

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0916400	(X3) Date Survey Completed 05/18/2023
Name of Provider or Supplier Trace Regional Hospital Abg	Street Address, City, State 1002 E Madison St, Houston, 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
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Radiometer ABL 90 Flex Plus blood gas analyzer records including quality control, maintenance and calibration verification records from 10/12/2021 through 5/18/23 and confirmation with testing personnel (TP) #7 (as listed on the Centers for Medicare and Medicaid Services 209 personnel form) at 12:00 p.m. on 5/18/2023, the laboratory failed to document as performed calibration verification on the Radiometer ABL 90 Flex Plus blood gas analyzer every 6 months for pCO₂, pH,</p>

pO₂. One of four required calibration verifications was missed during the timeframe reviewed, and two of three calibration verifications exceeded the six month timeframe required by the manufacturer. Findings include: 1. Calibration verification is required every 6 months on any assay which is calibrated with less than 3 levels of calibration material. The Radiometer ABL 90 Flex Plus blood gas analyzer uses a single calibrator level to perform calibrations. 2. The Radiometer ABL 90 Flex Plus blood gas analyzer records revealed calibration verification was performed on 9/30/2021, 8/31/2022 and on 5/16/2023. 3. TP #7 confirmed in an interview at 12:00 p.m. on 5/18/2023 that calibration verifications on pH, pCO₂ and pO₂ were not performed at the appropriate timeframe or frequency during the period of time reviewed. One of four verifications required was not performed. Two of three calibration verifications performed exceeded the 6 month timeframe required by the manufacturer.