Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D2018622	**(X3) Date Survey Completed** 08/11/2021
Name of Provider or Supplier Potomac Urology Center, Pc	**Street Address, City, State** 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 August 11, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
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 review of the laboratory's policies and procedures, quality control (QC) documentation, patient logs, Individualized Quality Control Plan (IQCP) and interviews, the laboratory failed to follow their established protocol for the performance of weekly controls prior to reporting patient results in the laboratory's electronic health record (EHR) for four weeks out of 13 months reviewed (June 2020 until July 2021). Findings include: 1. Review of the laboratory's procedure manual revealed a protocol for "Determination of Urinary Tract Infection Pathogens using Real-Time Reverse transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) -UTI+" which stated, "4.2 Test Procedure An Analytical run begins with a weekly calibration plate (Figure 1) containing: 1.) One set of positive controls (each containing Taq polymerase, reverse transcriptase, Primers and probe for each pathogen and the endogenous control containing known amounts of DNA or RNA templates); 2.) One set of no template controls (containing Taq polymerase, reverse transcriptase, Primers and probe for each pathogen and the endogenous control, no template DNA or RNA is included)" and "6.6 Acceptable limits for Controls The positive control and endogenous control must show amplification to pass. The

	negative control must be negative to pass If all controls pass, then the patient results can be reviewed and released." 2. Review of the laboratory's records revealed a document, "Clinical Molecular Biology Individualized Quality Control Plan (IQCP)" with laboratory director approval on 04/01/2020, which stated "2.0 Quality Control Plan-Molecular Testing Assays Functional Testing documentation-FREQUENCY-Weekly and upon receipt of a new lot of reagents." 3. Review of the laboratory's "QC Control Information Weekly" log sheets from June 2020 until July 2021 (13 months) revealed a lack of documentation of QC performed for the RT-QPCR UTI method for the following weeks: 09/28/2020-"No QC Run." 10/05/2020-"No QC Run." (QC ran 10/10/20.) 06/21/2021-"No controls run lack of inventory." 06/28/2021-"No controls run lack of inventory." (QC ran 7/6/2021.) The surveyor requested to review documentation of the QC for the weeks listed above. The laboratory provided no documentation for review. 4. Review of the laboratory's Excel spreadsheet of patient's tested with the RT-QPCR UTI method revealed the following: 09/28/2020 to 10/10 /2021-103 patients; 06/21/2021 to 07/07/2021-124 patients. A total of 227 patients. 5. In an exit interview with the laboratory director, medical director/owner, general manager, and testing personnel on August 11, 2021 at approximately 12:45 PM, the findings were confirmed.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of the laboratory's "Molecular UTI Monthly Quality Assurance Checklist", policies and procedures, quality control (QC) records, patient logs, and interviews, the laboratory's established Quality Assurance (QA) checklist failed to address analytic issues within the subspecialties of bacteriology and mycology. (Cross Reference D5401.) Findings include: 1. Review of the laboratory's policies and procedures, quality control (QC) records, and patient logs revealed the lack of weekly QC documentation for the Real-Time Reverse transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR)-UTI+ test for one (1) week in September 2020, 1 week in October 2020, two (2) weeks in June 2021 and 1 week in July 2021 (see D5401). 2. Review of the laboratory's "Molecular UTI Monthly Quality Assurance Checklist" from June 2020 to June 2021, revealed the following statements: 09/2020 (signed by Technical Supervisor as reviewed on 02/04/2021) "D) Quality Control-All QC with acceptable ranges? Y/N=N See notes in Weekly QC; If no, Corrective Acton performed Y/N=Y See notes in Weekly QC report; Complete Positive/Negative control for every analyte performed weekly? Y/N=N See notes in weekly QC report." 10/2020 (signed by Technical Supervisor as reviewed on 12/31/2020) "D) Quality Control-All QC with acceptable ranges? Y/N=N See notes; If no, Corrective Action performed Y/N= See notes; Complete Positive/Negative control for every analyte performed weekly? Y/N=Y" 06/2021 (signed by by Technical Supervisor as reviewed on 07/15/2021) "D) Quality Control-All QC with acceptable ranges? Y/N=Y; ... Complete Positive/Negative control for every analyte performed weekly? Y/N=N QC not performed for the week of 6/21/21 and 6/28/21. Lack of inventory." 3. Review of the laboratory's "Clinical Molecular Biology Individualized Quality Control Plan

	(IQCP)" signed by the Laboratory Director on 4/01/2020 revealed a statement, "3.0 Quality Assessment -If a deficiency is found during quality assessment, a corrective action report will be written by the technical supervisor or designee with a plan of improvement that will be reviewed and signed off by the laboratory director and then implemented by the technical supervisor. The approved corrective action will then be added to the procedure manual as an additional SOP or addendum to an existing SOP." The surveyor requested to review documentation of the corrective actions taken for the weeks with no QC performed. The laboratory provided no documentation for review. 4. In an exit interview with the laboratory director, medical director/owner, general manager, and testing personnel on August 11, 2021 at approximately 12:45 PM, the findings were confirmed.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory's Centers for Medicare and Medicaid Services (CMS) 116 form, policies and procedures, lack of documentation, and interviews, the laboratory failed to implement a mechanism to ensure the accuracy of manually transcribed patient results from the "UTI Plus - 3 Patient Plate Map" worksheet into the electronic health record (EHR) from March 2020 to August 2021 (seventeen months). Findings include: 1. Review of the laboratory's CMS-116 revealed the laboratory performs polymerase chain reaction (PCR) target assays for organisms in urine specimens using a laboratory developed test (LDT). 2. An interview with the Testing Personnel (TP) on 8/11/2021 at approximately 10:45 AM revealed patient test results from the QuantStudio 3 are interpreted and manually recorded on the "UTI Plus - 3 Patient Plate Map". The "Plate Map" interpretation is then transcribed to the patient report and scanned into the EHR. 3. Review of the laboratory's policy and procedures revealed a lack of a mechanism to detect clerical errors for manually transcribed results. Review of patient results from March 2020 until August 11, 2021 revealed no documentation of a review of manually transcribed patient test results. The surveyor requested to review documentation of review of manually transcribed patient test results. The laboratory provided no documentation for review. 4. In an exit interview with the laboratory director, medical director/owner, general manager, and testing personnel on August 11, 2021 at approximately 12:45 PM, the findings were confirmed.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where

	the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Centers for Medicare and Medicaid Services (CMS) 116 form, two (2) randomly selected patient reports, and an interview, the laboratory failed to ensure that fluorescent insitu hybridization (FISH) test reports include the correct performing laboratory name and address during the timeframe of February 2020 until the date of the inspection on August 11, 2021. Findings include: 1. Review of the laboratory's CMS 116 form revealed a laboratory name and physical facility location as follows: Potomac Urology Center, PC 1800 North Beauregard St. Suite 300 Alexandria, VA 22311 2. Review of two randomly selected patient FISH test reports (Specimen ID PU21-444 report date 05/20/2021 and Specimen ID PU20-533 report date 09/17/2020) revealed the statement, "Professional Component of the test was completed at Annapath-Urology Services, 4801 Tesla Drive Suite H, Bowie, MD 20715." The surveyor inquired where the interpretation of FISH results were performed. The Annapath owners stated the interpretation of FISH results were performed at the Potomac Urology address not the Annapath address. 3. In an interview with the owners of Annapath-Urology Services on August 11, 2021 at approximately 10:00 AM, the above findings were confirmed.