

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2013331	(X3) Date Survey Completed 06/16/2021
Name of Provider or Supplier Choctaw Regional Medical Center	Street Address, City, State 8613 Ms Hwy 12, Ackerman, MS	
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
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Abbott i-Stat blood gas records from installation on 12/21/20 through 6/11/21, patient blood gas log, lack of documentation of an Individualized Quality Control Plan (IQCP), and interview with testing personnel (TP) #12 (respiratory supervisor) at 4:00 pm on 6/16/21, the blood gas testing staff failed to include two levels of control material each day of patient testing from 12/26/20 through 6/11/21. Approximately 65 patient blood gas results were reported on days when no QC was performed during this time period. Findings include: 1. Review of Abbott i-Stat quality control (QC) records from 12/21/20 through 6/11/21 revealed QC was performed only during lot number/reagent changes or troubleshooting the analyzer. QC was performed on 12/21/20, 1/22/21, 1/25/21, 1/26/21, 3/2/21, 3/24/21, 4/28/21, and 5/26/21. 2. Review of blood gas patient test records from 12/26/20 through 6/11/21 revealed approximately 65 patient blood gas results were reported during this time with no documentation of performance of two levels of QC (QC 1 and QC 3 Precision) each day of patient testing. 3. There was no documentation of establishment of an IQCP, required after 1/1/16, if two levels of control are not included each day of patient testing. 4. Interview with the respiratory supervisor (TP #12) on 6/16/21 at 4:00 pm confirmed no IQCP was written for blood gas testing on the Abbott i-Stat and QC was only performed during lot number change of cartridges or troubleshooting with the analyzer.</p>

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on personnel records available the day of survey (6/16/21), the CMS (Centers for Medicare and Medicaid Services) 209 form and interview with testing personnel (TP) #12 (respiratory supervisor), the laboratory director had not ensured that TP #13 through #17 as listed on the CMS-209 personnel form had received the appropriate training to perform blood gas testing with the Abbott i-Stat analyzer prior to testing patients. Findings Include: 1. Based on lack of training documentation available the day of survey, TP #13 through #17 had no documented training prior to performing blood gas testing on patients beginning on 12/21/2020. All TP had signed an attestation that they had read the Abbott i-Stat Operator's manual, but there was no documentation to indicate TP #13 - #17 had demonstrated adequate performance of the testing procedure. 2. Interview with TP #12 at 4:00 pm on 6/16/21 confirmed that initial training for TP #13 through #17 had not included demonstrating proper performance of the testing procedure to include testing, quality control performance, and maintenance.

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 review of personnel records from 11/7/18 through 6/16/21, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and interview with testing personnel (TP) #12 (respiratory supervisor), the technical consultant (TC) failed to evaluate and document the performance of TP #14 and #16 who perform moderate complexity blood gas testing at least semiannually during the first year of employment. Findings include: 1. Review of the personnel records for TP #14 and #16 revealed there was no semiannual evaluation/competency documented by the technical consultant during the first year of testing patients using a moderate complexity blood gas testing procedure. TP #14 began employment on 11/8/19 and TP #16 began employment on 1/21/20. 2. Interview with TP #12 at 4:00 pm on 6/16/21 confirmed there was no semiannual evaluation/competency performed on TP #14 or #16 during their first year of testing patient samples.

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 testing personnel (TP) records including the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interview with TP #12 as listed on the CMS-209 (respiratory supervisor), the technical consultant (TC) failed to evaluate annually and document the performance of TP #12 through #16 who are responsible for performing moderate complexity blood gas testing. Findings include:

1. Based on personnel records available for review on the day of survey, there were no annual evaluations/competencies performed by the technical consultant on the following TP since the last survey on 11/7/18: a. TP # 12, # 13, #15 - No annual evaluations performed in 2019, 2020 or 2021. b. TP # 14 - No annual evaluations performed in 2020 or 2021. c. TP # 16 - No annual evaluation performed in 2021 2. Interview with TP#12 confirmed that the annual evaluation/competencies for TP #12 through #16 that were available for review had not been documented as performed by the technical consultant.