Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0908714	10/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Aurora Fond Du Lac Clinic	210 Wisconsin American Dr, Fond Du Lac, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records, phone call with technical consultant, staff A, and interview with a technical consultant, staff B, the laboratory used Siemens Enzyme Verifier for calibration verification on aspartate aminotransferase (AST) past the expiration date. Findings include: 1. Review of calibration verification records for the Siemens Xpand chemistry analyzer showed calibration verification for AST was run on September 3, 2021. Further review showed the expiration date for Siemens Enzyme Verifier, Lot 0GJ361, used for the calibration verification expired on September 1, 2021. 2. Phone call with staff A on October 12, 2021 at 2:30 PM confirmed the Siemens Enzyme Verifier used for the AST calibration verification on September 3, 2021 was expired at time of use. 3. Interview with staff B on October 12, 2021 at 2:35 PM confirmed the laboratory used Siemens Enzyme Verifier for calibration verification on AST past the expiration date.
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 maintenance checklists and interview with the technical consultant, staff B, the laboratory had not documented required maintenance for the Sysmex XS-1000i hematology analyzer for ten of eighteen weekly maintenance requirements and one of four monthly maintenance requirements from May 2020 through August 2020. Findings include: 1. Review of the "Sysmex XS-1000i Maintenance List" showed requirements for daily, weekly, and monthly tasks. Further review showed maintenance was not documented for the following: May 2020: three of five weekly maintenance requirements. June 2020: two of four weekly maintenance requirements. July 2020: two of four weekly maintenance requirements. August 2020: three of five weekly maintenance requirements and monthly maintenance. 5. Interview with the staff B on October 12, 2021 at 12:00 PM confirmed the laboratory had not documented required maintenance for the Sysmex XS-1000i hematology analyzer for ten of eighteen weekly maintenance requirements and one of four monthly maintenance requirements from May 2020 through August 2020.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of performance specification verification and corrective action records and interview with the technical consultant, staff B, the laboratory had not maintained records of corrective action when equipment is not performing as expected for Alcor miniiSED erythrocyte sedimentation rate (ESR) analyzer. Findings include: 1. Review of the performance specification verification records showed the laboratory had performed performance specification verification for the Alcor miniiSED on serial numbers 00103 in June 2020 and 00669 in October 2020. No documentation was found on corrective action logs as to why the replacement analyzer was put in service. 2. Review of corrective action logs showed corrective action documented on the Alcor miniiSED starting on October 7, 2020 with the serial number 00103 documented on the top of the log instead of the current analyzer serial number of 00669. Further review showed no other corrective action documented for problems and actions taken for the Alcor miniiSED when replacement analyzers were required due to the equipment not performing as expected. 3. Interview with the staff B on October 12, 2021 at 1:05 PM confirmed the miniiSED currently in use is serial number 00669 and the laboratory did not complete the performance specification verification for serial number 0655. Further interview confirmed the laboratory had not maintained records of corrective action when equipment is not performing as expected for Alcor miniiSED ESR analyzer.