Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0964598	07/15/2026
Name of Provider or Supplier	**Street Address, City, State**	
Urology Of Virginia, , Pllc	225 Clearfield Avenue, Virginia Beach, VA	

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	An announced CLIA recertification survey was conducted at Urology of Virginia on July 14-15, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Urology of Virginia was not in compliance with the applicable Conditions and Standards under 42 CFR part 493 CLIA Regulations. Specific deficiencies are as follows:
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: A. Based on the review of laboratory policies and procedures, equipment records, and interviews, the laboratory failed to follow their established policy to monitor equipment temperatures for molecular EpiCheck testing for ten (10) months of the 10 months reviewed. Review timeframe 8/01/25 through 6/30/26. The findings include: 1. During an entrance interview with the Technical Consultant (TC) on 7/14/26 at 10: 10am, the TC stated that in 2025 the laboratory added the molecular Bladder EpiCheck test for random urine samples of previously diagnosed bladder cancer patients. 2. Review of the laboratory's PCR-EpiCheck Policies and Procedures manual revealed a director approved qPCR Bladder EpiCheck test procedure that included the following equipment maintained at the specified temperatures indicated below: Heat

	Block at 37C and 65C, Incubator at 37C, and Thermal Probe at 95C and 60C. 3. Review of the laboratory's PCR Lab Maintenance logs, PCR Bladder EpiCheck Equipment records/repair manual, and PCR Equipment Binders #1 and #2 for the 10 months of 8/01/25 through 6/30/26 revealed a lack of documented temperature monitoring for the equipment listed above. 4. In an interview with the primary testing personnel on 7/14/26 at 04:40pm, it was confirmed that temperatures for the heat block, incubator, and probe were not monitored. B. Based on review of laboratory policy and procedures, Pathology logs and maintenance records, and an interview, the laboratory failed to document monitoring of pathology termperatures and humidity on six (6) days during the twenty-one (21) months reviewed. Review timeframe 9/01/24 - 6/30/26. Findings include: 1. Review of laboratory policy and procedures revealed a Pathology Procedure that included daily monitoring of temperatures and humidity. 2. Review of Pathology Daily Quality Control (QC) logs, Pathology Record of Daily maintenance and temperature checks revealed no temperature and humidity documentation on the following 6 days of patient testing: 4/01/25, 4/07/25, 4/25/25, 5 /7/25, 12/20/25, and 3/30/26. 3. In an exit interview on 7/15/26 at 4:30pm with the Technical Supervisor and Laboratory Director, the findings were confirmed.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedures, Pathology logs and maintenance records, and an interview, the laboratory failed to document maintenance of pathology equipment on nine (9) days during the twenty-one (21) months reviewed. Review timeframe 9/01/24 - 6/30/26. Findings include: 1. Review of laboratory policy and procedures revealed a Pathology equipment program that included maintance for the tissue processor, embeddng center, slide stainer, coverslipper, microtome. 2. Review of Pathology Maintenance and Cleaning Schedule logs revealed daily tasks for the Tissue Pocessor, Embedding Center, Microtome, waterbath, slide stainer, cover slipper and distiled water system. Review of the maintnance logs for 9/01/24 - 6/30/26 revealed no documented daily maintenance on the following 9 days of patient testing: 4/1/25, 4/25/25, 5/7/25, 9/4/25, 9/5/25, 9/13/25, 9/18/25, 9/19/25, and 9/20/25. 3. In an exit interview on 7/15/26 at 4:30pm with the Technical Supervisor and Laboratory Director, the findings were confirmed.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by:

	A. Based on a review of the laboratory's policies and procedures, pathology quality control (QC) and patient logs, and interview, the laboratory failed to follow their established policy to document daily Hematoxylin and Eosin (H&E) stain acceptability for ten (10) days with one hundred nine (109) patient cases stained /processed/evaluated during the twenty two (22) months reviewed. Review timeframe 9/01/24 - 6/30/26. The findings include: 1. Review of the laboratory's policies and procedures revealed a "Quality Control and Quality Assurance Program" that included a H&E staining policy that stated the first set of stained slides are to be evaluated for quality control. 2. Review of the pathology records and Path Daily QC logs from 9/01 /24 through 6/30/26 revealed a lack of H&E control slide documentation for following 10 days and number of patient cases: 2/07/25 - 13 cases 2/18/25 - 10 cases, 2/19/25 - 17 cases, 3/23/26 - 10 cases, 4/16/25 - 6 cases, 4/17/25 - 9 cases, 4/18/25 - 6 cases, 4 /30/25 - 12 cases, 5/01/25 - 10 cases, and 5/02/25 - 8 cases for a total of 109 patient cases 3. In an exit interview on 7/15/26 at 4:30pm with the Technical Supervisor and Laboratory Director, the findings were confirmed. B. Based on a review of the laboratory's policies and procedures, quality control (QC) logs, patient logs, and interview, the laboratory failed to follow their established policy to document immunohistochemical (IHC) stain acceptability for six (6) days with 22 patient cases stained/processed/evaluated during the twenty-two (22) months reviewed. Review timeframe 9/01/24 - 6/30/26. 1. Review of the Non-Gyn Cytology Technical Procedure for Papanicolaou Staining revealed that quality control slides are to be evaluated daily for stain quality and contamination. 2. Review of the laboratory's 9/01 /24 - 6/30/26 Cytology QC/QA logs and Path Lab IHC Logs revealed no documentation of quality control slide evaluation on the following 6 days and number of patient cases: 6/18/25 - 7 cases, 6/19/25 - 3 cases, 6/20/25 - 7 cases, 6/23/25 - 2 cases, 6/24/25 - 2 cases, and 6/25/25 - 1 case a total of 22 patient cases. 3. In an exit interview on 7/15/26 at 4:30pm with the Technical Supervisor and Laboratory Director, the findings were confirmed