

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2181359	(X3) Date Survey Completed 03/05/2025
Name of Provider or Supplier Thedacare Family Medicine Gateway	Street Address, City, State 3925 N Gateway Drive, Appleton, 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>(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 a technical supervisor, staff A, the laboratory did not perform calibration verification every six months on one of one Beckman Coulter DxH520 Hematology analyzers. Findings include: 1. Review of Beckman Coulter DxH520 hematology analyzer calibration verification records showed calibration verification was performed December 23, 2023, June 18, 2024, and January 8, 2025 Further review showed no additional calibration verification when due on December 18, 2024. 2. Interview with staff A on March 5, 2025, at 12:20 PM confirmed the laboratory was testing patients on the hematology analyzer between December 18, 2024, and January 8, 2025. Further interviewed</p>

confirmed the laboratory did not perform calibration verification every six months on the Beckman Coulter DxH520 hematology analyzer.