Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0884857	02/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Aurora Health Care Metro Inc - Metro East -	3003 W Good Hope Rd, 2nd Floor Oncology, Milwaukee, 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 procedures and calibration verification records and interview with the technical consultant, the laboratory did not perform calibration verification every six months for five of five analytes requiring calibration verification on the Siemens Dimension Analyzer. Findings include: 1. Review of the 'Analytical Measurement Range (AMR) Validation - Siemens Dimension Analyzer' procedure and attachment showed the process for validating the AMR included measurement of a low, middle, and high point of the reportable range for each analyte requiring validation. The 'AMR / Linearity Verification' attachment for the Dimension analyzer

	revealed a verification requirement every six months for Sodium, Potassium, Chloride, Aspartate Aminotransferase (AST) and Calcium. 2. Review of AMR validation records showed the laboratory performed AMR validations on the following dates for each of the five required analytes: AST June 1, 2024 February 4, 2025 Calcium July 1, 2022 February 1, 2023 February 23, 2024 June 13, 2024 August 6, 2024 Sodium, Potassium and Chloride July 1, 2022 January 19, 2023 August 14, 2023 January 31, 2024 August 6, 2024 3. Interview with the technical consultant on February 6, 2025, at 12:15 PM confirmed the laboratory performed the AMR validation procedure to meet the calibration verification requirement at CFR 493.1255 (b). Further interview confirmed the laboratory did not perform calibration verification on the Dimension analyzer for AST, Calcium, Sodium, Potassium and Chloride every six months in 2023 and 2024.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of laboratory records and interview with the administrative Laboratory Director (staff A), the laboratory did not evaluate the relationship between manual and automated white blood cell (WBC) differentials twice annually in two of the last two years. Findings include: 1. Review of records of manual and automated WBC differential comparison testing showed the laboratory completed the last documented comparison in October 2022. No records of comparisons in 2023 or 2024 were available. 2. Interview with Staff A on February 6, 2025, at 11:10 AM confirmed testing personnel did not document WBC differential comparisons in 2023 or 2024. Item 2: Based on surveyor review of laboratory records and interview with the administrative Laboratory Director (staff A), the laboratory did not evaluate the relationship between the two Sysmex Hematology analyzers used to perform complete blood counts (CBC) twice annually in one of the two last years. Findings include: 1. Review of instrument comparison records showed the laboratory compared CBC results from the Sysmex XN1000 and the Sysmex XN450 hematology analyzers in September 2023 and in June and December 2024. No additional records were available from the last two years. 2. Interview with Staff A on February 6, 2025, at 11:10 AM confirmed testing personnel had not completed twice annual comparisons in 2023 between the two hematology analyzers used to perform CBC testing in the laboratory.