

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1061153	(X3) Date Survey Completed 12/06/2018
Name of Provider or Supplier Cornerstone Specialty Hospital Of Muskogee	Street Address, City, State 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 12/06/18. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the CEO, the CCO/director of nursing, the lead respiratory therapist, and the RML support/technical consultant #2 during an exit conference at the conclusion of the survey.
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, quality control policy, and interview with the CCO /director of nursing and the RML laboratory support/technical consultant #2, the laboratory failed to follow its written quality control plan. Findings include: (1) At the beginning of the survey, the CCO/director of nursing stated to the surveyor the laboratory performed patient arterial and venous blood gas testing (i.e. pH, pO2, and pCO2) using the i-STAT1 analyzer and G3+ test cartridges; (2) Later in the survey, the CCO/director of nursing and the RML laboratory support/technical consultant #2 explained the laboratory utilized an IQCP (Individualized Quality Control Plan) for the testing; (3) The surveyor reviewed the IQCP and identified the QCP (Quality Control Plan) included the following: (a) The electronic simulator check will be performed each week; (b) Two levels of external liquid control materials will be</p>

tested once per month and when a new lot number of test cartridges is received. (4) The surveyor then reviewed QC (Quality Control) records from 05/01/17 through 11/30/18 and identified instances when the laboratory failed to follow its QCP for performance of the electronic simulator checks and testing of the external liquid control materials. The specific findings follow: (a) Weekly electronic simulator checks had not been performed: (i) Between 10/17/17 and 11/01/17 (ii) Between 12/24/17 and 01/02/18 (iii) Between 06/27/18 and 07/20/18 (iv) Between 08/30/18 and 09/13/18 (b) Monthly testing of 2 levels of external liquid control materials had not been performed during October 2018. (5) The surveyor asked the CCO/director of nursing and the RML laboratory support/technical consultant #2 if patient blood gas testing had been performed during the time periods listed above. The CCO/director of nursing and the RML laboratory support/technical consultant #2 searched the testing records and identified the following examples of patient blood gas testing performed when the laboratory failed to follow its QCP for the i-STAT1 analyzer and G3+ test cartridges: (a) Patient #1: Testing performed on 10/17/17 (b) Patient #2: Testing performed on 10/25/17 (c) Patient #3: Testing performed on 10/29/17 (d) Patient #4: Testing performed on 11/01/17 (e) Patient #5: Testing performed on 06/28/18 (f) Patient #6: Testing performed on 06/29/18 (g) Patient #7: Testing performed on 07/08/18 (h) Patient #8: Testing performed on 07/11/18 (i) Patient #9: Testing performed on 07/13/18 (j) Patient #10: Testing performed on 07/20/18 (k) Patient #11: Testing performed on 08/30/18 (l) Patient #12: Testing performed on 08/31/18 (m) Patient #13: Testing performed on 09/02/18 (n) Patient #14: Testing performed on 09/07/18 (o) Patient #15: Testing performed on 09/13/18 (p) Patient #16: Testing performed on 10/29/18 (q) Patient #17: Testing performed on 10/30/18 NOTE: D5445 was cited at the previous recertification survey performed 04/26/17.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the CCO/director of nursing and the RML laboratory support/technical consultant #2, the technical consultant failed to ensure that testing persons performing moderate complexity testing had been evaluated semiannually during the first year of testing. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records for the 13 individuals who performed the moderate complexity arterial and venous blood gas testing (i.e. pH, pO₂, and pCO₂) using the i-STAT1 analyzer and the G3+ test cartridges. The surveyor identified the following: (a) Testing Person #7 - The initial training for this person was completed on 04/28/18. There was no evidence a semiannual evaluation had been performed (due 10/18). (2) The surveyor reviewed the records with the CCO/director of nursing and the RML laboratory support /technical consultant #2 who both stated there were no records available to prove testing person #7 had been evaluated semiannually.