Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2117092	02/01/2022
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 02/01/2022. The findings were reviewed with 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 and interview with technical consultant #1, the laboratory failed to follow the written technical consultant competency policy based on the job responsibilities as listed in Subpart M for three of three technical consultants. Findings include: (1) The surveyor reviewed personnel records for competency assessments performed during 2020 and 2021. There was no evidence competencies had been performed for technical consultant #1, technical consultant #2, and technical consultant #3 based on job responsibilities in 2020; (2) The surveyor asked technical consultant #1 if a written policy to evaluate the technical consultants, based on job responsibilities, was available and if competencies had been performed during the review period. Technical consultant #1 stated to the surveyor on 02/01 /2022 at 02:10 pm, a policy to evaluate the technical consultants annually based on job responsibilities was written but competencies had not been documented as performed in 2020.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the

	laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to follow the calibration verification procedure for one of two calibrations. Findings include: (1) On 02/01/2022 at 01:45 pm, technical consultant #1 stated the following to the surveyor: (a) BUN, Chloride, Creatinine, Ionized Calcium, Potassium, Sodium, and TO2 (Chem 8+ cartridge) was performed on the iSTAT (serial number 21401690) analyzer; (2) The surveyor reviewed the laboratory's written IQCP procedure and under the section titled, "4. Calibration Verification" it stated, "a. Calibration verification material is available from the manufacturer. Calibration verification will be performed twice per year."; (3) The surveyor reviewed 2021 and 2022 calibration verification records through the day of the survey (02/01/2022) and identified the following: (a) Calibration had not been performed since 06/12/2021. (4) The surveyor reviewed the findings with technical consultant #1. Technical consultant #1 stated on 02/01/2022 at 02:45 pm, the calibration verification procedure had not been followed 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 technical consultant #1, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for two of 24 months. Findings include: (1) On 02/01/2022 at 01:45 pm, technical consultant #1 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. (a) Weekly maintenance (i) Clean SRV Tray (b) Quarterly maintenance (i) Clean SRV (3) The surveyor reviewed maintenance records for 24 months (January 2020 through December 2021) and identified the following: (a) There was no evidence the weekly maintenance had been performed (i) Between 06 /01/2021 and 06/15/2021 (ii) Between 06/15/2021 and 07/06/2021 (b) There was no evidence the quarterly maintenance had been performed (i) Since 07/01/2021 (4) The surveyor reviewed the records with technical consultant #1, who stated on 02/01/2022 at 02:20 pm, the weekly maintenance and quarterly had not been documented as performed as required.
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 #1, the laboratory failed to follow their policy for monitoring the effectiveness of their IQCP. Findings include: (1) On 02/01/2022 at 01:45 pm, technical consultant #1 stated the following to the surveyor: (a) BUN, Chloride, Creatinine, Ionized Calcium, Potassium, Sodium, and TO2 (Chem 8+ cartridge) was performed on the iSTAT (serial number 21401690) 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 #1 and asked if there was documentation of a QA review to evaluate the QCP annually. Technical consultant #1 stated to the surveyor on 02/01 /2022 at 02:10 pm a QA review had not been documented as performed annually as stated in the policy.