

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0652398	(X3) Date Survey Completed 12/30/2019
Name of Provider or Supplier Fitzgibbon Hospital Resp Care	Street Address, City, State 2305 S 65 Highway, Marshall, MO	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of blood gas proficiency testing (PT) records for 2019 and interview with technical consultant (TC) #1, the laboratory failed to obtain signed attestation documentation from the testing analyst (s) and laboratory director for one of three PT events to show PT samples were tested in the same manner as patient specimens. Findings: 1. No documentation was available to show the laboratory obtained signed attestation from the testing analyst(s) and laboratory director for first blood gas PT event of 2019. 2. Interview with TC #1 on December 30, 2019 at 11:30 AM confirmed the laboratory failed to have attestation documentation for the first PT event of 2019.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on review of the quality assurance program, lack of competency documentation for seven of seven testing personnel for 2018/2019 and interview with technical consultant (TC) #1, the laboratory failed to follow written policies to assess competency of staff performing blood gas testing on the Optimedical CCA-TS2 and AVOXimeter 400 blood gas analyzers. Findings: 1. The "ABG (arterial blood gas) Lab Quality Assurance Program; Staff Competency" policy states, "Newly hired employees and staff therapists will receive training on the ABG (Optimedical CC-TS2) and CO-OX (AVOXimeter 400) machines and be expected to complete an annual competency to maintain proficiency in the use of the machines and drawing and analyzing blood gases." 2. No documentation was available to show newly hired or staff therapists received initial training and annual competency evaluations specific for blood gas testing procedures on the Optimedical CCA-TS2 and AVOXimeter analyzers for 2018 and to date December 30, 2019. 3. Interview with TC # 1 on December 30, 2019 at 11:30 AM confirmed the laboratory failed to follow the written personnel competency policy.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing and interview with technical consultant (TC) #1 the laboratory failed to verify the accuracy of non-regulated blood gas analytes performed on the AVOXimeter and Optimedical CCA-TS2 blood gas analyzers at least twice annually for 2018 and 2019. Findings: 1. No documentation was available to show the laboratory verified the accuracy for the following non-regulated blood gas analytes at least twice annually for 2018 and 2019: AVOXimeter 400 -oxyhemoglobin -carboxyhemoglobin -methemoglobin Optimedical CCA-TS2 -bicarbonate -total co2 - oxygen saturation 2. Interview with TC #1 on December 30, 2019 at 11:30 AM confirmed the laboratory failed to have a system to verify the accuracy of non-regulated blood gas analytes.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of patient blood gas reference intervals (normal values) included on laboratory information system (LIS) test reports, approved normal values included in the approved procedure manual and interview with technical consultant (TC) #1, the laboratory failed to ensure total carbon dioxide (TCO2) normal values as determined by the laboratory were available for interpretation. Findings: 1. The LIS patient test

reports included a TCO2 normal value of (24-30 mEq/L). 2. The approved procedure manual included a TCO2 normal value of (23-29 mEq/L). 3. Interview with TC #1 on December 30, 2019 at 11:30 AM confirmed the differences between TCO2 normal values included on LIS test reports and those included in the approved procedure manual.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on review of 2019 proficiency testing (PT) results and interview with technical consultant (TC) #1, the laboratory director failed to ensure the laboratory followed the approved corrective action plan for PT results found to be unacceptable. Findings: 1. Review of PT results for third event 2019 showed the laboratory received an unacceptable result of 81 mmHg for pCO2 for specimen BG-15. The PT provider stated an expected result of 19-30 mmHg for specimen BG-15 2. The approved correction plan states, "All remedial action must be documented and maintained for two years. 3. No documentation was available to show the laboratory initiated remedial/corrective action for the unacceptable pCO2 result for specimen BG-15. 4. Interview with TC # 1 on December 30, 2019 at 11:30 AM confirmed the laboratory director failed to ensure personnel follow the approved corrective action plan for unacceptable PT results.

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 review of performance/competency evaluations and interview with technical consultant (TC) #1, individuals serving as technical consultants (TC #1 and TC #2) failed to evaluate and document the performance for five of five testing personnel performing moderate complexity blood gas testing on the Optimedical CCA-TS2 nd AVOXimeter 4000 at least annually for 2018 and to date December 30, 2019. Findings: 1. No documentation was available to show TC #1 and/or TC #2 conducted performance/competency evaluations at least annually for five testing personnel performing tests on the AVOXimeter 4000 and the Optimedical CCA-TS2 blood gas analyzers for 2018 and to date December 30, 2019. The evaluations did not include a process to evaluate and document the competency of staff performing test procedures on the blood gas analyzers. 2. Interview with TC #1 on December 30, 2019 at 11:30

AM confirmed TC #1 and/or TC #2 failed to evaluate and document the performance of testing personnel performing tests on the blood gas analyzers for 2018 and to date December 30, 2019.