Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D0453618	10/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Saunders Medical Center	1760 County Road J, Wahoo, NE	

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 laboratory's procedure, review of calibration records, lack of calibration verification records, and an interview with the general supervisor the laboratory failed to perform calibration verification every six months for the electrolytes tested on the chemistry instrument. Findings are: 1. The laboratory's procedure for Dimension EXL 200 indicates "A 3-point cal verification is required every 6 months for Na/K/Cl." 2. Review of calibration records for the chemistry

	instrument in use revealed only two point calibrations for sodium, potassium and chloride. 3. The laboratory failed to provide documentation of calibration verification performed on the electrolytes tested on the chemistry instrument for 2020 and 2021. 4. Interview with the general supervisor on 10/12/2021 at 12:17 PM, confirmed the required calibration verifications for these analytes had not been performed every six months for 2020 and 2021.