Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0205041	(X3) Date Survey Completed 07/07/2022
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency testing (PT) records and interview with the Chief Executive Officer (CEO), the Laboratory Director (LD) failed to sign the API Microbiology attestation statement documents in 2022. Findings include: 1. On the day of survey, 07/07/2022 at 09:44 am, review of API records revealed, the attestation statement documents for bacteriology Events 1 and 2 in 2022 were not signed by the LD. 2. The CEO confirmed the finding above on 07/07/2022 at 12:45 pm.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory policies and interview with the Chief Executive Officer (CEO), the laboratory failed to establish a competency assessment policy to assess the competency for 3 of 3 Technical Supervisors (TS) for their supervisory responsibilities in microbiology from 09/17/2021 to 07/07/2022 Findings include: 1.

	On the day of survey, 07/07/2022 at 08:47 am, the CEO could not provide a competency assessment policy for 3 of 3 TS for their supervisory responsibilities in bacteriology (On the CMS 2019 Personnel #5, #6 and #7) from 09/17/2021 to 07/07/2022. 2. The CEO could not provide documentation of TS competency for 3 of 3 TS from 09/17/2021 to 07/07/2022. 3. The CEO confirmed the findings above on 07/07/2022 around 12:45 pm.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Biorad CFX 96 RT-PCR analyzer validation records and interview with Chief Executive Officer (CEO),the laboratory failed to establish criteria for acceptable performance specifications for the 23 of 23 bacteriology analytes performed on 2 of 2 Biorad CFX 96 RT-PCR analyzers from 08/15/2021 to 07/07/2022. Findings Include: 1. On the day of survey, 07/07/2022 at 09:06 am, review of the 2 of 2 Biorad CFX 96 RT-PCR analyzers validation records revealed, the validation performed on 08/15/2022 did not include the acceptable criteria for performance specifications for precision and accuracy. 2. Review of CMS116 form showed annual testing for bacteriology was 418. 3. The CEO confirmed the finding above on 07/07/2021 around 12:45 pm.
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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Chief Executive Officer (CEO), the laboratory failed to evaluate the relationship between 2 of 2 Biorad CFX96 RT-PCR analyzers in February, 2022. Findings: 1. On the day of Survey 07/07/2022 at 11:15 am, The CEO could not provide comparison of test results between 2 of 2 Biorad CFX96 RT-PCR analyzers for bacteriology in February, 2022 2. Review of CMS116 form showed annual testing for bacteriology was 418. 3. The CEO confirmed the above finding on 07/07/2022 at 12:45 pm.