

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0229791	<b>(X3) Date Survey Completed</b> 11/30/2023
<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 November 29-30, 2023 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 and includes the Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems.
<b>D5400</b>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on a review of policies and procedures, user guide, Polymerase Chain Reaction (PCR) Worksheet documentation, patient test logs, maintenance logs, lack of documentation, tour, and interviews, the laboratory failed to: 1. follow established policy for No Template Control documentation on their PCR Worksheets in three of thirteen months reviewed while reporting two hundred eighteen patients' PCR Urinary Tract Infection (UTI) Multiplex Panels (timeframe: September 29, 2022 to 11/30/23) CROSS REFERENCE D5401; 2. document weekly contamination procedures per their established PCR laboratory protocol for five of fifty-six weeks reviewed while reporting fifty patient urine UTI Multiplex Panel assays (9/29/22 to 11/30/23) CROSS REFERENCE D5433 A; 3. document every three month PCR hood contamination maintenance per established protocol during eight of thirteen months reviewed (9/29/22 - 11/30/23) CROSS REFERENCE D5433 B; 4. define/document function checks</p>

for centrifuge revolutions per minute and/or rotator speed and circumference, for one standing Thermo Scientific Sorvall/ST Plus centrifuge utilized in PCR laboratory for the isolation of urinary tract microbiota DNA during the thirteen month review timeframe (9/29/22-11/30/23) CROSS REFERENCE D5435.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:  
Based on a review of policies, Polymerase Chain Reaction (PCR) Worksheet documentation, patient test logs, lack of documentation, and interviews, the laboratory failed to follow the established policy for No Template Control (NTC) documentation on their PCR Worksheet in three (3) of thirteen (13) months reviewed while reporting two hundred eighteen (218) patients' PCR Urinary Tract Infection (UTI) Multiplex Panels (timeframe: September 29, 2022 to 11/30/23). Findings include: 1. Review of the laboratory's PCR Lab Policies and Procedures manual revealed the following UTI Multiplex Panel quality control (QC) instruction: Performing the Instrument Run for qPCR Amplification QuantStudio 7: "First run of the day-NTC must also be run on the TaqMan Array Card (TAC). Record the NTC placement on the TaqMan PCR Worksheet and label the NTC tube in correspondence with the worksheet. All subsequent TACs of the day do not require an NTC if the first NTC passes." 2. The inspector requested to review the TaqMan PCR Worksheets with NTC QC documentation for the 13 month timeframe of September 2022 (new test platform initiation) to the date of the inspection on 11/30/23. The worksheet records revealed missing NTC QC documentation during the following months: December 2022 (on dates of single runs: 12/7/22, 12/8/22, 12/9/22, 12/15/22); January 2023 (on dates of single runs: 1/5/23, 1/9/23, 1/12/23, 1/19/23); May 2023 (on date of single run 5/17/23). 3. The patient test logs corresponding with the TaqMan PCR Worksheets outlined above revealed 218 patients' were assayed/reported without documentation of the daily NTC on nine dates in December 2022, January 2023, and May 2023. 4. An exit interview with the primary PCR testing personnel, laboratory manager, director of laboratory operations, and laboratory director on 11/30/20, at 3:00 PM, confirmed the above findings.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must 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. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

A. Based on review of procedures, maintenance logs, lack of documentation, and interviews, the laboratory failed to document weekly contamination procedures per their established protocol for the Polymerase Chain Reaction (PCR) laboratory for five (5) of fifty-six (56) weeks reviewed while reporting fifty (50) patient urine PCR Urinary Tract Infection (UTI) Multiplex Panel assays (timeframe: September 29, 2022 to November 30, 2023). Findings include: 1. Review of the laboratory's PCR Lab Policies and Procedures manual revealed the following maintenance protocol: PCR Contamination Control- "The essential parts of this contamination control program include space and time separation of pre- and post-PCR activities, use of physical aids, use of ultraviolet (UV) light, use of aliquot PCR reagents, incorporation of negative controls, and use of one or more of various contamination control methods that use chemical and biochemical reactions. Weekly, the technician will weekly inspect and wipe rotors and buckets of PCR lab centrifuge with 70 % ETOH." 2. Review of the laboratory's PCR Cleaning and Maintenance Logs for the timeframe of 9/29/22 to 11/30/23 revealed the following weeks in calendar year 2023 with no documentation of the weekly maintenance protocols outlined above: January 16-20 (7 patient PCR assays reported); January 23-31 (5 patient PCR assays reported); February 27-March 3 (15 patient PCR assays reported); March 13-17 (10 patient PCR assays reported); April 3-7 (13 patient PCR assays reported). The inspector requested to review documentation for the weekly contamination protocols for the 5 weeks above. No additional documentation was available. A total of 50 patient PCR UTI assays were reported without documentation that PCR weekly contamination controls were followed (inspection and wipe rotors/buckets of PCR lab centrifuge with 70 % ETOH). 3. An exit interview with the primary PCR testing personnel, laboratory manager, director of laboratory operations, and laboratory director on 11/30/20, at 3:00 PM, confirmed the above findings.

B. Based on review of procedures, maintenance logs, lack of documentation, and interviews, the laboratory failed to document every three month Polymerase Chain Reaction (PCR) hood contamination maintenance per their established protocol during eight (8) of thirteen (13) months reviewed (timeframe: 9/29/22 to 11/30/23). Findings include: 1. Review of the laboratory's PCR Lab Policies and Procedures manual revealed the following maintenance protocol: PCR Contamination Control: "The laboratory's PCR hood UV light will be changed every three months to ensure optimal sterilization." 2. Review of the laboratory's PCR hood maintenance records during the 13 months reviewed (9/29/22 to 11/30/23) revealed no documentation on the log under parameter heading ("Every 3 months change UV light") for a period of 8 months (from 9/29/22 to 5/4/23). The inspector requested to review additional documentation. No records were available. 3. An exit interview with the primary PCR testing personnel, laboratory manager, director of laboratory operations, and laboratory director on 11/30/20, at 3:00 PM, confirmed the above findings.

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**  
 CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on a laboratory tour, review of procedures, user guide, maintenance logs, lack of documentation, and interviews, the laboratory failed to define/document function checks for centrifuge revolutions per minute (RPM) and/or rotator speed and circumference, for one (1) standing Thermo Scientific Sorvall/ST Plus centrifuge utilized in the Polymerase Chain Reaction (PCR) laboratory for the isolation of urinary tract microbiota (UTM) DNA during the thirteen month review timeframe (PCR testing start date of 9/29/22 up to the date of the inspection 11/29-11/30//23). Findings include: 1. During an entrance tour on 11/29/23, the inspectors noted a Thermo Scientific Sorvall/ST Plus centrifuge in use in the PCR microbiology laboratory. 2. Review of the laboratory's PCR Lab Policies and Procedures manual revealed the following two protocol instructions: Sample Preparation and DNA Extraction for UTM Assays: "Centrifuge Sample- Centrifuge the sample plate in the standing centrifuge at 2250 x g for 15 minutes at room temperature." Performing the Instrument Run for qPCR Amplification QuantStudio 7: "Loading TAC into Centrifuge- Place loaded spin racks into the standing centrifuge. Centrifuge the array card twice in the standing centrifuge for 1 minute each time at 331 x g (1200 RPM)." 3. Review of the PCR centrifuge user's guide (Thermo Fisher Scientific Instructions for Use) revealed the following statements, "In order to keep this product able to perform the intended applications reliably and safely, ongoing preventative maintenance is necessary. Thermo Fisher Scientific recommends having the centrifuge and accessories serviced once a year by an authorized service technician. The service checks: electrical connections, suitability of set up, centrifuge door lock /safety system, rotor and fixation of rotor, anti vibration mounts. A validation of the centrifuge is recommended." 4. Review of the PCR laboratory's maintenance documentation revealed one record of RPM verification for the Thermo Scientific standing centrifuge outlined above. The inspector noted that Tidewater Medical Sales Service technician documented a speed check at 3000.1 RPM on 7/18/23. The inspector requested to review centrifuge RPM verification records for the procedural speed requirements outlined above for the timeframe of initiated PCR patient testing in September 2022 up to 11/30/23. No documentation was available for review. The inspector inquired regarding the protocol for RPM checks at 2250 x g and 331 x g (1200 RPM). The laboratory manager stated on 11/30/23 at 2:30 PM, "we do all equipment maintenance annually and we can reach out to Tidewater Medical or another vendor to have them return to verify the additional speed." 5. An exit interview with the primary PCR testing personnel, laboratory manager, director of laboratory operations, and laboratory director on 11/30/20, at 3:00 PM, confirmed the above findings.