

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D1021288	(X3) Date Survey Completed 12/21/2021
Name of Provider or Supplier A2cl-Aurora Health Center Manitowoc County	Street Address, City, State 5300 Memorial Drive-Attn Lab Supervisor, Two Rivers, 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	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory did not perform and document calibration verification procedures for five chemistry analytes at least once every 6 months twice in the last two years. Findings include: 1. Review of chemistry calibration verification records show calibration verification was performed for Sodium (Na), Potassium (K),</p>

Chloride (Cl), Calcium (Ca) and aspartate aminotransferase (AST) in December 2019, June 11, 2020, and January 14, 2021. 2. Interview with the technical consultant on December 21, 2021 at 1:00 PM confirmed the January 2021 calibration verification was more than six months after the previous occurrence and that calibration verification had not been performed within six months after the January 14, 2021 event.