Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0688158	02/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Tennessee Valley Urology Center Pc	400 Berywood Trail Nw, Suite B, Cleveland, 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with the laboratory's lead testing person, the laboratory failed to provide specimen labeling instructions for urine and semen specimen collection from May 2022 to February 13, 2023. The findings include: 1. Review of the laboratory's collection procedure manual for urine and semen specimen collection failed to provide specimen labeling instructions for urine and semen specimen collection. 2. Interview with the laboratory's lead testing person on 02/13/23 at 10:45 am confirmed the laboratory failed to provide specimen labeling instructions in the laboratory's collection procedure manual for urine and semen specimen collection from May 2022 (when new procedure was adopted) to February 13, 2023.
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 direct observation of the laboratory, review of the laboratory's environmental logs, and interview with the laboratory's lead testing person, the laboratory failed to monitor laboratory humidity for 25 of 25 months from January 2021 through February 13, 2023. The findings include: 1. Observation of the laboratory on 2.13.2.2023 at 10:30 a.m. revealed a thermometer/hygrometer on the laboratory counter. 2. Review of the laboratory's environmental logs revealed no documentation of humidity from January 2021 through February 13, 2023. 3. Interview on 2.13.2023 at 10:45 a.m. with the laboratory's lead testing person confirmed the laboratory failed to monitor laboratory humidity for 25 of 25 months from January 2021 through February 13, 2023.