Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2068160	10/29/2020
Name of Provider or Supplier	**Street Address, City, State**	
Ascensionst John Medical Center Cath Lab /Radiology	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 recertification survey was performed on 10/29/2020. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant and point of care technician at the conclusion of the survey.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with technical consultant, the laboratory failed to ensure an expired test cartridge was not available for use. Findings include: (1) On 10/20/2020 at 11:40 am, the technical consultant stated to surveyor #1 the Radiology department used the iSTAT 1 analyzer to perform Creatinine testing, using the CREA cartridge; (2) The technical consultant escorted surveyor #2 to the Radiology department. Four CREA test cartridges (used to perform creatinine testing) were observed at room temperature (lot #A20122, expiration date of 10/28/2020); (3) Surveyor #2 reviewed the findings with the technical consultant, who stated on 10/29/2020 at 11:50 am, the expired CREA cartridges were available for use.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records, procedure manual, and interview with the technical consultant, the laboratory failed to ensure the performance specification of reportable range had been demonstrated; and failed to ensure the reportable ranges were utilized for new test methods. Findings include: ACT CARTRIDGE (1) On 10/29/2020 at 11: 55 am, the technical consultant stated the following to the surveyor: (a) The laboratory performed ACT (Activated Clotting Time) testing using the ACT cartridge and the iSTAT1 analyzer; (b) A new iSTAT 1 handheld analyzer (serial number 379666) was available for patient use on 06/10/2019. (2) The surveyor reviewed the performance specification records for the new analyzer and identified the laboratory had not demonstrated the reportable range; (3) The surveyor reviewed the records with the technical consultant who stated on 10/20/2020 at 01:10 pm, the reportable range had not been demonstrated as indicated above AVOXIMETER 1000E (1) On 10/29/2020 at 11:50 am, the technical consultant stated the following to surveyor #2: (a) The laboratory performed oxygenated hemoglobin, deoxyhemoglobin, methemoglobin, and carboxyhemoglobin testing used to calculate total hemoglobin using the AVOXimeter 1000E; (b) A new analyzer (serial number 6586) was available for patient use on 11/27/2018. (2) The surveyor reviewed the performance specification records for the new analyzer and identified the following for the reportable ranges for total hemoglobin: (a) The laboratory had demonstrated a reportable range of 4.5 - 25 g /dL. (3) The surveyor then requested documentation to verify the reportable ranges that were being utilized by the laboratory. The following was identified: (a) The laboratory was using a reportable range of 4 - 25 g/dL. (4) The surveyor reviewed the findings with the technical consultant, who stated on 10/29/2020 at 02:15 pm, the laboratory was not using the reportable range for total hemoglobin that had been demonstrated by the laboratory.