

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0964598	(X3) Date Survey Completed 08/14/2024
Name of Provider or Supplier Urology Of Virginia, , Pllc	Street Address, City, State 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, PLLC on August 14, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5401	<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: A. Based on a review of the laboratory's maintenance logs, procedures, and interviews, the laboratory failed to document performance of cytology instrument monthly preventative maintenance per written procedure for four (4) of twenty-three (23) months reviewed (survey timeframe: September 2, 2022 up to the date of the inspection on August 14, 2024). Findings include: 1. Review of the laboratory's Non-GYN Cytology Maintenance Logbook for the survey timeframe of 9/2/22 to 8/14/24 revealed monthly Thin Prep 2000 Processor Maintenance Schedule log sheets that delineated a General Cleaning protocol to be checked off monthly. The inspector noted that the logs for June 2023, November 2023, February 2024, and April 2024 lacked documentation that the monthly General Cleaning protocols were performed. 2. Review of the laboratory's Non-GYN Cytology Procedure Manual revealed the following titled procedure protocols Tissue Tek DRS 2000 Automatic Slide Stainer Preventative Maintenance for Cytology - "The Tissue Tek DRS 2000 is an automatic precision instrument that should be kept in optimal operating condition by performing the required preventative maintenance. The solution reservoirs and slide baskets are washed with tap water, mild detergent, and/or a 10% bleach solution once a month."</p>

Recording Routine Maintenance Protocol - "Principle-It is important to keep all routine/preventative maintenance performed in the cytology laboratory. Monthly preventative maintenance is to be performed on the ThinPrep once a month and documented on the maintenance schedule via initial/date. Perform all general maintenance listed on the cytology lab maintenance logs and document via initial/date that you have done so." 3. The inspector requested documentation that the monthly maintenance outlined above was performed per procedure in June, November of calendar year 2023 and February, April of 2024. No additional documentation was available for review. 4. An interview with the Director of Laboratory Services on 8/14/24 at 3:30 PM confirmed the above findings. B. Based on a review of cytology maintenance logs, procedures, and interviews, the laboratory failed to document, per written procedure, monthly centrifuge maintenance for 4 of 23 months, and fume hood maintenance for three (3) of 23 months reviewed (survey timeframe: September 2, 2022 to the date of the inspection on August 14, 2024). Findings include: 1. Review of the laboratory's Non-GYN Cytology Maintenance Logbook for the survey timeframe of 9/2/22 to 8/14/24 revealed Cytology Lab Maintenance Schedule log sheets that delineated the following protocols to be checked off monthly: Clean and Lubricate Centrifuge, Check Fume Hood Filter. The inspector noted there was no documentation for the monthly maintenance during the following months: Clean /Lubricate Centrifuge - June 2023, November 2023, January 2024, April 2024; Check Hood Filter- June 2023, December 2023, April 2024; Seven (7) of 23 months reviewed lacked maintenance documentation. 2. Review of the laboratory's Non-GYN Cytology Procedure Manual revealed the following titled procedure protocols: Preventative Maintenance Megafuge Centrifuge Protocol - "Clean the centrifuge and grease the trunnions of the swing out rotors monthly"; LabConco Fume Adsorber Preventative Maintenance Protocol - "Replacement of the activated charcoal filter is indicated after first odor breakthrough monitored/documentated by personnel"; Tissue Tek DRS 2000 Automatic Slide Stainer Preventative Maintenance for Cytology - "Replace the activated carbon filter monthly, or sooner if fume monitoring reveals elevated reagent vapors." Recording Routine Maintenance Protocol - "Principle-It is important to keep all routine/preventative maintenance performed in the cytology laboratory. Perform all general maintenance listed on the cytology lab maintenance logs and document via initial/date that you have done so." 3. The inspector requested to review documentation that the monthly maintenance outlined above was performed per log and procedure instructions for the 4 months in calendar year 2023 and 3 months in 2024 as noted above. No additional documentation was available for review. 4. An interview with the Director of Laboratory Services on 8/14/24 at 3:30 PM confirmed the above findings.

D5429

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
 Based on a review of manufacturer operator's manual, maintenance logs, and interview, the laboratory failed to document performance of semi-annual cytology instrument preventative waste tube maintenance per manufacturer's instructions in calendar year 2023 and up to the date of the inspection on August 14, 2024. Findings include: 1. Review of the laboratory's CYTYC Corporation ThinPrep 2000 Operator's

Manual revealed the following required preventative maintenance protocol (Section 5 Maintenance, Waste Tube Replacement/Semi-Annual) that stated, "The tubing inside the waste control box must be replaced every six months." 2. Review of the laboratory's Non-GYN Cytology Maintenance Logbook for the timeframe of calendar year 2023 and up to 8/14/24 revealed one record for the semi-annual ThinPrep 2000 waste tube maintenance outlined above (documented on 10/2/23). 3. The inspector requested to review additional documentation that the waste tube semi-annual maintenance was performed in calendar year 2023 and year to date 2024. No additional records were available for review. 4. An interview with the Director of Laboratory Services on 8/14/24 at 3:30 PM confirmed the above findings.