Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0915768	01/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ascension St John Jane Phillips	3500 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 01/12/2022. The findings were reviewed with the technical consultant and point of care manager at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
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 the technical consultant, the laboratory failed to follow the manufacturer's instructions for one of four thermal probe checks. Findings include: (1) On 01/12/2022 at 09:45 am, the technical consultant stated to the surveyor: (a) Critical care unit performed ACT (Activated Clotting Time) testing using the iSTAT 1 analyzer (serial number# 389292) and the ACT cartridge; (b) Cath laboratory performed the ACT, PT/INR (Prothrombin Time/International Normalized Ratio), and Sodium, Potassium, Hematocrit testing using the iSTAT 1 analyzer (serial number# 21393155) and ACT cartridge and EG6+ cartridge. (2) The surveyor reviewed the manufacturer's operator's manual for performing the thermal probe check. The instructions stated the following: (a) "A quality check is performed on the thermal probes each time the external Electronic Simulator is used. To complete this check, the surface temperature of the external Electronic Simulator must not fluctuate. If this condition is not met, the thermal probe is not completed. Therefore, i-STAT recommends that the thermal probe check be verified every six months.". (3) The surveyor reviewed 2020 and 2021 thermal probe check records. For one of four records, the surveyor could not locate a

	thermal probe check between 11/13/2019 and 10/26/2020; (4) The surveyor reviewed the findings with the technical consultant. The technical consultant stated on 05/12 /2022 at 02:40 pm the laboratory could not locate a thermal probe check between 11 /13/2019 an 10/26/2020 as indicated above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with the technical consultant the laboratory failed to follow written quality control policies for one of 12 months. Findings include: (1) On 01/12/2022 at 10:10 am, the technical consultant stated the following to the surveyor: (a) ROM (Rupture of Fetal Membrane) testing was performed in the laboratory using the Amnisure ROM test kit; (b) Activated Clotting Time testing was performed in the critical care unit laboratory using the iSTAT1 analyzer (serial number# 389292) and the ACT cartridge; (c) An IQCP (Individualized Quality Control Plan) had been developed for the above test systems. (2) The surveyor reviewed the IQCP that had been developed for each test system. The QCP (Quality Control Plan) portion of the IQCP required 2 levels of external quality control materials be tested once every 30 days; (3) The surveyor reviewed QC (quality control) records for 12 months (January 2021 through December 2021) and identified the laboratory failed to follow the written QCP of performing quality control testing every 30 days. Quality control testing had not been performed as follows: (a) Amnisure ROM (i) Between 06/28/2021 and 08/13/2021 (b) ACT (i) Between 12/29/2020 and 02/01/2021 (4) The findings were reviewed with the technical consultant who stated on 01/12/2022 at 02:55 pm, the laboratory had not performed quality control testing as required by the QCP.