Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0396363	01/31/2024
Name of Provider or Supplier	**Street Address, City, State**	
Krohn Clinic Ltd	610 W Adams St, Black River Falls, 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) 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 for the Vitros 5600 analyzer in 2022 and 2023 and interview with the technical consultant, the calibration verification process for twelve of twelve analytes performed with MicroWell Range Verifiers did not include a mid-point value. Findings include: 1. Review of calibration verification records showed the laboratory used MicroWell Range Verifiers to perform calibration verification procedures in April and October of 2022 and 2023.

	The records showed personnel tested verifiers near the upper and lower limits of the reportable range for twelve analytes. The records do not show the results of a mid-point value for any of the twelve analytes. 2. Interview with the technical consultant on January 31, 2024, at 12:30 PM confirmed a mid-point value sample was not tested as part of the calibration verification process.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of quality control records and interview with the technical consultant, the laboratory did not include a negative quality control (QC) material for three of nine reagents reported with graded reactivity. Findings include: 1. Review of the 'Krohn Clinic Blood Bank QC Log' showed the routine QC process for blood bank reagents included a negative and graded positive test result for the following reagents: Anti-D, AHG (anti-human globulin), A cells, B cells, Screening Cells I and II. The log showed only graded positive evaluation of Anti-A, Anti-B, and Coombs Check Cells (CCC). 2. Interview with the technical consultant on January 30, 2024, at 3:45 PM confirmed the laboratory's procedures did not ensure personnel tested an expected negative quality control sample with Anti-A, Anti-B, and CCC each day of patient testing.