

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D2202217	(X3) Date Survey Completed 10/01/2021
Name of Provider or Supplier Children's Nebraska Outpatient Surgery Center	Street Address, City, State 110 North 175th Street Suite 1600, Omaha, NE	
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>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: (1) Water quality. (2) Temperature. (3) Humidity. (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 review of manufacturer's cartridge stability, lack of documentation, and interview with the technical consultant the laboratory failed to monitor and document the temperature of the location where testing cartridges are stored. Findings are: 1. Review of manufacturer's cartridge stability revealed cartridges should be stored at 15 to 30 degrees Celsius. 2. No documentation of room temperature recordings could be presented at time of survey for the days of testing performed on 7/12/2021 and 1/28/2021. 3. Interview with the technical consultant on 9/24/2021 at 12 PM confirmed the laboratory had no documentation of room temperature recorded.</p>