

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D0317612	<b>(X3) Date Survey Completed</b>  01/19/2023
<b>Name of Provider or Supplier</b>  Simpson General Hospital	<b>Street Address, City, State</b>  1842 Simpson Hwy 149, Mendenhall, MS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> 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 chemistry laboratory records from 7/22/2021 through 1/19/2023 and confirmation by the respiratory supervisor/testing personnel (TP) #8 at 2:00 p.m. on 1/19/2023, the laboratory failed to document as performed calibration verification (CVM) on the Siemens Rapid Point 500e blood gas analyzer every 6 months for pCO<sub>2</sub>, pH, pO<sub>2</sub>. Findings include: 1. Calibration verification is required every 6 months on any assay which is calibrated using less than 3 levels of calibration</p>

material. 2. The Siemens Rapid Point 500e Blood Gas Analyzer does not use 3 levels of calibration material during routine calibration. 3. The Siemens Rapid Point 500e procedure indicates the 6 month calibration verification (CVM) will be run every March and September for pH, pCO<sub>2</sub>, and pO<sub>2</sub>. 3. Calibration verification was last performed on the Siemens Rapid Point 500e for pH, pCO<sub>2</sub> and pO<sub>2</sub> during installation on 3/9/2021. 4. The Respiratory supervisor/TP #8 confirmed in an interview at 2:00 p.m. on 1/19/2023 that the CVM (calibration verification) on pH, pCO<sub>2</sub> and pO<sub>2</sub> was not performed every 6 months as stated in the instructions and had not been performed since installation on 3/9/2021.