

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0964598	<b>(X3) Date Survey Completed</b> 09/01/2022
<b>Name of Provider or Supplier</b> Urology Of Virginia, , Pllc	<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 on August 31, 2022 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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, Fluorescence in-situ Hybridization (FISH) equipment logs, patient logs, lack of documentation, and interviews, the laboratory failed to document performance of weekly maintenance /cleaning for three of three pathology laboratory instruments (one Abbott tissue processor and two Abbott Molecular ThermoBrite System units) per the written procedure for twelve (12) weeks during a twenty (20) month review (timeframe January 2021 through August 2022) while processing eighty-seven (87) patient pathology cases. Findings include: 1. Review of the laboratory's FISH procedure manual revealed the following three protocols: VIP 2000 Operating Procedure and Maintenance Policy that outlined: "Weekly/After Each Use: Clean up drips/spills inside the VIP 2000 tissue processor. Gently wipe temperature probes to remove liquid. The safety hood should be wiped. Clean and inspect the reagent bins."; ThermoBrite Operating Procedure and Maintenance Policy that outlined: "After Each Use: wipe off condensation from inside lid, remove the slide separator and remove rubber cement from the underside using forceps. Clean the warmer plate with 70% alcohol. Allow the inside lid and warmer plate to air dry before closing lid."; Weekly</p>

Maintenance and Cleaning Log with duty check list instructions: "VIP 2000 Processor: Clean reagent bins and surrounding areas, wipe temperature probes, clean safety hood, inspect all reagent bins. ThermoBrite: Wipe down heater plate with 70% alcohol, dry condensation on inside lid, remove glue from slide separator". 2. Review of FISH equipment and patient logs from January 2021 through August 2022 revealed no documentation of the Abbott VIP 2000 and ThermoBrite weekly procedures outlined above on the following weeks of testing and number of patient cases processed: 01/04/21 - 1 accession (UVM21-0003); 01/06/21 - 2 accessions (UVM 21-0043, -0050); 01/07/21 - 1 accession (UVM21-0070); 01/08/21 - 1 accession (UVM21-0079); 01/21/21 - 3 accessions (UVM21-0198, -0217, -0194); 01/22/21 - 1 accession (UVM21-0231); 01/25/21 - 1 accession (UVM21-0232); 01/26/21 - 1 accession (UVM21-0247); 01/27/21 - 2 accessions (UVM21-0265, -0266); 01/29/21 - 3 accessions (UVM21-0278, -0280, -0285); January 2021 - two of four weeks lacked records for outlined protocols while reporting sixteen patient cases. 02/09/21 - 4 accessions (UVM21-0385, -0386, -0387, -0389); 02/10/21 - 1 accession (UVM21-0410); 02/11/21 - 1 accession (UVM21-0426); 02/12/21 - 1 accession (UVM21-0442); February 2021 - one of four weeks lacked records for outlined protocols while reporting seven patient cases. 03/15/21 - 1 accession (UVM21-0800); 03/17/21 - 2 accessions (UVM21-0809, -0817); 03/19/21 - 1 accession (UVM21-0868); 03/22/21 - 1 accession (UVM21-0873); 03/23/21 - 2 accessions (UVM21-0882, -0888); 03/24/21 - 1 accession (UVM21-0908); 03/25/21 - 5 accessions (UVM21-0915, -0916, -0918, -0923, -0920); March 2021 - one of four weeks lacked records for outlined protocols while reporting thirteen patient cases. 05/06/21 - 1 accession (UVM21-1338); 05/10/21 - 1 accession (UVM21-1367); 05/12/21 - 1 accession (UVM21-1390); 05/14/21 - 1 accession (UVM21-1406); May 2021 two of four weeks lacked records for outlined protocols while reporting four patient cases. 06/02/21 - 1 accession (UVM21-1546); 06/03/21 - 2 accessions (UVM21-1585, -1598); 06/07/21 - 1 accession (UVM21-1624); 06/09/21 - 3 accessions (UVM21-1653, -1657, -1658); June 2021 - one of four weeks lacked records for outlined protocols while reporting seven patient cases. 07/01/21 - 1 accession (UVM21-1891); 07/09/21 - 2 accessions (UVM21-1957, -1960); 07/12/21 - 1 accession (UVM21-1962); 07/13/21 - 1 accession (UVM21-1983); 07/14/21 - 2 accessions (UVM21-1996, -2004); 07/15/21 - 2 accessions (UVM21-2013, -2024); 07/16/21 - 2 accessions (UVM21-2041, -2043); July 2021 - two of four weeks lacked records for outlined protocols while reporting eleven patient cases. 09/07/21 - 2 accessions (UVM21-2614, -2619); 09/08/21 - 4 accessions (UVM21-2624, -2626, -2636, -2637); 09/09/21 - 1 accession (UVM21-2653); September 2021 - one of four weeks lacked records for outlined protocols while reporting seven patient cases. 05/23/22 - 12 accessions (UVM21-1878, -1880, -1875, -1888, -1888, -1889, -1915, -1931, -1927, -1929, -1974, -1975); May 2022 - one of four weeks lacked records for outlined protocols while reporting twelve patient cases. 06/16/22 - 10 accessions (UVM21-2171, -2179, -2208, -2218, -2222, -2252, -2274, -2282, -2288, -2289); June 2022 - one of four weeks lacked records for outlined protocols while reporting ten patient cases. The above outlined dates lacked VIP 2000 and ThermoBrite weekly maintenance and cleaning procedure documentation for the 87 patient cases processed. 3. The inspector inquired regarding the discrepancies of the patient FISH log sheets with the lack of maintenance recorded on the VIP 2000/ThermoBrite FISH lab logs for dates of patient testing. During a follow up interview with the laboratory tech and director of laboratory operations on 9/1/22 at approximately 11 AM, the cytologist explained that "the instrument logs are typically recorded on the day or the day after the FISH runs are completed". No additional documentation was available for the inspector to review to verify the maintenance procedures were followed/completed for the above outlined cases processed in the FISH laboratory room. 4. A follow up interview with the director of laboratory operations on 9/1/22 at

approximately 11:30 AM confirmed the above findings.