Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0205041	03/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Center For Urologic Care Of Berks Cnty	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 review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the Chief Executive Officer (CEO), the laboratory director (LD)/designee and testing personnel (TP) failed to attest to the routine integration of samples into the patient workload for 3 of 3 Microbiology PT events performed in 2023. Findings include: 1. On the day of survey, 03/19/2024 at 11:02 am., review of the laboratory's API PT records revealed the following attestation statements were not signed by the LD/designee or TP: 2023 Microbiology 1st, 2nd, and 3rd events - Bacteriology UTI panel: Bio-Rad CFX Molecular Bacti-Urine/Molecular Resistance Genes-Urine 2. The CEO confirmed the findings above on 03/19/2024 at 1:00 pm. *Repeat Deficiency
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 lack of documentation and interview with the Chief Executive Officer

	(CEO), the laboratory failed to establish and follow a procedure to assess the competency of 1 of 1 clinical consultant (CC) for their consultant responsibilities in 2022 and 2023. Findings include: 1. On the day of survey, 3/19/2024 at 9:16 am, the laboratory failed to provide a policy that stated how to assess the competency for 1 of 1 CC (CMS 209 personnel #2) for their consultant responsibilities in 2022 and 2023. 2. The laboratory could not provide documentation of CC competency assessment for 2022 and 2023. 3. The CEO confirmed the findings above on 3/19/2024 at 1:00pm.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of 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 2023. Findings Include: 1. On the day of survey, 03/19/2024 at 11:02 am., review of the laboratory's API Microbiology PT records revealed that the laboratory did not verify the accuracy for the following analytes (Molecular resistance genes) that were not graded by the PT agency in 2023: 1st event: UTI Panel Molecular Resistance Genes-Urine (UTI-01 through UTI-05) - Class A Beta-lactamase (CTX-M Group 1), (KPC) - Trimethoprim (dFrA) - Oxacillin (mecA) - Fluoroquinolone (qnr) - Sulfonamide (sul) - Vancomycin A & B (vanA, vanB) 2nd event: - CTX-M Group 1, KPC, dFrA, qnr and sul (UTI-07, UTI-09) - mecA (UTI-06 through UTI-10) - vanA and vanB (UTI-06, UTI-08 through UTI-10) 3rd event: - CTX-M Group 1 and KPC (UTI-12 through UTI-14) - dFrA and sul (UTI-12 through UTI-15) - mecA (UTI-11 through UTI-15) - qnr (UTI-12, UTI-13) - vanA and vanB (UTI-11, UTI-12, UTI-14) 2. The API Proficiency Testing performance Evaluation form states "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 03/19/2024 at 1:00 pm.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). 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 2 of 3 API Microbiology testing events in 2023. Findings Include: 1. On the day of survey, 03/19/2024 at 11:02 am., review of the laboratory's API PT records revealed that the laboratory did not verify

	the accuracy for the following analytes (molecular bacteria-urine) that were not scored by the PT agency in 2023: - 1st event: Enterobacter cloacae (UTI-05) - 3rd event: Staphylococcus sp. (UTI-13) 2. The API Proficiency Testing performance Evaluation form states " 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 03/19/2024 at 1:00 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 twice a year the relationship between 2 of 2 Biorad CFX96 RT-PCR analyzers used for microbiology testing performed from 07/07 /2022 to the date of survey. Findings include: 1. On the day of survey, 03/19/2024, the laboratory failed to provide documentation of the biannual comparison studies for the following instruments used for Microbiology testing (molecular bacterial identification /resistance genes) performed from 07/07/2022 to 03/19/2024: - Biorad CFX96 RT-PCR analyzer (serial number CT057029) v. Biorad CFX96 RT-PCR analyzer (serial number CT005708). 2. The CEO confirmed the findings above on 03/19/2024 at 1:00 pm. *Repeat deficiency