

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0389833	(X3) Date Survey Completed 02/03/2025
Name of Provider or Supplier West Suburban Center For Arthritis	Street Address, City, State 601 N Barker Rd Ste 110, Brookfield, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's temperature logs and procedures, and interview with the technical consultant, the laboratory did not define an acceptable temperature range that was consistent with the manufacturer's acceptable range for three of three Abbott Architect chemistry reagents stored at room temperature. Findings include: 1. Review of laboratory's temperature logs showed no established room temperature range for the main laboratory area where reagents and supplies were stored. 2. Review of laboratory procedures showed albumin, calcium, and creatinine testing reagents for the Abbott Architect chemistry analyzer were to be stored at 15-30 C. 3. Interview with the technical consultant on February 3, 2025, at 3: 00 PM confirmed the laboratory had not defined an acceptable range for reagents stored at room temperature.</p>