Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2117092	10/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ascension St John Bartlesville	3550 Se Frank Phillips Blvd, Bartlesville, 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 10/25/19. The findings were reviewed with the laboratory coordinator and technical consultant #1 at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policy and interview with the laboratory coordinator, the laboratory failed to follow their written technical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) During the survey, the surveyor reviewed personnel records for competency assessments performed during 2018 and 2019. There was no evidence competencies had been performed for the technical consultant, based on their job responsibilities; (2) The surveyor asked the laboratory coordinator if a written policy to evaluate the technical consultant based on job responsibilities was available. The technical consultant provided the policy for the surveyor to review titled: "Technical Consultant Competency"; (3) The surveyor reviewed the policy which stated, "The Technical Consultant will be evaluated for competency by the laboratory director on an annual basis. This will be accomplished during one of the regular quarterly meetings of the Laboratory Director to the St. John Urgent Care."; (4) The surveyor asked the laboratory coordinator if competencies based on job responsibilities had been performed during the review period as required by policy. The laboratory coordinator stated annual competencies had not been performed.

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 perform maintenance procedures as required by the manufacturer. Findings include: (1) At the beginning of the survey, the laboratory coordinator stated to the surveyor CBC (Complete Blood Count) testing was performed using the Sysmex XP-300 analyzer; (2) Later during the survey, the surveyor reviewed the manufacturer's weekly maintenance requirements as stated on the manufacturer's maintenance logs: (a) Clean SRV Tray (3) The surveyor then reviewed maintenance records from April 2018 through September 2019. There was no evidence the weekly maintenance had been performed: (a) Between 06/19/18 and 07/01//18 (4) The surveyor reviewed the records with the laboratory coordinator, who stated the weekly maintenance had not been documented as performed as indicated above.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under 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 director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 1 of 5 events. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records. It was identified for 1 of 5 events, the attestation statements had been signed approximately 3 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Hematology Second event of 2018 - The samples had been tested on 07/26/18 and the attestation statement had not been signed by the laboratory director until 10/10/18; (2) The surveyor reviewed the findings with the laboratory coordinator and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.