

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0229791	<b>(X3) Date Survey Completed</b> 12/29/2021
<b>Name of Provider or Supplier</b> Urology Of Virginia, Pllc- Clinical Lab	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Urology of Virginia, PLLC -Clinical Lab on December 28-29, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows:
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality assurance (QA) manual, manufacturer's operation manual, system maintenance logs, lack of documentation, and interviews, the laboratory failed to document performance of their Aqua Treatment Service Water System annual maintenance during the twenty-seven (27) months reviewed (timeframe: September 2019 to date of the survey on December 29, 2021). 1. Review of the laboratory's QA policy manual revealed a water quality system manufacturer's operation guide (Aqua Treatment Service, INC. Installation and Operation Maintenance Manual) which stated: Manual Cover page: "It is important that those responsible for the installation of this equipment, as well as the owner/operator, read this manual and carefully follow the instructions and guidelines."; Cleaning Requirements (page 9) stated: "A minimum of once yearly cleaning and UV Disinfection lamp replacement." 2. Review of the available laboratory maintenance logs from September 2019 to 12/29/21 revealed no documentation of the water</p>

system's maintenance as outlined by the manufacturer. The inspector requested to review the annual water maintenance of cleaning/lamp replacement for calendar year 2020 and year to date 2021. No records were available for review. The technical supervisor (TS) stated on 12/29/21 at approximately 11 AM: "I will ask our director for those records. We have the invoices for annual maintenance for years prior. I am not sure if the maintenance was performed in 2020 or this year." 3. The director of laboratory services stated on 12/29/21 at approximately 1:00 PM: "I have reviewed the installation instructions and reached out to our Hydrologix representative that installed the water quality system. He has confirmed that the UV disinfection system needs a bulb and sub-micron filter changed annually. We did not get their field service in to get this done in 2019, 2020, or this year." 4. The TS and director of laboratory services confirmed the above findings on 12/29/21 at approximately 1:30 PM.