Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1068377	09/12/2023
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 09/12/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, technical consultant #1, and technical consultant #2 during an exit conference performed at the conclusion of the survey.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant #1, the laboratory failed to follow the manufacturer's storage instructions for three of three cases of Sophia II Antigen test kits. Findings include: (1) On 09/12/2023 at 11:05 am, technical consultant #1 stated that testing was performed using the Sophia II analyzer; (a) On 09/12/2023 at 11:05, observation of the storage room located outside of the laboratory identified the following; (i) One case containing 12 Sophia 2 SARS Antigen test kits, lot #708714. The manufacturer's storage requirement, as stated on the box was 15-30 degrees C (Centigrade); (ii) One case containing 12 boxes of Strep A+ Antigen test kits, lot #708838. The manufacturer's storage requirement, as stated on the box was 15-30 degrees C (Centigrade); (iii) One case containing 12 boxes of Flu A+B Antigen test kits, lot #708494. The manufacturer's storage requirement, as stated on the box was 15-30 degrees C (Centigrade). (2) Interview with technical consultant #1 on 09/12/2023 at 11:05 am confirmed the temperature of the storage room was not being monitored.
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 technical consultant #1, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures during the review period of January 2023 through August 2023. Findings include: (1) On 09/12/2023 at 12:05 am, technical consultant #1 stated CBC (Complete Blood Count) testing was performed using the Sysmex XP-300 analyzer; (2) A review of the manufacturer's maintenance log showed the following required weekly maintenance procedures: (a) "Clean SRV Tray" (3) A review of maintenance logs from January 2023 through August 2023 identified no documentation weekly maintenance had been performed between: (a) 01 /14/2023 and 01/26/2023 (b) 02/21/2023 and 03/10/2023 (c) 03/10/2023 and 03/19 /2023 (d) 04/20/2023 and 04/30/2023 (e) 04/30/2023 and 05/11/2023 (f) 06/01/2023 and 06/14/2023 (g) 07/04/2023 and 07/17/2023 (4) The records were reviewed with technical consultant #1 who stated on 09/12/2023 at 12:10 am, weekly maintenance had not been documented as performed as shown above.
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 technical consultant #1, the laboratory failed to perform function checks as defined by the manufacturer for the iSTAT 1 analyzer during the review period of 12/01/2021 through the current date. Findings include: (1) On 09/12/2023 at 12:40 pm, technical consultant #1 stated the laboratory performed BUN, Sodium, Potassium, Chloride, CO2, Ionized Calcium, Glucose, and Creatinine testing using the Chem 8 + cartridge and the iSTAT 1 analyzer; (2) Review of the i-STAT Operator's manual stated in chapter 14 (quality control),"Check thermal control sensor twice a year"; (3) A review of records from 12/01/2021 through the current date identified no evidence the thermal probe checks had been performed prior to 06/07/2023; (4) The findings were reviewed with technical consultant #1 who stated on 09/12/2023 at 12:40 pm, the thermal probe checks had not been performed twice a year.