

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0406174	(X3) Date Survey Completed 12/29/2025
Name of Provider or Supplier Lakewood Health System - Browerville Clinic	Street Address, City, State 30535 241st Ave, Browerville, 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
D0000	. The Lakewood Health System - Browerville Clinic laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on December 23, 2025. The following standard-level deficiency was cited: 493.1254 Maintenance and function checks .
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:</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 and document function checks (calibration) for 2 of 2 temperature sensors in 2025. Findings are as follows: 1. The laboratory performed Hematology and Toxicology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 12:35 p.m. on 12/23/25. 2. The following temperature sensors were observed in use on 12/23/25: Smart Sense Temperature Sensor ID/Serial #: 28CC720B0E0000 Calibration Expiration Date: 06/19/25 Location: Refrigerator Use: Quality control material and patient specimen storage temperature monitoring Smart Sense Temperature Sensor ID/Serial #: 2823C70A0E0000 Calibration Expiration Date: 06/19/25 Location: Freezer Use: Patient specimen storage temperature monitoring 3. Function check documentation for this equipment was not found in laboratory records. The laboratory was unable to provide current certificates of calibration or function check documentation for the</p>

equipment upon request. 4. A procedure defining temperature sensor function check activities and frequency was not found during review of laboratory policies and procedures. The TC indicated the temperature sensors should be replaced when the calibration certificates expired. 5. In an interview at 3:35 p.m. on 12/23/25, the TC confirmed the above finding and stated the laboratory failed to replace the Smart Sense Temperature Sensors prior to calibration certificate expiration . .