Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 44D0234042	**(X3) Date Survey Completed** 06/21/2019
Name of Provider or Supplier Tennessee Urology Associates Pllc	**Street Address, City, State** 800 Oak Ridge Turnpike, Suite A-101, Oak Ridge, TN	
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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (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. This STANDARD is not met as evidenced by: ========== Based on review of temperature logs from July to December 2018 for the oven used in Molecular testing and the Refrigerator used for storage of Clinical Laboratory reagents and interviews with the Molecular Testing Supervisor and the Clinical Laboratory Supervisor, the laboratory failed to maintain temperatures consistent with the procedural and manufacturer's requirements. The findings include: 1. Review of temperature logs for the oven used in Molecular Testing revealed 12 days between 7/27/18 and 8/16/18 out of range low and 10 days between 9/2/18 and 10/21/18 out of range high. 2. Review of temperature logs for the Clinical Laboratory Refrigerator revealed 26 days between 8/1/18 and 12 /06/18 out of range low. 3. Interviews with the Molecular Testing Supervisor and the Clinical Laboratory Supervisor at approximately 3:00 p.m. June 20th, 2019 confirmed the laboratory failed to maintain temperatures consistant with the procedural and manufacurer's requirements from July to December 2018. ==========