Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0394447	03/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Kaukauna Clinic Sc	305 E 12th St, Kaukauna, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with a technical consultant, procedures for two of two test systems reviewed did not include the laboratory's reference intervals (normal ranges). Findings include: 1. Review of the procedures for the Eci immunoassay and the Sysmex XP-300 hematology test systems showed no reference ranges or normal values included in the procedures. Review of the procedure manual showed no evidence of a separate procedure that included reference ranges for testing performed on the Eci or Sysmex XP-300 analyzers. 2. Interview with a technical consultant (staff A) on March 9, 2023 at 1:00 PM

	confirmed the laboratory's procedures did not include reference ranges for testing performed on the Eci immunoassay or Sysmex XP-300 hematology analyzer. D5403 was previously cited on March 26, 2021.
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 maintenance logs and interview with a technical consultant, testing personnel did not clean the sample rotor valve on the Sysmex XP-300 hematology analyzer in two of four quarters in 2022. Findings include: 1. Review of maintenance logs for the Sysmex XP-300 hematology analyzer showed the manufacturer requires cleaning the sample rotor valve quarterly or every 4500 samples. Review of the maintenance logs from 2022 showed testing personnel only documented cleaning of the sample rotor valve on May 23 and August 9, 2022. 2. Interview with a technical consultant (staff A) on March 9, 2023 at 1:30 PM confirmed the laboratory did not perform the sample valve cleaning in the first or fourth quarter in 2022.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with a technical consultant, the laboratory did not have procedures requiring documentation of corrective actions taken and did not have a defined mechanism in place to document unacceptable control results and corrective actions taken for five of five analyzers in the laboratory. Findings include: 1. Review of laboratory records showed no documented corrective actions taken when a control run was not acceptable for the Sysmex XP-300 hematology analyzer, CA620 coagulation analyzer, Vitros 4600 and Eci analyzers, or the Triage analyzer. 2. Interview with a technical consultant (staff A) on March 9, 2023 at 11:00 AM confirmed the laboratory did not have a mechanism to document corrective actions taken when control results did not meet the laboratory's established criteria for acceptability.