Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2018622	02/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Potomac Urology Center, Pc	3700 Joseph Siewick Dr Ste 300, Fairfax, 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 Potomac Urology Center, PC on February 26, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes the Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on a tour, review of procedures, manufacturer user manual, and interviews, it was observed that the laboratory failed to: 1. follow the written/approved safety protocols in the Reverse Transcription- Polymerase Chain Reaction (RT-PCR) laboratory after a physical move on February 26, 2024 for twelve (12) of 12 months up to the date of the inspection, February 26, 2025 - CROSS REFERENCE D5401; 2. follow the manufacturer's instructions for contamination prevention in the RT-PCR laboratory during twenty-two months of review (timeframe: April 25, 2023 to the date of the recertification inspection on 2/26/25) - CROSS REFERENCE D5411.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	(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 tour, review of procedures, and interviews, it was observed that the laboratory failed to follow the written/approved safety protocol in the Reverse Transcription- Polymerase Chain Reaction (RT-PCR) laboratory after a physical move on February 26, 2024 for twelve (12) of 12 months up to the date of the inspection, February 26, 2025. Findings include: 1. During a tour of the RT-PCR laboratory on 2/26/25 at 11 AM, the inspector noted no eye wash or safety goggles located near the entrance nor within the PCR laboratory. The inspector inquired regarding the location of an eye wash or safety wash shower and the location of safety eyewear storage. The office manager and primary testing personnel stated on 2/26/25 at 11:30 AM, "We moved to this new laboratory location in February 2024 and have not added an eye wash yet. We do not have safety goggles". 2. Review of the RT-PCR laboratory procedures revealed protocol instructions: Section 13.4 Protective Equipment - "Standard safety precautions should be utilized when performing these procedures. In the event of a spill, an emergency eyewash is located less than 10 feet from the laboratory testing area." ThermoFisher RT-PCR Site Preparation Check List - "The following required safety equipment must be available at the installation site: eyewash, safety shower, eye protection" 3. An exit interview with the primary testing personnel and the practice general manager on 2/26/25 at 2:00 PM confirmed the above findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a tour, review of procedures, manufacturer user manual, and interviews, the laboratory failed to follow the manufacturer's instructions for contamination prevention in the Reverse Transcription- Polymerase Chain Reaction (RT-PCR) laboratory during the twenty-two months of review (timeframe: April 25, 2023 to the date of the recertification inspection, February 26, 2025). Findings include: 1. During a tour of the laboratory on 2/26/25 at 11 AM, the inspector noted a ThermoFisher QuantStudio 3 thermocycler in use (serial number 272312229) for RT-PCR. The inspector noted that laboratory coats were not visibly present near the entrance nor within the RT-PCR laboratory. The inspector also noted refrigerators in the dedicated PCR laboratory that were marked as in use for storage of microbiology/fungal RT-PCR patient and clinical trial testing and that the lead testing personnel wore a personal hooded type jacket over a scrub top. 2. Review of the laboratory developed test (LDT) procedure (RT-PCR's- Detection of Pathogens, Antibiotic Resistance Markers, and Fungi) revealed a protocol statement under Section 13.2, "All appropriate measures should be taken to avoid contamination of patient specimens. Lab coats must be worn". 3. Review of the ThermoFisher QuantStudio 3 user guide

	revealed manufacturer's instructions: General Procedures: Preparing Reactions - "Follow manufacturers procedures to prepare reactions. Good RT-PCR laboratory practice includes wearing clean gloves and a clean lab coat. Do not wear the same gloves and lab coat that you have previously used when handling amplified products or preparing samples."; Installation and Operation: - "Ensure lab coats are available before installation and use of the instrument." 4. The inspector inquired as to the location/storage of dedicated RT-PCR laboratory coats utilized for reduction of contamination during the high sensitivity techniques. The primary testing personnel stated on 2/26/25 at 12:30 PM, "I have not been using laboratory coats.". The office manager also stated at 12:30 PM, "We have not provided PCR lab coats" 5. An exit interview with the primary testing personnel and the practice general manager on 2/26 /25 at 2:00 PM confirmed the above findings.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) (b)(2) Verification of the test procedures performed and establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) CLIA database, CMS CLIA Certification form (CMS 116), laboratory tour, review of analyzer performance verification records, lack of documentation, and an interview, the technical supervisor (TS) failed to document performance specification validation for laboratory developed testing (LDT) after the Reverse Transcription- Polymerase Chain Reaction (RT-PCR) analyzer was moved and installed in a new physical location in February 2024 up to the date of the inspection on February 26, 2025 prior to the laboratory reporting fifteen thousand nine hundred eight (15,098) patient pathogen test results. Findings include: 1. During pre-survey preparation, the inspector noted in the CMS CLIA database that the laboratory provided the following request on 2/26/24: Change of physical address from 1800 North Beauregard St- Suite 300 in Alexandria, Virginia 22311 to 3700 Joseph Siewick Dr. Ste 300 in Fairfax, Virginia 22033. The inspector noted that the laboratory director's submitted recertification CMS 116 form confirmed the Fairfax, Virginia address. 2. During a tour of the laboratory on 2/26/25 at 11:00 AM, the inspector noted a ThermoFisher QuantStudio 3 thermocycler (serial number 272312229) in use for RT-PCR LDT. The inspector inquired if the analyzer was moved from the Alexandria, Virginia location in 2024 and inquired regarding the laboratory's policy for verification/validation after a physical move. The primary testing personnel stated that the analyzer was moved in 2024 and a decision was made to run a calibration after the move. 3. Review of the RT-PCR LDT performance validation notebook revealed one method validation study for the analyzer outlined above (reviewed and approved by the laboratory director on 4 /23/21). The inspector requested to review verification studies reviewed/approved by the TS after the physical move in 2024. Documentation was not available for review. 4. Review of the patient test logs revealed three hundred eighty-eight (388) patient panels analyzing 15,098 pathogen results were reported during the twelve months after moving to the new laboratory location. 5. An exit interview with the primary testing personnel and the practice general manager on 2/26/25 at 2:00 PM confirmed the above findings.