

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1003569	(X3) Date Survey Completed 06/11/2026
Name of Provider or Supplier Specialty Care, Inc Abbott Northwestern	Street Address, City, State 800 East 28th Street, Minneapolis, 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	A validation survey was completed 06/11/2026, and a standard level deficiency was cited.
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's temperature documents, direct observation and an interview with staff, the laboratory failed to document corrective action when the storage room temperature exceeded the manufacturer's and the laboratory's acceptable range for 2 of 51 days reviewed (April-June 2025) a. A review of the laboratory's storage room temperature charts revealed: 1. "If the temperature exceeds 10-25 C [degrees Celsius] make the necessary temperature adjustments and call Lab manager. Do not use the affected cartridges until the Quality Control has been verified." 2. "QA Room Temperature Limits 10-25 C 50-77 F [degrees Fahrenheit]". 3. June 16, 2025; Temp Min/max= 10/30. June 17, 2025; Temp Min/max=9/30. The max temperature exceeded the laboratory's define range by 5C (degrees Celsius). b. On 06/11/2026 at 9: 35 AM an observation of the storage room revealed the following items (sampling) stored in the room: 1. 4 boxes Medtronic Heparin Assay Cartridges Red; Manufacturers storage requirements: Room Temperature 10C -25C; lot number: 233818364; Expiration Date: 07/13/2026. c. During an interview on 06/11/2026 at 11: 15 AM, Technical Consultant #1 and Testing Person #11 (as listed on the CMS-209) confirmed quality control was not performed or documented, and no corrective actions were documented.</p>