Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0689771	(X3) Date Survey Completed 10/31/2024
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	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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 Gem Premier 3500 blood gas records, and interview with Respiratory Supervisor, testing personnel (TP) #13, as listed on the Centers for Medicare and Medicaid Services (CMS) 209 form, the blood gas testing personnel failed to perform the calibration verification on the Gem Premier blood gas analyzer at least once every 6 months for pH, PCO2 and CO2 for two of four sixth-month calibration verification procedures due. Findings include: 1. Review of the Gem

	Premier records for pH, pCO2 and CO2 from last survey on 2/23/2023 through 10/31 /2024, revealed that a calibration verification using performance verification product (PVP) was not performed on the blood gas tests every 6 months as required by the manufacturer. The Gem Premier records revealed the PVP was performed on 2/24 /2023 and 7/18/2024. Two of the four sixth-month calibration verifications were not performed. 2. Interview with the Respiratory Supervisor (TP #13) on 10/31/2024 at 2: 00 p.m., confirmed the (PVP) calibration verification on pH, PCO2, and CO2 tests had not been performed every 6 months.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of Respiratory testing personnel (TP) records, including the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interview with the Laboratory Manager and Respiratory Supervisor, the Laboratory Director /Technical Consultant (LD/TC) failed to evaluate and document the performance of six of fourteen Respiratory testing personnel at least semiannually during the first year of moderate complexity testing. Findings include: 1. Review of the Respiratory (blood gas) personnel records since the last survey on 2/23/2023 revealed no semiannual evaluation available for the performance of six of fourteen testing personnel. a. TP #11 initial training - 4/24/2023, semiannual evaluation due - 10/2023 b. TP #12 initial training - 4/11/2023, semiannual evaluation due - 10/2023 c. TP #14 initial training - 6 /08/2023, semiannual evaluation due - 12/2023 d. TP #15 initial training - 6/20/2023, semiannual evaluation due - 12/2023 e. TP #17 initial training - 7/26/2023, semiannual evaluation due - 01/2024 f. TP #19 initial training - 6/01/2023, semiannual evaluation due - 12/2023 2. The Respiratory Supervisor confirmed in an interview on 10/31/2023 at 3:00 p.m., there was no semiannual evaluation/competency performed TP #11, TP #12, TP #14, TP #15, TP #17 and TP #19. 3. The LD/TC failed to document semiannual competency evaluations on six of fourteen new blood gas testing personnel.