

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0689771	(X3) Date Survey Completed 06/24/2021
Name of Provider or Supplier North Sunflower Medical Center	Street Address, City, State 840 N Oak Ave, Ruleville, 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 Gem Premier 3500 blood gas records from 1/11/19 through 6/22/21 and confirmation with testing personnel (TP) #13 (respiratory supervisor) as listed on the CMS (Centers for Medicare & Medicaid Services) 209 form at 3:00 pm on 6/24/21, the laboratory failed to perform the calibration verification on the Gem Premier blood gas analyzer every 6 months for pH, pCO2 and pO2. Findings include: 1. Review of the respiratory Gem Premier records for pH, pCO2 and pO2 from 10/25/18</p>

until 6/22/21 revealed that calibration verification using PVP (performance verification product) was performed on 1/24/19, 10/29/20, and 6/22/21. 2. The manufacturer requires calibration verification every 6 months. The time frame of calibration verifications exceeds the manufacturer's requirement. 2. During an interview at 3:00 pm on 6/24/21, TP #13 (respiratory supervisor) confirmed that the (PVP) calibration verification on pH, pCO₂, and pO₂ tests had not been performed every 6 months.