

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2239259	(X3) Date Survey Completed 07/29/2022
Name of Provider or Supplier Quitman Community Hospital	Street Address, City, State 340 Getwell St, Marks, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Centers of Medicare and Medicaid Services (CMS) database proficiency Casper report, review of laboratory records, and interview with the laboratory manager-testing personnel #1 (TP#1) at 2:30 p.m. on 7/28/22, the laboratory failed to enroll and participate in an HHS approved proficiency testing (PT) program for Hematology (Complete Blood Count) and Chemistry (general chemistry, toxicology and blood gases). Findings Include: 1. Based on review of the CMS Casper report for proficiency testing, the laboratory did not generate a report for any proficiency testing program for the year 2022. 2. Based on review of laboratory documents there was no documentation on the day of survey of enrollment or participation in an HHS approved proficiency program for hematology, general chemistry, toxicology and blood gases for 2022. 3. The laboratory manager (TP#1) confirmed at 2:30 p.m. on 7/28/22 that the laboratory had not enrolled in proficiency testing for hematology, general chemistry, toxicology and blood gas testing.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p>

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the epoc blood gas system standard operating procedure, lack of documentation of calibration verification, and interview with testing personnel (TP) #6-respiratory supervisor at 11:00 a.m. on 7/29/22, the laboratory failed to perform calibration verification on the epoc blood gas system every 6 months for pH, pCO₂ and pO₂. Findings include: 1. Review of the epoc blood gas reader records from installation on 10/27/21 through 7/29/22 revealed calibration verification/linearity was performed on the epoc blood gas system for blood gases (pH, pCO₂, pO₂) on 10/28/21 during installation. 2. The epoc System Standard Operating Procedure states to "Follow the calibration verification procedure to verify accuracy of test results over an extended measurement range of a test. While commercial calibration verification sets contain five levels, verification of the measurement range can be accomplished using lowest, highest and mid levels." 3. A call to the epoc Technical Support line confirmed calibration verification is required by the manufacturer initially and every 6 months on all tests performed. 4. TP #6-respiratory supervisor confirmed in an interview at 11:00 a.m. on 7/29/22 that calibration verification had only been performed on 10/28/21. This exceeds the timeframe required for calibration verification.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(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-- 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.

This STANDARD is not met as evidenced by:

Based on review of the epoc Blood Gas reader records from 10/27/21 through 7/29/22, patient blood gas log, lack of documentation of an Individualized Quality Control

Plan (IQCP), and interview with testing personnel (TP) #6 (respiratory supervisor) at 11:00 a.m. on 7/29/22, the blood gas testing staff failed to include at least two levels of control material each day of patient testing from 11/1/21 through 7/29/22. Approximately nine patient blood gas results were reported when no QC was performed during this time period. Findings include: 1. Review of epoc quality control (QC) records from installation on 10/27/21 through 7/29/22 revealed no QC was performed on days when patients were tested and blood gas results reported. QC was performed only during installation with accuracy and precision verification. 2. Review of blood gas patient test records from 10/27/21 through 7/29/22 revealed nine patient blood gas results were reported during this time with no documentation of performance of two levels of QC (Eurotrol level 1 and Eurotrol level 3). 3. There was no documentation of establishment of an IQCP for the epoc Blood Gas system, required after 1/1/16, if two levels of control are not included each day of patient testing. 4. Interview with TP #6-respiratory supervisor at 11:00 a.m. on 7/29/22 confirmed no IQCP was written for blood gas testing on the epoc system blood gas reader and QC was only performed during installation. There were nine patient samples reported during this time when no QC was performed.