Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0390360	04/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
A2cl Aurora Health Center - Good Hope Rd	3003 W Good Hope Rd, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records, procedures, and manufacturer instructions and interview with the AP (Anatomic Pathology) Support Supervisor, the laboratory did not define room temperature or humidity requirements for the one of one dermatopathology laboratory room with histology equipment that were consistent with the Leica CM1950 cryostat manufacturer's instructions used in the laboratory. Findings include: 1. Review of maintenance records from the dermatopathology laboratory from the last 12 months showed the logs did not include acceptable humidity and temperature ranges for the dermatopathology laboratory. 2. Review of laboratory procedures showed no evidence of a defined temperature or humidity range for the dermatopathology laboratory. 3. Review of the manufacturer's instructions for the Leica CM1950 cryostat showed the manufacturer defined the acceptable room temperature as between 18 and 35 Celsius (C) with less than 60% relative humidity. 4. Interview with the AP support supervisor (staff C) on April 17, 2023 at 10:15 AM confirmed room temperature and humidity requirements consistent with the manufacturer's requirements had not been defined for the dermatopathology laboratory and confirmed testing personnel used a Leica CM1950 cryostat in the dermatopathology laboratory.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory maintenance records and interview with the technical consultant, testing personnel did not perform and document one of four quarterly LED (light emitting diode) calibrations for the Sysmex CA coagulation analyzer in 2022. 1. Review of the monthly 'Sysmex CA 500/600 Maintenance Checklists' from 2022 showed testing personnel only documented quarterly LED calibrations in February, July, and October. 2. Interview with the technical consultant on April 17, 2023 at 3:15 PM confirmed the LED calibrations were not completed and documented quarterly in 2022 as required by the manufacturer.
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: Item 1: Based on surveyor review of D-dimer calibration records, observation of reagents in the laboratory and interview with testing personnel, the laboratory has not performed a calibration or calibration verification of the D-dimer assay every six months since June 27, 2022. Findings include: 1. Review of D-dimer calibration records showed the last calibration or calibration verification was performed on June 27, 2022 with reagent lot 00875. Review of the 'Coagulation Calibration Curve Documentation' form showed the laboratory required calibration verification every six months if a new reagent lot calibration was not performed during that time. 2. Observation of the Sysmex CA analyzer on April 17, 2023 at 3:15 PM showed testing personnel were using lot 00875 for D-dimer testing at the time of the survey and

	showed the last calibration testing personnel performed was on June 27, 2022. 3. Interview with testing personnel (staff B) on April 17, 2023 at 3:15 PM confirmed the D-dimer assay calibration verification was due in December 2022 and confirmed testing personnel had not performed a calibration or calibration verification since June 27, 2022. Item 2: Review of calibration verification records for the Dimension EXL analyzer and interview with testing personnel and the technical consultant revealed testing personnel had not performed calibration verification every six months as required for sodium, potassium and chloride electrolytes. Testing personnel had not performed three of the last four calibration verification events. Findings include: 1. Review of calibration verification records showed testing personnel performed calibration verification in March 2021 and March of 2022. No calibration verification records were available for September 2021, September 2022 or March 2023. 2. Interview with testing personnel (staff B) and the technical consultant (staff A) on April 17, 2023 at 3:10 PM confirmed testing personnel had not performed calibration verification on the Dimension EXL analyzer three of the last four times the calibration verification was due. This is a repeat deficiency previously cited on February 17, 2015.