Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0229791	10/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Urology Of Virginia, Pllc- Clinical Lab	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 - Clinical Lab on August 28-29, 2025 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 - Clinical Lab was not in compliance with the applicable Conditions and Standards under 42 CFR part 493 CLIA Regulations. Specific deficiencies are as follows:
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification form (CMS-116), laboratory's policies and procedures, calibration verification records, lack of documentation and interviews, the laboratory failed to establish and follow a policy for the comparison of the Immunochemistry testing performed on the laboratory's two Roche Diagnostics Cobas e 411 analyzers in calendar year 2024. Findings include: 1. Review of the laboratory's CMS-116 revealed the laboratory utilizes the Roche Diagnostics Corporation analyzer to perform Prostrate Specific Antigen (PSA), free PSA, Testosterone, 25-hydroxy Vitamin D patient testing. 2. During the entrance interview on 10/28/25 at 10:00 am with the Director of Laboratory Services and the Technical Supervisor (TS), it was revealed that the laboratory utilizes two (2) Roche Cobas e 411 analyzers for Immunochemistry testing and that patient PSA and Testosterone testing is performed on both. 3. Review of the laboratory's policies and procedures revealed the lack of a policy or procedure to twice annually perform and

	evaluate PSA and Testosterone result comparisons tested on the lab's two Roche Cobas analyzers. 4. Review of the available calibration verification records revealed the lab performed verification studies on both Cobas analyzers (Serial numbers 1135-01 and 1134-30) on 7/28/25 for PSA and on 8/1/25 for testoserone. The documentation lacked a comparison of the calibration verification data evaluating the difference between values from the two Cobas instrumentsand whether the differences were acceptable. 5. In an interview on 10/29/25 at 11:57 AM, the TS was asked about instrument comparison studies for PSA and testosterone. The TS stated that there was no comparison study but that calibration verification had been successfully performed for both anayltes and instruments. The TS confirmed that no additional calibration verification documentation was available for review. 6. In an exit interview on 10/29 /25 at 1:55 PM with the Laboratory Director, Director of Laboratory Services and TS, the findings were confirmed.