Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0264812	10/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Urological Associates Of Savannah, Pc	230 East Derenne Avenue, Savannah, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on October 16, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
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 observation by the surveyor during a tour of the laboratory, review of temperature requirements posted by the manufacturer on boxes of controls used in testing of testosterone, free PSA and total PSA levels on the Beckman Access 2 endocrinology analyzer, review of temperature logs for the freezer where controls are stored and staff interview, the laboratory failed to store controls at the temperature required by the manufacturer. Findings include: 1. Observation by the surveyor during a tour of the laboratory revealed BioRad Liquicheck Controls are stored in a frost free freezer. 2. Observation by the surveyor also revealed the storage temperature posted on the control vials by the manufacturer is negative 20 to negative 70 degrees centigrade. 3. Review of temperature logs for the freezer where controls are stored revealed the temperature is outside the acceptable range on 20 of 20 days in September 2018, 19 of 22 days in August 2018 and 10 of 21 days in May 2018. 4. Interview with technical consultant/laboratory supervisor (see CMS 209) in the

	conference room at approximately 12:30 pm confirmed the manufacturer's acceptable temperature range is negative 20 to negative 70 degrees centigrade and the temperature of the freezer where controls are stored does not maintain the acceptable range.