Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0994726	12/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Community Hospital	3100 Sw 89th Street, Oklahoma City, 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 11/28/2023 through 12/01/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, laboratory supervisor, laboratory consultant, director of nursing, laboratory manager, and quality assurance specialist during an exit conference performed at the conclusion 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 observation and interview with the laboratory supervisor, the laboratory failed to ensure blood collection tubes were stored as required by the manufacturer, in three of three supply rooms. Findings include: (1) Observation of the supply rooms on 11/28/2023 at 11:45 am, identified the following: (a) Nursing Medical Surgery room - East i. 28 BD Vacutainer serum, lot # 2200887, storage temperature of 4-25 degrees C (Centigrade); ii. 10 BD Vacutainer SST, lot # 3206576, storage temperature of 4-25 degrees C; iii. 24 BD Vacutainer K2 EDTA tubes 7.2mg, lot # 2321385, storage temperature of 4-25 degrees C; iv. 10 BD Vacutainer buffered Na Citrate, 0.109M, 3.2%, lot # 3074232, storage temperature of 4-25 degrees C; v. 15 BD Vacutainer PST Gel and Lithium Heparin 83 Units, lot # 3163707, storage temperature of 4-25 degrees C. (b) Nursing Medical Surgery room - West i. 50 BD Vacutainer PST Gel and Lithium Heparin 83 Units, lot # 3194806, storage temperature of 4-25 degrees C;

	ii. 75 BD Vacutainer K2 EDTA tubes 7.2mg, lot # 3163678, storage temperature of 4-25 degrees C; iii. 19 BD Vacutainer K2 EDTA tubes 10.8mg, lot # 2200157, storage temperature of 4-25 degrees C. (c) Material Management room i. 160 BD Vacutainer Na Fluoride Potassium Oxalate 10mg/8mg, lot # 3163696, storage temperature of 4-25 degrees C; ii. 133 BD Vacutainer SST tubes, lot # 3206576, storage temperature of 4-25 degrees C; iii. 920 BD Vacutainer Gel and Lithium Heparin tubes 83 Units, lot # 3222769, storage temperature of 4-25 degrees C. (2) Interview with the laboratory supervisor on 11/28/2023 at 12:37 pm confirmed the temperatures were not being monitored in the supply rooms.
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 and interview with the laboratory consultant and the laboratory supervisor, the laboratory failed to utilize the demonstrated reportable ranges for one of one new test method. Findings include: (1) On 11/28/2023 at 11:00 am, the laboratory consultant and the laboratory supervisor stated the laboratory began performing glucose, BUN (blood Urea Nitrogen), Chloride, Sodium, and CO2 testing using the CHEM 8+ cartridge and the iSTAT1 analyzer on 03/07/2023; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) Glucose - 30.0 - 587.0 mg/dL (b) BUN - 5.0 -134.0 mg/dL (c) CO2 - 9.0 - 42.0 mmol/L (3) Interview with the laboratory consultant and the laboratory supervisor on 11/28/2023 at 4:23 pm confirmed the laboratory was using the following manufacturer's reportable ranges: (a) Glucose - 20.0 - 700.0 mg/dL (b) BUN - 3.0 -140.0 mg/dL (c) CO2 - 5.0 - 50.0 mmol/L