

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405647	(X3) Date Survey Completed 06/03/2021
Name of Provider or Supplier Sanford Wheaton Medical Center	Street Address, City, State 401 12th Street North, Wheaton, MN	
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 observation, document review, and interview with laboratory personnel, the laboratory failed to perform calibration verification on a Hematology analyzer at least once every 6 months in 2019, 2020, and 2021. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 06/03/21. 2. A Stago STA Satellite hematology analyzer was observed as present and available for use during the</p>

tour. The GS indicated the laboratory began D-Dimer testing using this analyzer on 01/22/19. 3. D-Dimer calibration verification was required every six months as indicated in the D-Dimer - STA Stago R Max, STA Compact Max, and STA Satellite procedure found in the electronic procedure software, PolicyTech. 4. D-Dimer calibration verification documentation was not found in laboratory records. The laboratory was unable to provide calibration verification documentation upon request. 5. Laboratory records indicated 138 patient samples (Pt) received D-Dimer testing between 06/22/19 and date of survey, 06/03/21. See below. Time frame Pt tested 06/22/19-12/31/19 9 01/01/20-12/31/20 64 01/01/21-06/03/21 65 6. In an interview at 1:25 p.m. on 06/03/21, the GS confirmed the above finding.