Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D2144257	**(X3) Date Survey Completed** 08/19/2021
Name of Provider or Supplier Ascension St John Clinic Urgent Care - Bixby	**Street Address, City, State** 7333 E 121st St South, Suite 101, Bixby, 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 08/19/2021. The findings were reviewed with technical consultant #1 and the laboratory coordinator at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant
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 instructions, and interview with the laboratory coordinator, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for 6 of 18 months. Findings include: (1) On 08/19/2021 at 10:40 am, the laboratory coordinator stated to the surveyor that CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer; (2) The surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for weekly maintenance were as follows: (a) Clean SRV Tray (3) The surveyor then reviewed maintenance records for 18 months (January 2020 through June 2021). There was no evidence the weekly maintenance had been performed: (a) Between 02/01/2020 and 02/18/2020 (b) Between 12/15/2020 and 01/01/2021 (c) Between 01/20/2021 and 02/01/2021 (d) Between 02/16/2021 and 03/02/2021 (e) Between 03/23/2021 and 04/13/2021 (f) Between 06/01/2021 and 06/15/2021 (4) The surveyor reviewed the records with the laboratory coordinator, who stated on 08/19/2021 at 12:25 pm, the weekly maintenance had not been performed as required.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY

	CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory consultant, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory coordinator, the laboratory failed to ensure the individual who performed the duties and

	responsibilities of the technical consultant, met the qualifications for 3 of 7 competency evaluations performed and 1 of 7 proficiency testing attestation forms. Findings include: COMPETENCY EVALUATION (1) On 08/19/2021, the surveyor reviewed records for 7 persons performing moderate complexity testing in 2019, 2020, and 2021. The records showed the evaluations for 3 of 7 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #3 - The 01/23/2020 and 12/18/2020 evaluations had been performed by the laboratory coordinator (this person had earned a bachelors degree in clinical laboratory science but did not have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible); (b) Testing Person #8 - The 09/27/2019 and 03/21/2021 evaluations had been performed by the laboratory coordinator; (c) Testing Person #25 - The 08/15 /2020 and 02/12/20201 evaluations had been performed by the laboratory coordinator; (2) The surveyor explained to the laboratory coordinator that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The laboratory coordinator stated to the surveyor on 08/19/2021 at 12:17 pm, the evaluations had been performed by an individual who did not meet the years of experience of a technical consultant. PROFICIENCY TESTING ATTESTATION FORMS (1) On 08 /19/2021, the surveyor reviewed 2020 and 2021 proficiency testing records and identified that 1 of 7 attestation statements had been signed by an individual who did not meet the minimal educational qualifications of a technical consultant or designee. The attestation statement had been signed by the laboratory coordinator (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The following attestation statement had been signed by the laboratory coordinator: (a) First 2021 Chemistry Core Event (2) The surveyor reviewed the records with the laboratory coordinator. On 08/19/2021 at 12:25 pm, the laboratory coordinator stated the attestation statement, as indicated above, had been signed and dated by an individual who did not meet the regulatory qualification requirements of a technical consultant or designee.