

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0317431	(X3) Date Survey Completed 08/04/2022
Name of Provider or Supplier Baptist Medical Center Leake	Street Address, City, State 1100 Hwy 16 East, Carthage, 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 for Medicare and Medicaid Services (CMS) data system for proficiency testing and the laboratory's proficiency testing (PT) records since the last survey on 11/11/20, the laboratory failed to enroll in an HHS approved proficiency testing program for blood gas testing - pH, pO₂, and pCO₂ - performed on the Radiometer ABL80 Co-Ox Flex analyzer for Event 1 of 2021 and Event 1 of 2022. Findings include: Review of the CMS data system for proficiency testing and the laboratory's PT records since the last survey on 11/11/20 revealed no documentation of the performance of proficiency testing for blood gas testing - pH, pO₂, and pCO₂ - performed on the Radiometer ABL80 Co-Ox Flex analyzer for Event 1 of 2021 and Event 1 of 2022. The laboratory's annual test volume for pH, pO₂, and pCO₂ is 645.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification</p>

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 calibration verification records since the last survey on 11/11/20 and confirmation by Testing Personnel #8 listed on the CMS 209 personnel form, the laboratory failed to perform calibration verification on the Radiometer ABL80 Co-Ox Flex analyzer for blood gas testing - pH, pO₂, and pCO₂ - at least every six months from 2/2/21 until 7/27/22. Findings include: Review of calibration verification records since the last survey on 11/11/20 revealed calibration verification was performed on blood gas testing on the Radiometer ABL80 Co-Ox Flex analyzer on 2/2/21 and 7/27/22. There was no documentation of performance of calibration verification for the sixteen months from 2/2/21 until 7/27/22. Testing Personnel #8 confirmed calibration verification was not performed on blood gas testing from 2/2/21 until 7/27/22.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
 Based on review of temperature logs and external quality control (QC) records, including total hemoglobin calibration records, for the Radiometer ABL80 Co-Ox Flex analyzer since the last survey on 11/11/20, a technical consultant failed to document review of QC records, total hemoglobin calibration records, and temperature logs since 11/11/20, for the evaluation of the competency of the staff. Findings include: Review of temperature logs and external quality control records, including total hemoglobin calibration records, for the Radiometer ABL80 Co-Ox Flex analyzer revealed no documentation of review of these records by a technical consultant since the last survey on 11/11/20.