

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2018622	(X3) Date Survey Completed 04/25/2023
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 April 25, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The laboratory was not in compliance with the following CLIA Condition: 493.1250 D5400: Analytic Systems. The specific deficiencies cited are as follows:
D5400	<p>ANALYTIC SYSTEMS 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 tour, review of laboratory's policies and procedures, method validation records, patient records, lack of documentation and interviews, the laboratory failed to: 1. follow their established policy for acceptable specimens for a laboratory developed test (LDT), the "UTI+ Method", for five-hundred fifty (550) rectal swab specimens from August 2021 until the date of the survey on April 25, 2023 (see D5401); 2. validate the performance specifications of a laboratory developed test (LDT), "UTI+ Method" utilizing rectal swab specimens, prior to reporting 550 patient results from August 2021 until the date of the survey on April 25, 2023 (see D5423).</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</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.

This STANDARD is not met as evidenced by:

Based on a tour of the laboratory, review of the laboratory's policies and procedures, method validation records, patient records, lack of documentation and interviews, the laboratory failed to follow their established policy for acceptable specimens for a laboratory developed test (LDT), the "UTI+ Method", for five-hundred fifty (550) rectal swab specimens from August 2021 until the date of the survey on April 25, 2023. The findings include: 1. During a tour of the laboratory on April 25, 2023, at approximately 10:30 AM, the surveyor observed a specimen rack on a shelf in the laboratory containing ten (10) plastic tubes of liquid labeled with patient information. The surveyor inquired with the primary testing personnel (TP) as to the type of specimen contained in the tubes. The TP stated the test tubes contained a liquid suspension prepared from individual patient rectal swabs for analysis utilizing the laboratory's "UTI+ Method". 2. Review of the laboratory's policies and procedures revealed a protocol, "UTI+ Method" (signed by the laboratory director on 5/4/2021), which detailed instructions for collection of urine samples by males and females. The protocol lacked documentation of instructions for the collection of rectal swabs. The surveyor requested to review the collection instructions for rectal swabs for analysis utilizing the "UTI+ Method". The laboratory provided no documentation to review. 3. Review of the laboratory's records revealed a validation record for the "UTI+ Method", "Validation for Molecular Urinary Tract Infection and Antibiotic Resistance Testing by Real Time PCR" (signed by the laboratory director on 4/23/2023). The validation record lacked documentation of the performance of validation of the rectal swab specimen type. The surveyor requested to review the validation documentation for the "UTI+ Method" utilizing the rectal swab specimen type. The laboratory provided no documentation to review. 4. Review of patient records from August 2021 until the date of the survey on April 25, 2023 revealed 550 rectal swab specimens were collected and analyzed utilizing the "UTI+ Method". 5. In an exit interview with the laboratory director and testing personnel on April 25, 2023, at approximately 1:00 PM, the above findings were confirmed.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on a tour of the laboratory, method validation records, Food and Drug

Administration's (FDA's) CLIA test categorization database, patient records, lack of documentation and interviews, the laboratory failed to validate the performance specifications for the rectal swab specimen type prior to testing patients utilizing the "UTI+ Method", laboratory developed test (LDT), for five-hundred fifty (550) rectal swab specimens from August 2021 until the date of the survey on April 25, 2023. The findings include: 1. During a tour of the laboratory on April 25, 2023, at approximately 10:30 AM, the surveyor observed a specimen rack on a shelf in the laboratory containing ten (10) plastic tubes of liquid labeled with patient information. The surveyor inquired with the primary testing personnel (TP) as to the type of specimen contained in the tubes. The TP stated the test tubes contained a liquid suspension prepared from individual patient rectal swabs for analysis utilizing the laboratory's "UTI+ Method". 2. Review of the FDA's database revealed no listing or categorization for the "UTI+ Method". 3. Review of the laboratory's method validation records revealed a validation record for the "UTI+ Method", "Validation for Molecular Urinary Tract Infection and Antibiotic Resistance Testing by Real Time PCR" (signed by the laboratory director on 4/23/2021). The validation record lacked documentation of the validation of the performance characteristics for the "UTI+ Method" when utilizing the rectal swab specimen type. The surveyor requested to review the validation documentation for the "UTI+ Method" when utilizing the rectal swab specimen type. The laboratory provided no documentation to review. 4. Review of patient records from August 2021 until the date of the survey on April 25, 2023 revealed 550 rectal swab specimens were collected and analyzed utilizing the "UTI+ Method". 5. In an exit interview with the laboratory director and testing personnel on April 25, 2023, at approximately 1:00 PM, the above findings were confirmed.