Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1068377	07/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ascension St John Urgent Care South Memorial	8131 S Memorial Dr, Ste 102, 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 07/14/2021. The findings were reviewed with 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. 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 retain records for at least 2 years for 1 of 18 months. Findings include: (1) On 07/14/20201 at 09:45 am, the laboratory coordinator stated to surveyor #1 CBC (Complete Blood Count) testing was performed using the Sysmex XP-300 analyzer; (2) Surveyor #2 reviewed Levy Jenning records between January 2020 through June 2021 with the following identified: (a) Records between 03/04/2020 and 03/31/2020 were not available (3) Surveyor #2 ask the laboratory coordinator if the records between 03/04/2020 and 03 /31/2020 could be located; (4) The laboratory coordinator stated on 07/14/2021 at 11: 08 am records between 03/04/2020 and 03/31/2020 for CBC testing could not be located. Surveyor #2 could not determine if the records for the above months had been monitored and evaluated for shifts and trends for 1 of 18 months.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing

	performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory coordinator, the laboratory failed to review and evaluate proficiency testing results for 1 of 8 events. Findings include: (1) On 07/14/2021, surveyor #2 reviewed 2019, 2020, and 2021 proficiency testing records (total of 8 events) and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2021 Hematology Event (i) WBC (White Blood Cell) - 3 of 5 results exhibited a positive bias (aa) HSY-03 - SDI of 2.5 (bb) HSY-04 - SDI of 2.5 (cc) HSY-05 - SDI of 2.0 (2) Surveyor #2 further reviewed the records and could not locate documentation verifying the biases had been identified and addressed; (3) Surveyor #2 then reviewed the records with the laboratory coordinator, and asked if the biases had been addressed. The laboratory coordinator stated on 07/14 /2021 at 11:00 am the biases had not been addressed as indicated above.
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 4 of 18 months. Findings include: (1) On 07/14/20201 at 09:45, the laboratory coordinator stated to surveyor #1 that CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer; (2) Surveyor #2 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) Surveyor #2 then reviewed maintenance records for 18 months (January 2020 through June 2021). There was no evidence the weekly maintenance had been performed: (a) Between 04/23/2020 and 05/06/2020 (b) Between 08/08/2020 and 08/20/2020 (c) Between 11/13/2020 and 11/28/2020 (d) Between 05/30/2021 and 06/17/2021 (4) Surveyor #2 reviewed the records with the laboratory coordinator, who stated on 07/14/20201 at 11:03 am, 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 8 competency evaluations performed and signed 3 of 9 proficiency testing attestation forms. Findings include: COMPETENCY EVALUATION (1) On 07/14/20201, surveyor #2 reviewed records for 8 persons performing moderate complexity testing in 2019, 2020, and 2021. The records showed the evaluation for 3 of 8 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #1 - The 12/20/2019 evaluation 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 #13 - The 08/12/2019 and 09/14/2020 evaluations had been performed by the laboratory coordinator; (c) Testing Person #28 - The 06/18 /2020 and 05/21/2021 evaluations had been performed by the laboratory coordinator; (2) Surveyor #2 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 07/14/2021 at 10:58 am, 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 07 /14/20201, surveyor #2 reviewed 2019, 2020, and 2021 proficiency testing records and identified that 3 of 9 attestation statements had been signed by an individual who did not meet the minimal educational qualifications of a technical consultant or designee. The attestation statements 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 statements had been signed by the laboratory coordinator: (a) First 2020 Hematology Event (b) Second 2020 Hematology Event (c) Third 2020 Chemistry Core Event (2) Surveyor #2 reviewed the records with the laboratory coordinator. On 07/14/20201 at 11:01 am, the laboratory coordinator stated the attestation statements, 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.