Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0303287	06/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Urology Specialists, Pc	4704 Whitesburg Drive Suite 100, Huntsville, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the Procedure Manual for moderate complexity testing and an interview with the Office Manager, the current Laboratory Director failed to review and approve the Procedure Manual for moderate complexity testing upon starting as the Laboratory Director. This was noted from February 2021 when the change in the Laboratory Director occurred to the date of the current survey (06/22/2022). The findings include: 1. A review of electronic CMS records revealed the facility submitted a CMS-116 application on 1/29/2021 for a change in the Laboratory Director, with an effective date of 2/18/2021. 2. A review of the Procedure Manual for moderate complexity testing revealed the former Laboratory Director reviewed and signed the manual on 12/04/2020 and 11/30/2021. There was no documentation (by evidence of a signature and date) the current Laboratory Director had reviewed and approved the moderate complexity testing procedures. 3. During an interview on 06/22/2022 at 12:15 PM, the Office Manager confirmed the former Laboratory Director reviewed the Procedure Manual for moderate complexity testing annually. The Office Manager further stated they were under the impression the current Laboratory Director was only responsible for the high complexity testing [Polymerase Chain Reaction (PCR)].
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 a review of environmental logs and an interview with the General Supervisor, the laboratory failed to document the actual temperatures and humidity in the Polymerase Chain Reaction (PCR) Laboratory. This was noted from March 2021 (when patient testing started) to June 2022 (current survey). The findings include: 1. A review of environmental logs revealed the room temperature (20 - 25 degrees Celsius), humidity (20 - 80%), and freezer temperature (-10 to -30 degrees Celsius) had check mark each day reviewed. The laboratory failed to record the daily values for temperatures and humidity. 2. During an interview on 06/22/2022 at 1:15 PM, the General Supervisor confirmed the values were not being documented; the staff documented reviews with a check mark only.