

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1018117	(X3) Date Survey Completed 05/11/2021
Name of Provider or Supplier Advanced Urology Associates Of Florida, Pa	Street Address, City, State 1986 35th Ave, Vero Beach, FL	
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 recertification survey was conducted on May 11, 2021. Advanced Urology Associates of Florida clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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 record review and interview, the laboratory failed to record the temperatures and humidity of the rooms where testing was performed from 05/11/2019 to 05/11/2021. Findings: 1. Review of quality control documents showed there were no logs recording the temperature and humidity of the room where testing was performed in the laboratory. Review of the Architect System Operations Manual for the chemistry instrument noted the room temp should be 15 to 30 degrees Celsius (C) (59 to 86 degrees Fahrenheit (F)) and the humidity of the room should be 10% to 85% (percent). Review of the Tissue Tek Vacuum Infiltration Processor Operations Manual for the histology instrument Operations Manual noted the room temperature should be 10 to 35 degrees C (50 - 95 degrees F). 2. Review of the Daily Temperature Chart for the PCR (Polymerase Chain Reaction) room showed the humidity of the room was not recorded. Review of the Applied Biosystems QuantStudio 12K Flex Real-Time PCR System user guide noted the humidity of the room should be 20% to 80%. Review of the King Fisher Duo Prone Brief Users Manual noted the humidity of</p>

the room should be "maximum relative humidity of 80%. for temperatures up to 31 degrees C decreasing linearly to 50% relative humidity at 40 degrees C." 3. Review of quality control documents showed there were no logs recording the temperature of the room in the embedding/draw station room. Review of the Leica EG1160 Paraffin Embedding Center Operations Manual for the histology instrument noted the room temperature should be 18 to 35 degrees C. On 04/07/21 at 1:40 PM, the General Supervisor stated they did not record the temperature and humidity in the main lab, the humidity in the PCR room and the temperature in the embedding/draw station room.