Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D0674155	11/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Midwest Ob Gyn Clinic Pc	1410 N 13th Street, Norfolk, 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) (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 calibration records, lack of calibration verification records, and interview with the technical consultant, the laboratory failed to perform calibration verification every 6 months on their chemistry instrument, Vitros 350, on analytes sodium, potassium, and chloride in 2025. 1. Laboratory records revealed starting in 2025 the laboratory began using two calibrators for sodium, potassium, and chloride calibrations. 2. Review of laboratory records revealed the laboratory did not perform calibration verification on analytes sodium, potassium, and chloride in 2025. 3.

	Interview with the technical consultant on 11/4/2025 at 11:38 AM, confirmed the laboratory failed to perform calibration verification on analytes sodium, potassium, and chloride every six months in 2025.