

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0396502	<b>(X3) Date Survey Completed</b>  09/03/2025
<b>Name of Provider or Supplier</b>  Bland Clinic-Vmh	<b>Street Address, City, State</b>  100 Melby St, Westby, 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>(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 laboratory record review and interview with the technical consultant, the laboratory did not meet the requirement of performing calibration verification at least once every six months on their i-STAT chemistry analyzer for one of four calibration verifications required in the past two years. Findings include: 1. Review of laboratory records from the past two years revealed the laboratory conducted calibration verification on its i-STAT chemistry analyzer in December 2023, June 2024, and June 2025. Further review of the laboratory records revealed no evidence that the laboratory performed calibration verification on the i-STAT in December 2024 to meet the six-month requirement. 2. Interview with the technical consultant on</p>

September 4, 2025, at 2:20 PM, confirmed the laboratory did not perform i-STAT calibration verification in December 2024 to meet the six-month calibration verification requirement.