Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2112538	09/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Community Hospital	9800 Broadway Extension, 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 09/04/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, vice president of clinical services/system CNO, quality assurance manager, laboratory manager, and laboratory supervisor during an exit conference performed at the conclusion of the survey.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, laboratory supervisor, and quality assurance manager, the laboratory failed to ensure proficiency testing samples were tested by personnel who routinely performed patient testing. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor, the following testing was performed at the point of care in the hospital: (a) Blood Gas (pH, pCO2, pO2) and Lactate testing were performed by the nursing and respiratory therapy staff using the iSTAT 1 analyzer and the CG4+ cartridge; (b) Troponin I testing was performed by the nursing staff using the iSTAT 1 analyzer and the cTnI cartridge. (2) The surveyor asked the laboratory manager for clarification of who performed the above testing. The laboratory manager stated the following to the surveyor: (a) There were eleven nursing and respiratory therapy staff members who routinely performed Blood Gas and Lactate testing at the point of care; (b) There were six nursing staff members who routinely performed Troponin I testing at the point of care. (2) The surveyor reviewed proficiency testing records and identified that 9 of 10 events performed in 2018 and 2019 had been tested by the same person (respiratory therapist) or laboratory personnel as follows: (a) Blood Gas and

	Lactate testing (i) AQI-A 2018 Event - 5 of 5 samples (AQ-01, AQ-02, AQ-03, AQ-04, AQ-05) had been tested by respiratory therapist #1; (ii) AQI-B 2018 Event - 5 of 5 samples (AQ-06, AQ-07, AQ-08, AQ-09, AQ-10) had been tested by respiratory therapist #1; (iii) AQI-C 2018 Event - 5 of 5 samples (AQ-11, AQ-12, AQ-13, AQ-14, AQ-15) had been tested by respiratory therapist #1; (iv) AQI-A 2019 Event - (AQ-01, AQ-02, AQ-03, AQ-04, AQ-05) had been tested by respiratory therapist #1; (v) AQI-B 2019 Event - (AQ-06, AQ-07, AQ-08, AQ-09, AQ-10) had been tested by respiratory therapist #1. (b) Troponin I testing (i) PCARM-A 2018 Event - 5 of 5 samples (PCAR-01, PCAR-02, PCAR-03, PCAR-04, PCAR-05) had been tested by laboratory testing person #7; (ii)PCARM-C 2018 Event - 5 of 5 samples (PCAR-11, PCAR-12, PCAR-13, PCAR-14, PCAR-15) had been tested by a previous laboratory testing person; (iii) PCARM-A 2019 Event - 5 of 5 samples (PCAR-01, PCAR-02, PCAR-03, PCAR-04, PCAR-05) had been tested by laboratory testing person #7; (iv) PCARM-B 2019 Event - 5 of 5 samples (PCAR-06, PCAR-07, PCAR-08, PCAR-09, PCAR-10) had been tested by laboratory testing person #4. (3) The surveyor reviewed the findings with the the laboratory manager, laboratory supervisor, and quality assurance manager, who stated the following: (a) Blood Gas and Lactacte proficiency testing had not been rotated among the operators who routinely perform the testing; (b) Tropoinin I proficiency testing had been performed by laboratory staff instead of persons who routinely perform the patient testing at the point of care.
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 manager, laboratory supervisor, and quality assurance manager, the laboratory failed to review and evaluate verification data prior to implementing a new iSTAT analyzer. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor one iSTAT 1 analyzer was used to perform point of care Blood Gas (pH, pCO2, pO2) and Lactate testing using the CG4+ cartridge and Troponin I testing using the cTnI cartridge; (2) The quality assurance manager stated to the surveyor a new iSTAT 1 analyzer was put into use to perform Blood Gas, Lactate, and Tropoinin I testing at the point of care on 03/13/19; (3) The surveyor reviewed the performance specification records for the analyzer. The documentation showed the performance specifications had been demonstrated on 03/06/19, but the data had not been reviewed and signed off as approved by the laboratory until 09/03/19; (4) The records were reviewed with the laboratory supervisor, laboratory manager, and quality assurance manager. All stated the performance specifications had not been signed and dated as approved prior to putting the analyzer into use for patient testing.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)

	(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (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 the laboratory supervisor and laboratory manager, the laboratory failed to define the number and type of quality control testing when implementing an IQCP. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor the following was performed at the point of care by respiratory therapy and nursing staff using the iSTAT 1 analyzer: (a) Troponin I testing using the cTnI test cartridge; (b) pH, pCO2, pO2, and Lactate testing using the CG4+ cartridge. (2) Later during the survey, the laboratory supervisor stated to the surveyor IQCP's (Individualized Quality Control Plan) had been developed for the test systems; (3) The surveyor reviewed the IQCP's. The QCP (Quality Control Plan) portions of the IQCP's did not include the number and type of QC (Quality Control) materials; (4) The surveyor reviewed the QCP with the laboratory supervisor and laboratory manager. Both stated the QCP did not include the number and type of QC testing for the test systems.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with the quality assurance manager and laboratory manager, the laboratory failed to ensure that blood products were stored under appropriate conditions in the Satellite Refrigerator. Findings include: (1) During the survey, the quality assurance manager and laboratory manager stated the following to the surveyor: (a) The blood bank department in the laboratory opened 05/17/19; (b) Units of packed red blood cells, used for patient transfusions, were routinely stored in the laboratory blood bank refrigerator. It was the policy of the laboratory to perform alarm checks on the refrigerator on a monthly basis; (c) The laboratory was staffed Monday through Friday, 6:00 am - 6:30 pm; (d) The hospital acquired an additional blood bank refrigerator on 05/16/19 (small Helmer refrigerator), located in the Med Surg area of the hospital (the laboratory denoted the refrigerator as the Satellite Refrigerator); (e) At 6:00 pm each evening, units of packed red blood cells, crossmatched for specific patients, were transferred to the satellite refrigerator and stored in the event a patient required a transfusion when the laboratory was not

	staffed. (2) The surveyor reviewed alarm check records for 2019. There were no records to substantiate the alarm checks for the Satellite Refrigerator had been performed prior to putting into use and monthly since the refrigerator had been put into use on 05/16/19; (3) The surveyor reviewed the records with the quality assurance manager and laboratory manager and asked if alarm checks had been performed on the Satellite Refrigerator prior to putting into use and monthly since. Both stated alarm checks had not been performed prior to putting into use and had not been performed monthly.
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 laboratory supervisor and laboratory manager, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor the following was performed at the point of care by respiratory therapy and nursing staff using the iSTAT 1 analyzer: (a) Troponin I testing using the cTnI test cartridge; (b) pH, pCO2, pO2, and Lactate testing using the CG4+ cartridge. (2) Later during the survey, the laboratory supervisor stated to the surveyor IQCP's (Individualized Quality Control Plan) had been developed for the test systems; (2) The surveyor reviewed the IQCP's (dated as approved 08/2019). The QA (Quality Assessment) portion of the IQCP's did not include a schedule for evaluating the QCP's (Quality Control Plan) to ensure they continued to provide accurate and reliable results; (3) The surveyor reviewed the records with laboratory supervisor and laboratory manager and asked if there was a policy to address how the laboratory will monitor the IQCP's, including the frequency of the reviews. The laboratory supervisor and laboratory manager stated to the surveyor a policy had not been written.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the quality assurance manager, the laboratory director failed to delegate responsibilities, in writing, to the technical consultant. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor the following was performed at the point of care by respiratory therapy and nursing staff using the iSTAT 1 analyzer: (a)

	Troponin I testing using the cTnI test cartridge; (b) pH, pCO2, pO2, and Lactate testing using the CG4+ cartridge. (2) Later during the survey, the surveyor reviewed proficiency testing records for 2018 and 2019 and identified the attestation statements had been signed as follows: (a) First Event AQI-A 2018 (for Blood Gas (pH, pCO2, pO2) and Lactate testing) had been signed by previous technical consultant #1; (b) First Event PCARM-A 2018 (for Troponin I testing) had been signed by previous technical consultant #1; (c) Second Event AQI-B 2018 had been signed by previous technical consultant #2; (d) Second Event PCARM-B 2018 had been signed by previous technical consultant #2; (e) Third Event AQI-C 2018 had been signed by the laboratory manager (listed as technical consultant #3 on the Laboratory Personnel Report form CMS-209); (f) Third Event PCARM-C 2018 had been signed by the laboratory manager; (g) First Event AQI-A 2019 had been signed by the quality assurance manager (listed as technical consultant #2 on the form CMS-209); (h) First Event PCARM-A 2019 had been signed by the laboratory supervisor (listed as technical consultant #1 on the form CMS-209); (i) Second Event AQI-B 2019 had been signed by the laboratory supervisor; (j) Second Event PCARM-B 2019 had been signed by the laboratory supervisor. (3) The surveyor asked the quality assurance manager if the laboratory director had delegated the technical consultants the above responsibility. The quality assurance manager provided the surveyor with a policy titled, "Technical Consultant Delegation". The surveyor reviewed the delegation form, which provided the laboratory name and location as the sister location located on Southwest 89th Street in Oklahoma City and was not for this laboratory location; (4) The surveyor reviewed the documentation with the quality assurance manager who stated the delegation was not for this laboratory and was specific for the sister laboratory located on Southwest 89th Street. NOTE: The Interpretive Guidelines state "The laboratory director may delegate to a technical consultant, in writing, the responsibilities in: 493.1407(e)(3), (4), (5), (6), (7), (11), (12), and (13)."