Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0862392	03/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ascension St John Medical Center Labor & Delivery	1923 S Utica, Tulsa, 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 findings were reviewed with the emergency department and point of care testing site manager, point of care technician, and point of care coordinator during an exit conference performed at the concluision of the survey.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the point of care coordinator and point of care technician, the laboratory failed to ensure materials were stored as required. Findings include: (1) At the beginning of the survey, the point of care coordinator stated to the surveyor the following testing was performed in Labor and Delivery: (a) AmniSure ROM (Rupture of [fetal] membranes) test for detecting amniotic fluid in the vaginal discharge of pregnant women; (b) Pro-Lab Diagnostics AmnioTest Nitrazine Yellow Swabs for the detection of amniotic membrane rupture in pregnant women. (2) During the survey, the point of care technician stated to the surveyor test kits and control materials for the Amnisure test were stored in the Supply Office for Labor and Delivery, which was located in a room down the hall from Labor and Delivery; (3) The surveyor then observed the materials stored in the Supply Office. The following were observed: (a) 1 package of Amnisure ROM test positive and negative controls (lot #557017540) with a storage requirement of 2-25 degrees C (Centigrade); (b) 1 package of Amnisure ROM test positive and

	negative controls (lot #557018252) with a storage requirement of 2/25 degrees C; (c) 1 Amnisure ROM test kit (lot #560015) with a storage requirement of 4-25 degrees C; (d) 1 Amnisure ROM test kit (lot #557017109) with a storage requirement of 4-25 degrees C.(4) (4) The surveyor asked the point of care technician if the temperature of the Supply Office was monitored to ensure the materials were being stored as required. The point of care technician stated the temperature was not monitored.
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 point of care coordinator, the laboratory failed to follow written quality control policies. Findings include: (1) At the beginning of the survey, the point of care coordinator stated the following to the surveyor: (a) Pro-Lab Diagnostics AmnioTest Nitrazine Yellow Swabs for the detection of amniotic membrane rupture in pregnant women was performed in Labor and Delivery; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (Individualized Quality Control Plan) that had been developed for the test system. The QCP (Quality Control Plan) portion of the IQCP required 3 levels of external quality control materials be tested once a month and with each new lot or shipment; (3) The surveyor then reviewed quality control records from January 2017 through January 2018 and identified the laboratory failed to follow the written QCP of performing quality control testing once a month. Quality control testing had not been performed between: (a) 05/31/17 and 07/06/17 (4) The findings were reviewed with the point of care coordinator who stated the laboratory had not performed quality control testing as required by the QCP.
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 the point of care coordinator, the laboratory failed to follow their policy for monitoring the effectiveness of their IQCP. Findings include: (1) At the beginning of the survey, the point of care coordinator stated the following to the surveyor: (a) The laboratory performed AmniSure ROM (rupture of fetal membranes) and Pro-Lab Diagnostics AmnioTest Nitrizine Yellow

	Swabs testing; (b) IQCP's (Individualized Quality Control Plans) had been developed for the test systems. (2) The surveyor reviewed the IQCP (dated as effective 10/14 /15). The QA (Quality Assessment) portion of the IQCP stated, "Monitoring of this plan will occur annually at minimum"; (3) The surveyor then reviewed records for the testing. There was no evidence of QA reviews for the IQCP's between the effective date of 10/14/15 and 03/23/17; (4) The surveyor reviewed the records with the point of care coordinator and asked if an annual QA review had been performed in 2016. The point of care coordinator stated an annual QA reviews had not been performed in 2016.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the point of care coordinator, the technical consultant failed to evaluate testing persons performing moderate complexity testing at least annually. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records for 12 persons who performed testing during 2016 and 2017. For 1 of the 12 persons (testing person #1), there was no evidence an annual evaluation had been performed for Amniotest in 2016; (2) The surveyor reviewed the findings with the point of care coordinator and point of care technician. Both stated the annual evaluation had not been performed for Amniotest in 2016 for the testing person.