Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1035189	04/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Cornerstone Specialty Hospitals Shawnee	1900 Gordon Cooper Dr 2nd Fl Nursing, Shawnee, 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 director of quality measurement, chief executive officer, laboratory consultant, chief operating officer, chief nursing officer, corporate director of quality, laboratory director and lead laboratory technologist during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant
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, and interview with the lead laboratory technologist, the laboratory failed to ensure an analyzer and blood collection tubes were stored as required by the manufacturer. Findings include: (1) At the beginning of the survey, the lead laboratory technologist stated the following to the surveyor: (a) Arterial Blood Gas (G3+ cartridge: pH, pCO2, pO2) testing was performed using the Abbott iSTAT analyzer (serial #326971). (b) BD Vacutainer Lithum Heparin tubes (107 tubes Lot#8345616) were used for arterial blood gas testing. (2) Later during the survey, the surveyor reviewed the manufacturer's environmental requirements for the analyzer and blood collection tubes. The manufacturer's required a room temperature as follows: (a) Abbott iSTAT- range of

	16-30 degrees C (Celsius) (b) BD Vacutainer blood collection tubes - range of 4-25 degrees C (3) The surveyor reviewed laboratory records from January 2018 through December 2018. There was no evidence that the room temperature, where the analyzer and blood collection tubes were maintained, had been monitored at an acceptable range of 16-25 degrees C to accommodate the analyzer and blood collection tubes; (4) The surveyor asked the lead laboratory technologist if the room temperature, where the arterial blood gas analyzer and the blood collection tubes were maintained, was being monitored. The lead laboratory technologist stated the room temperature was being monitored but not documented.
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 laboratory consultant and the lead laboratory technologist, the laboratory failed to follow written their quality control policy. Findings include: (1) At the beginning of the survey, the lead laboratory technologist stated the following to the surveyor: (a) The Abbott iSTAT analyzer was used to performed Arterial Blood Gas testing in the laboratory; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP that had been developed for the test system. The QCP (Quality Control Plan) portion of the IQCP stated "a. Calibration verification (5 levels) will be performed on each meter every 6 months to verify the accuracy of the meter."; (3) The surveyor then reviewed records from January 2017 through July 2018 and identified the laboratory failed to follow their written QCP of performing calibration verification every 6 months. Calibration verification had not been performed between: (a) 12/21/17 and 10/17/18; (4) The findings were reviewed with the laboratory consultant and the lead laboratory technologist who stated the laboratory had not performed calibration verification every 6 months 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, written policies, and interview with the laboratory consultant and the lead laboratory technologist, the laboratory failed to follow their

	written quality assessment monitoring policy. Findings include: (1) At the beginning of the survey, the lead laboratory technologist stated the following to the surveyor: (a) The Abbott iSTAT analyzer was used to performed Arterial Blood Gas testing in the laboratory; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP that had been developed for the test system. The QA (Quality Assessment Monitoring) portion of the IQCP required "Monitoring of this plan will occur annually at minimum, and reevaluation will be considered when any changes occur with the following: Testing Personnel, environment, specimens, reagents, test systems". (3) The surveyor then reviewed QA records from January 2017 through December 2018 and identified the laboratory failed to follow the written QA of performing an annual IQCP review in 2017; (4) The findings were reviewed with the laboratory consultant and the lead laboratory technologist who stated the laboratory had not performed the annual IQCP evaluation as required by the QA.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory consultant and the lead laboratory technologist, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2017, 2018 and 2019 proficiency testing records. It was identified for 2 of 5 events, the attestation statements had been signed approximately 2-7 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Second event of 2018 (identified by the proficiency testing program as AQI-B) - The samples had been tested on 06/27/18 and the attestation statement had not been signed by the laboratory director until 01/31/19; (b) Third event of 2018 (identified by the proficiency testing program as AQI-C) - The samples had been tested on 11/05/18 and the attestation statement had not been signed by the laboratory director until 01/31/19; (2) The surveyor reviewed the findings with the laboratory consultant and the lead laboratory technologist and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory consultant and the lead laboratory technologist, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory consultant and lead laboratory technologist, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Findings include: (1) At the beginning of the survey, the surveyor reviewed records for 5 persons performing moderate complexity testing in 2018 and 2019. The records indicated the evaluations for 4 of 5 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #3 (i) The 12/20/18 evaluation had been performed by the lead laboratory technologist (this person had earned an associate degree in applied

	science). (b) Testing Person #4 (i) The 10/25/18 evaluation had been performed by the lead laboratory technologist. (c) Testing Person #6 (i) The 10/25/18 evaluation had been performed by the lead laboratory technologist. (d) Testing Person #7 (i) The 11 /23/18 evaluation had been performed by the lead laboratory technologist. (2) The surveyor explained to the lead laboratory technologist that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service).