Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0303287	07/02/2026
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
D0000	
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 the freezer temperature logs, and an interview with the Technical Consultant (TC), the Laboratory failed to document temperatures for the freezer in which the Chemistry QC was stored for 5 out of 18 days in October 2025. The findings include: 1. Based on a review of the freezer temperature logs, Testing personnel (TP) did not record the freezer temperature for 5 out of 18 days in October 2025. 2. TC confirmed the above findings during the exit interview on 7/2/26 at 1: 00pm.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that

	perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the humidity records, and an interview with the Technical consultant (TC), the laboratory failed to document corrective actions for out of range humidity for 14 out of 43 days in June and July 2024. The findings include: 1. Based on a review of the humidity records, the humidity was out of range for the following: a. 11 out of 20 days in June 2024, no corrective action documented. b. 3 out of 23 days in July 2024, no corrective action documented. 2. TC confirmed the above findings during the exit interview on 7/2/26 at 1:00pm.