

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0304677	(X3) Date Survey Completed 03/09/2023
Name of Provider or Supplier Tanner Medical Center East Alabama	Street Address, City, State 1032 Main Street South, Wedowee, AL	
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 a review of the Chemistry freezer records and an interview with Testing Personnel #1, the Laboratory failed to ensure freezer temperatures were within the laboratory's written acceptable limits. Freezer temperature were noted above acceptable ranges for 215 days from 2021 to 2022. The findings include: 1. A review of the Chemistry freezer temperature records revealed the freezer was above the laboratory's written policy of -20 to -25 degrees Celsius for a total of 215 days as follows: A) September through December 2021; 55 days B) January and February, April through November 2022; 160 days 2. During an interview on March 8, 2023, at 3:45 PM, Testing Personnel #1 confirmed the above findings.</p>