Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0976606	02/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Aurora Health Care Metro Inc - Racine	8400 Washington Ave, Ste 203, Racine, 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
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and procedures and interview with a technical consultant, the laboratory did not retain a copy of the discontinued XS1000i procedure including the dates of initial use and discontinuance at this laboratory. Findings include: 1. Review of maintenance records for the Sysmex XS-1000i analyzer showed the laboratory discontinued use of the analyzer for patient testing as of September 22, 2021. 2. Review of the electronic copy of the XS-1000i procedure showed the procedure was retired in May 2022. 3. Interview with a technical consultant (staff B) on February 6, 2023 at 11:40 AM confirmed the laboratory had not retained a copy of the test procedure for the Sysmex XS1000i with the dates of initial use and discontinuance at this laboratory.
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 surveyor review of calibration verification records and interview with testing personnel, the laboratory did not perform calibration verification at least once every six months for sodium, potassium, chloride, calcium and AST (aspartate transaminase) testing on the Dimension EXL analyzer in 2022. Testing personnel did not perform one of the last two calibration verification events on the Dimension EXL within six months of the previous event. Finding include: 1. Review of calibration verification records for the Dimension EXL analyzer showed testing personnel performed calibration verification for sodium, potassium, chloride, calcium and AST on January 17, 2022 and December 21, 2022. No other records of calibration verification in 2022 were available. 2. Interview with testing personnel (staff A) on February 6, 2023, at 2:00 PM confirmed testing personnel did not perform calibration verification on the Dimension EXL within six months of the January 2022 calibration verification event.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and records and interview with testing personnel and a technical consultant, testing personnel did not follow quality control procedures and did not document the corrective actions taken when control results were not acceptable for lactic acid dehydrogenase (LD) testing on the Dimension EXL analyzer on two of two days reviewed when major rule violations occurred. Findings include: 1. Review of the 'Quality Control Guidelines' procedure showed the laboratory identified the 2-2s rule (two consecutive QC results that exceed the mean value by more or less than 2 standard deviations) as a major rule violation. The procedure stated corrective action must be initiated and documented in the LIS or action log and patient results are not to be reported until acceptable QC results are obtained when a major rule violation occurs. 2. Review of laboratory quality control records in the laboratory information system (LIS) showed controls were not acceptable for LD testing on the Dimension EXL analyzer on December 17 and 19, 2022 (the laboratory was closed on Sunday, December 18, 2022). The record in the LIS showed testing personnel tested the LD control, level I, and obtained results that exceeded the mean value of the control by more than two SD (Standard Deviations)

	three times on December 17, 2022. Personnel recorded results at 8:38, 8:51 and 9:01 AM that were above the two SD limit identified in the LIS. Personnel only documentated "result within 3 SD, other level within 2SD" in the LIS. The level 1 control value was more than two SD above the mean when next recorded at 7:39 AM on December 19, 2022. Testing personnel commented in the LIS, "result within 3SD, other level within 2SD". No other corrective actions were documented in the LIS. 3. Review of the corrective action logs for the Dimension EXL showed testing personnel documented no corrective actions on the log on December 17 or 19, 2022. 4. Interview with a technical consultant (staff B) on February 6, 2023 at 1:30 PM confirmed additional corrective actions should have been taken and documented when the control value was repeatedly out of range. 5. Interview with testing personnel (staff A) on February 6, 2023 at 2:00 PM confirmed testing personnel did not document the corrective actions taken when controls were not acceptable.