Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2085975	04/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ascension St John Urgent Care Claremore	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 04/26/2022. The findings were reviewed with technical consultant #1 and technical consultant #3 at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
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 technical consultant #3, the laboratory failed to review and evaluate proficiency testing results for one of 11 events. Findings include: (1) On 04/26/2022, a review of 2021 and 2022 proficiency testing records revealed the following biases (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) 2021 Second Hematology Event (i) MCH (Mean Corpuscular Hemoglobin) - three of five results exhibited a positive bias (aa) Sample HSY-06 - SDI of 2.0 (bb) Sample HSY-08 - SDI of 3.3 (cc) Sample HSY-09 - SDI of 2.4 (2) There was no evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with technical consultant #3. Technical consultant #3 stated on 04/26/2022 at 12:15 pm the biases had not been addressed.
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 #3, the laboratory failed to follow their policy for monitoring the effectiveness of their IQCP. Findings include: (1) On 04/26/2022 at 10:55 am, technical consultant #3 stated the following to the surveyor: (a) BUN, Chloride, Creatinine, Ionized Calcium, Potassium, Sodium, and TO2 (Chem 8+ cartridge) was performed using the iSTAT analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as approved on 06/30 /2020). The section titled, "Quality Assessment Monitoring" stated, "a. Monitoring of this plan will occur annually at minimum, and reevaluation will be considered whey any changes occur with the following: Testing personnel, environment, specimens, reagents, test system"; (3) The surveyor reviewed records for 2020 and 2021 and could not locate annual QA reviews since the IQCP had been approved on 06/30 /2020; (4) The surveyor reviewed the records with technical consultant #3 and asked if there was documentation of a QA review to evaluate the QCP annually. Technical consultant #3 stated to the surveyor on 04/26/2022 at 12:25 pm a QA review had not been documented as performed annually as stated in the policy.