specimen Collection Kit - 15 of lot #303725HA with an expiration date of 01/31/2023. (2) Interview with technical consultant #1 on 05/11 /2023 at 09:25 am confirmed the collection supplies were used to collect patient samples to send to the reference laboratory for testing and were available for use.
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 and interview with technical consultant #1, the laboratory failed to demonstrate the performance specifications for one of one replacement analyzer. Findings include: (1) On 05/11/2023 at 09:20 am, technical consultant #1 stated the following: (a) The laboratory performed Sodium, Potassium, Chloride, CO2, Ionized Calcium, Glucose, BUN, and Creatinine testing using the iSTAT 1 analyzer and the Chem 8+ cartridge; (b) The laboratory began using iSTAT 1 (serial number 399412) to replace iSTAT 1 (serial number 322246) on 03/06/2023. (2) A review of records in 2023 identified no evidence the performance specifications (i.e., accuracy, precision, reportable range) had been demonstrated for the replacement iSTAT 1 analyzer; (3) The findings were reviewed with technical consultant #1 who stated on 05/11/2023 at 11:40 am, the laboratory had not demonstrated the performance specifications for the replacement analyzer.
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 technical consultant #1, the laboratory failed to perform calibration verification procedures at least once every six months for one of one test system during the review period of July 2021 through the current date. Findings include: (1) On 05/11/2023 at 09:20 am, technical consultant #1 stated the laboratory performed Sodium, Potassium, Chloride, CO2, Ionized Calcium, Glucose, BUN, and Creatinine testing using the iSTAT 1 analyzer and the Chem 8+ cartridge; (2) A review of records from July 2021 through the current date identified no evidence calibration verification had been performed at least once every six months during the review period; (3) The records were reviewed with technical consultant #1 who stated on 05/11/2023 at 12:15 pm, calibration verification procedures had not been performed every six months.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to follow their policy for monitoring the effectiveness of their QCP (Quality Control Plan) for one of one test system during the review period of July 2021 through the current date. Findings include: (1) On 05/11/2023 at 09:20 am, technical consultant #1 stated the following: (a) The laboratory performed Sodium, Potassium, Chloride, CO2, Ionized Calcium, Glucose, BUN, and Creatinine testing using the iSTAT 1 analyzer and the Chem 8+ cartridge; (b) An IQCP (Individualized Quality Control Plans) had been developed for the test system. (2) A review of the IQCP for the test system identified that QA (Quality Assessment) reviews of the QCP (Quality Control Plan) were to be performed on an annual basis; (3) A review of records for the test system from July 2021 through the current date identified no documentation that annual QA reviews had been performed during the review period; (4) The records were reviewed with technical consultant #1 who stated on 05/11/2023

	at 12:18 pm, annual QA reviews had not been documented as performed for the above test system.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for one of ten persons during the review period of July 2021 through the current date. Findings include: (1) A review of personnel records for ten persons performing moderate complexity testing during the review period of July 2021 through the current date identified no evidence an annual competency evaluation had been performed for one of ten testing persons as follows: (a) Testing Person #15 - Not performed during the review period. (2) The records were reviewed with technical consultant stated on 03/27/2023 at 02:04 pm, the annual evaluation had not been performed.