

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2188285	<b>(X3) Date Survey Completed</b>  01/05/2023
<b>Name of Provider or Supplier</b>  Mchs - Eau Claire Advanced Care At Home	<b>Street Address, City, State</b>  1221 Whipple St, Eau Claire, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> 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 calibration verification records and interview with a technical consultant, staff A, the laboratory did not perform calibration verification every six months on two of two Abbott I-Stat chemistry analyzers for the Chem 8+ and CG4+ cartridges in 2021 and 2022. Finding include: 1. Review of calibration verification records showed calibration verification performed on the Abbott I-Stat chemistry analyzers on March 16, 2021, and December 29, 2022. Further review</p>

showed no evidence of additional calibration verification performed on the analyzers in 2021 and 2022. 2. Interview with the staff A on January 5, 2023, at 9:48 AM confirmed the laboratory did not perform calibration verification every six months on two of two Abbott I-Stat chemistry analyzers for the Chem 8+ and CG4+ cartridges in 2021 and 2022.