Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 39D0205041	**(X3) Date Survey Completed** 12/16/2025
Name of Provider or Supplier Center For Urologic Care Of Berks Cnty	**Street Address, City, State** 1320 Broadcasting Road, Suite 200, Wyomissing, PA	
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	A routine recertification survey was conducted by the Pennsylvania State Agency for Center for Urologic Care of Berks County on 12/16/2025. The laboratory was found out of compliance with the following conditions: 493.1250 Condition: Analytic Systems
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the Chief Executive officer (CEO), the laboratory failed to verify the accuracy of the PT results obtained for 3 of 3 API Microbiology testing events in 2024. Findings Include: 1. On the day of survey, 12/16/2025 at 10:39 am., review of the laboratory's API PT records revealed that the laboratory did not verify the accuracy for the following analytes that were not scored by the PT agency due to non-consensus for 3 of 3 API PT events performed in 2024: - API 2024 (1st event): Not Graded Bio-Rad CFX/ Resistance Gene: CTX-M; UTI-02, UTI-03 Bio-Rad CFX/ Resistance Gene:dfrA; UTI-02, UTI-03 Bio-Rad CFX/ Resistance Gene:KPC; UTI-02, UTI-03 Bio-Rad CFX/ Resistance Gene:mecA; UTI-01, UTI-02; UTI-03; UTI-04; UTI-05 Bio-Rad CFX/ Resistance Gene:NDM; UTI-02, UTI-03 Bio-Rad CFX/ Resistance Gene:qnr; UTI-02, UTI-03 Bio-Rad CFX/ Resistance Gene:sul; UTI-02, UTI-03 Bio-Rad CFX/ Resistance Gene:vanA; UTI-01, UTI-02; UTI-03; UTI-04; UTI-05 Bio-Rad CFX/ Resistance Gene:vanB; UTI-01, UTI-02; UTI-03; UTI-04; UTI-05 - API 2024 (2nd event): Not Graded Bio-Rad CFX/ Resistance Gene: NDM; UTI-06, UTI-07; UTI-09; UTI-10 Bio-Rad CFX/ Resistance Gene: qnr; UTI-06, UTI-

	08; UTI-09; UTI-10 Bio-Rad CFX/ Resistance Gene: sul; UTI-06, UTI-07; UTI-09; UTI-10 Bio-Rad CFX/ Resistance Gene: vanA; UTI-06, UTI-07; uti-08; UTI-09; UTI-10 Bio-Rad CFX/ Resistance Gene: vanB; UTI-06, UTI-07; UTI-08; UTI-09; UTI-10 - API 2024 (3rd event):Not Graded Bio-Rad CFX/ Resistance Gene: CTX-M; UTI-11, UTI-13; UTI-14; UTI-15 Bio-Rad CFX/ Resistance Gene:dfrA; UTI-11, UTI-13; UTI-14; UTI-15 Bio-Rad CFX/ Resistance Gene:KPC; UTI-11, UTI-13; UTI-14; UTI-15 Bio-Rad CFX/ Resistance Gene:mecA; UTI-11, UTI-12; UTI-13; UTI-14; UTI-15 Bio-Rad CFX/ Resistance Gene:NDM; UTI-11, UTI-13; UTI-14; UTI-15 Bio-Rad CFX/ Resistance Gene:qnr; UTI-11, UTI-13; UTI-14; UTI-15 Bio-Rad CFX/ Resistance Gene:sul; UTI-11, UTI-13; UTI-14; UTI-15 Bio-Rad CFX/ Resistance Gene:vanA; UTI-12; UTI-13; UTI-14; Bio-Rad CFX/ Resistance Gene:vanB; UTI-11, UTI-12; UTI-13; UTI-14 2. The API Proficiency Testing performance Evaluation form stated, " Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded.". 3. The CEO confirmed the findings above on 12/16/2025 at 11:00 am.
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 record review, lack of documentation, and interview with the Chief Executive Officer (CEO), the laboratory failed to meet applicable analytic systems requirements in 493.1251 through 493.1283 for year 2024. Refer to D5775
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) 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 do the following: This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of maintenance records and interview with the Chief Executive Officer (CEO), the laboratory failed to assess the maintenance and function checks as defined by the manufacturer for 5 of 5 micro-pipettors used in the microbiology laboratory from 01/03/2024 to 12/16/2025. Findings Include: 1. On the day of the survey, 12/16/2025 at 12:10 am, observation of the laboratory revealed 5 of 5 micro pipettes did not have calibrations dates. 2. The

	laboratory could not provide maintenance/function check records for the 5 of 5 micro pipettors used to perform microbiology testing from 01/03/2024 to 12/16/2025. 3. The CEO confirmed the findings above on 12/16/2025 at 12:30 am.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Chief Executive Officer (CEO), the laboratory failed to evaluate twice a year the relationship between test results using different methodologies and instruments for 2 of 2 Biorad CFX96 Real Time PCR analyzers used to perform molecular bacterial identification and resistance gene testing in 2024. Findings include: 1. On the day of the survey, 12/16/2025 at 10:30 am, the laboratory failed to provide documentation of the biannual comparison studies for the following 2 of 2 instruments used for Microbiology testing (molecular bacterial identification/resistance genes) performed in 2024: - Biorad CFX96 RT-PCR analyzer (serial number CT057029) v. Biorad CFX96 RT-PCR analyzer (serial number CT005708). 2. The laboratory performed 2400 urine culture analysis in 2024 (CMS 116, estimated annual volume, dated 12/11 /2025) 3. The CEO confirmed the findings above on 12/16/2025 at 11:30 am. **Repeat Deficiency**