Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2068852	06/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ascension St John Owasso Labor & Delivery	12451 E 100th St North, Owasso, 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 06/12/19. The findings were reviewed with the technical consultant and director of nursing 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 technical consultant, the laboratory failed to have a written technical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records for competency assessments performed during 2017, 2018 and 2019. There was no evidence competencies had been performed for the technical consultant, based on their job responsibilities between 09/07/17 and 04/09/19; (2) The surveyor asked the technical consultant if a written policy to evaluate the technical consultant based on job responsibilities was available and if additional competencies had been peformed; (3) The technical consultant stated a written policy to evaluate the technical consultant based on job responsibilities had not be written and additional competencies had not been performed.
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 their quality control policy. Findings include: (1) At the beginning of the survey, the technical consultant stated the following to the surveyor: (a) The Amnisure ROM (Rupture of Membrane) test kit was used to perform Rupture of Fetal Membrane testing in the laboratory; (b) The AmnioTest Nitrazine Yellow Swab test was used to detect the rupture of amniotic membrane in pregnant women; (c) An IQCP (Individualized Quality Control Plan) had been developed for each test system. (2) The surveyor reviewed the IQCP that had been developed for each test system. The QCP (Quality Control Plan) portion of the IQCP stated "b. Two levels of QC will be analyzed once a month."; (3) The surveyor then reviewed records from October 2017 through October 2018 and identified the laboratory failed to follow their written QCP as follows: (a) AmnioTest (i) Two levels of QC had not been performed between 01/12/18 and 3/02/18 (b) AmniSure Test (i) Two levels of QC had not been performed between 01/25/18 and 03 /13/18 (4) The findings were reviewed with the technical consultant who stated the laboratory had not performed two levels of QC monthly as required by the QCP.