Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 52D0979989	**(X3) Date Survey Completed** 02/19/2025
Name of Provider or Supplier Aurora Health Care Metro Inc - Kenosha South	**Street Address, City, State** 6811 118th Ave, Kenosha, WI	
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 surveyor review of laboratory records and interview the technical consultant, the laboratory did not perform calibration verification every six months for three of five chemistry analytes on the Siemens Xpand chemistry analyzer. Findings include: 1. Review of Siemens Xpand calibration verification records showed calibration verification was performed on calcium and AST on July 6, 2023, January 12, 2024, and July 11, 2024, while the sodium, potassium and chloride were performed on July 6, 2023, January 12, 2024 and August 13, 2024, one month after the due date of July 12, 2024. 2. Interview with the technical consultant on February 19, 2025, at 10:30 AM confirmed the laboratory did not perform calibration

	verification every six months for sodium, potassium and chloride on the Siemens Xpand chemistry analyzer.