

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0693572	(X3) Date Survey Completed 08/09/2022
Name of Provider or Supplier Lakeshore Medical Clinic, Llc D/B/A Aurora Health	Street Address, City, State 2000 E Layton Ave Ste 120, Saint Francis, 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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for 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 ensure testing personnel performed a calibration for the Innovance D dimer assay within six months after the November 29, 2021 calibration as required by the manufacturer. The laboratory used the expired calibration settings when they tested twenty-eight patients between June 1 and August 9, 2022. Findings include: 1. Review of calibration records for the Innovance D dimer assay on the Sysmex CA-660 coagulation analyzer showed testing personnel performed a calibration on November 29, 2021. The laboratory had not documented a calibration since November 29, 2021. 2. Interview with the technical consultant on August 9, 2022 at 3:40 PM confirmed the manufacturer requires calibration for the Innovance D dimer assay every six months and confirmed the laboratory did not calibrate the assay within six months after the November 29, 2021 calibration. Further interview revealed the laboratory used the expired calibration for testing sixteen patients in June, nine in July, and three in August 2022.</p>