Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0955865	03/31/2021
Name of Provider or Supplier	**Street Address, City, State**	
Awl Rawson Ave	7400 W Rawson Ave Suite G12, Franklin, 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 Quality Control (QC) records in chemistry, and interview with a technical consultant (Staff A), the laboratory did not assess the control values to identify problems and did not perform calibration verification when shift and trends in QC values were present and not corrected for three of three analytes reviewed. Findings include: 1. Review of QC records for the Beckman DXC chemistry analyzer from April and May 2020 showed shifts above the laboratory's

	established means for three analytes reviewed: Chloride: twenty-five of twenty-six values for QC level one were above the mean in April 2020 and twenty-one of twenty-two values for QC level one were above the mean in May 2020. Lactic Acid Dehydrogenase: twenty-four of twenty-four values for QC level one were above the mean in April 2020. Potassium: twenty-one of twenty-two values for QC level one were above the mean in May 2020. 2. Interview with Staff A on March 31, 2021 at 11: 30 AM, confirmed the laboratory did not assess the control values to identify problems and did not perform calibration verification when shifts and trends in QC values were present and not corrected for three of three analytes reviewed. This is a repeat deficiency from July 25, 2018.