Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1095189	(X3) Date Survey Completed 08/02/2019
Name of Provider or Supplier Ascension St John Nicu	**Street Address, City, State** 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 laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with point of care testing coordinator #1 and the RN supervisor at the conclusion of the survey.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(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-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with point of care testing coordinator #1, the laboratory failed to ensure quality control testing was rotated among the operators who performed patient testing. Findings include: (1) At the beginning of the survey, point of care testing coordinator #1 stated to the surveyors the nursing staff used two iSTAT 1 analyzers (serial numbers 307002 and 307325) to perform the following testing at the point of care in the NICU (Neonatal Intensive Care) department of the hospital: (a) pH, pCO2, pO2 testing using capillary, arterial, and venous samples and the G3+ cartridge; (b) Sodium, Potassium, Chloride, BUN, Creatinine, Calcium, CO2, Glucose, Hemoglobin, and Hematocrit testing using capillary, arterial, and venous samples and the Chem 8+ cartridge. (2) Point of care testing coordinator #1 stated to the surveyors the laboratory had developed an IQCP (Individualized Quality Control Program) which required three levels of quality control (QC) materials be tested on each analyzer on a monthly basis and before new lot numbers of cartridges were put into use; (3) Surveyor #1 then reviewed QC records for the above testing performed from January 2018 through July 2019. The records indicated QC had been performed by either the RN supervisor or point of care coordinator #1 on the following days for each hand-held analyzer and both cartridges (G3+ and Chem 8+): (a) Serial Number

	307002 - 01/02/18, 02/01/18, 03/01/18, 04/04/18, 05/02/18, 06/01/18, 07/02/18, 08/02/18, 09/06/18, 10/05/18, 11/01/18, 12/03/18, 01/02/19, 02/01/19, 03/01/19, 04/01/19, 05/01/19, 06/03/19, and 07/01/19 (b) Serial Number 307325 - 01/02/18, 02/01/18, 03/01/18, 04/04/18, 05/02/18, 06/01/18, 07/02/18, 08/02/18, 09/06/18, 10/05/18, 11/01/18, 12/04/18, 01/02/19, 02/01/19, 03/01/19, 04/01/19, 05/01/19, 06/03/19, and 07/01/19 (4) Surveyor #1 then reviewed the Laboratory Personnel Report (Form CMS-209) that had been completed by the laboratory for the survey. It listed 33 additional operators performing the testing in the NICU department; (5) Surveyor #1 reviewed the records with the RN supervisor and point of care coordinator #1. Both stated QC testing was routinely performed by the RN supervisor and point of care coordinator #1, and not rotated among the additional testing persons who performed the patient testing.