Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1061153	04/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cornerstone Specialty Hospital Of Muskogee	351 S 40th Street, Muskogee, 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 04/15/2021. The findings were reviewed with the laboratory lead, technical consultant, and the chief clinical officer during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory lead and technical consultant, the laboratory failed to follow the manufacturer's instructions for test timing for a blood gas cartridge for 1 of 6 patients. Findings include: (1) On 04/15/2021 at 09:50 am, the laboratory lead stated to the surveyor Arterial Blood Gas testing was performed in the laboratory using the G3+ cartridge and the iSTAT1 analyzer; (2) The surveyor reviewed the manufacturer's instructions under the section titled, "Mixing and Test Timing (time from collection to cartridge fill) for Chemistry and Blood Gas Cartridge". For test timing, the instructions stated, "Samples for pH, PCO2, PO2, TCO3 and ionized calcium should be tested within 10 minutes."; (3) The surveyor randomly reviewed 6 patient records from blood gas testing performed between 10/09/2019 through 02/13/2020. For 1 of 6 records, there was no evidence the laboratory followed the manufacturer's instructions for testing the patient within 10 minutes as follows: (a) Patient testing was performed on 10/24/2019. Although the result time was 01:23 pm, the time of specimen collection was not documented. (4) The surveyor reviewed the record with the technical consultant who stated on 04/15/2021 at 02:00 pm the laboratory could not

	prove the specimen was collected and tested within 10 minutes as required by the manufacturer.
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, written procedure, and interview with the laboratory lead and technical consultant, the laboratory failed to ensure the demonstrated reportable ranges were utilized for 1 of 1 new test method. Findings include: (1) On 04/15/2021 at 11:50 am, the laboratory lead stated to the surveyor, the laboratory began using the replacement iSTAT1 analyzer (Serial #317723) to perform Arterial Blood Gas testing on 01/31/2020; (2) The surveyor reviewed the performance specification records for test system and identified the laboratory had demonstrated a PCO2 reportable range of 18.6 - 98.4 mm Hg; (3) The surveyor then reviewed patient testing records and identified PCO2 results greater than 98.4 mm Hg (the highest value demonstrated by the laboratory) had been reported for 2 of 33 records reviewed: (a) Patient tested on 02/16/2020 - Reported as 101.0 mm Hg (b) Patient tested on 02/17/2020 - Reported as 99.7 mm Hg (4) The surveyor reviewed the records with the technical consultant who stated on 04/15/2021 at 02:05 pm, the laboratory was not utilizing the reportable range that had been demonstrated by the laboratory.
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 lead and the technical consultant, the laboratory failed to follow written quality control policies for 2 of 16 months. Findings include: (1) On 04/15/2021 at 09:50 am, the laboratory lead stated the following to the surveyor: (a) Arterial Blood Gas testing was performed in the laboratory using the G3+ cartridge and the iSTAT1 analyzer (serial number 317723); (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

	required 2 levels of external quality control materials be tested once every 30 days; (3) The surveyor then reviewed QC (quality control) records for 16 months (January 2020 through April 2021) and identified the laboratory failed to follow the written QCP of performing quality control testing every 30 days. Quality control testing had not been performed as follows: (a) Between 07/23/2020 and 09/29/2020 (b) Between 09/29 /2020 and 11/28/2020 (4) The findings were reviewed with the technical consultant who stated on 04/15/2021 at 01:15 pm, the laboratory had not performed quality control testing as required by the QCP.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory lead and the technical consultant, the technical consultant failed to evaluate personnel performing moderate complexity testing at least annually for 2 of 4 testing persons. Findings include: (1) On 04/15/2021 at 09:50 am, the laboratory lead stated to the surveyor Arterial Blood Gas testing was performed in the laboratory using the G3+ cartridge and the iSTAT1 analyzer; (2) The surveyor then reviewed personnel records for 4 persons performing Arterial Blood Gas Testing in the laboratory in 2019, 2020, and 2021. The records showed that annual evaluations had been not been performed as follows: (a) Testing Person #4 - Between 02/18/2018 and 02/14/2020 (b) Testing Person #14 - Between 12 /10/2019 and 02/04/2021 (3) The surveyor reviewed the findings with the technical consultant, who stated on 04/15/2021 at 10:30 am, annual evaluations had not been performed as shown above.