Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0266676	01/31/2024
Name of Provider or Supplier	**Street Address, City, State**	
Urology Center Of Columbus Llc	1021 Talbotton Road, Columbus, GA	

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 recertification survey was performed on January 1, 2024. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. NOTE: The CMS-2567 (Statement of Deficiencies) is an official , legal document,. All information must remain unchanged except for entering the Plan Of Correction (POC), correction dates, and the signature space. Any discrepancy n the original deficiency citation(s) will be reported the the Georgia Regional Office (RO) for referral the Office of the Inspector General (OIG) for possible fraud if the information is inadvertently changed by the provide/supplier, the State Survey Agency (SA) should be notified immediately. Conditions: D-2016 Successful Participation 493.803 (a)(b)(c) D-6000 Moderate Complexity Laboratory Director 493.1403
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 the American Proficiency Institute (API) Proficiency Testing (PT) provider documents and staff interview the laboratory failed to sign attestation statements for 6 events in 2022, and the 6 events in 2023. Findings: 1. Based on review of the API PT documents for the Specialty Hematology events 1,2,and 3 and the Specialty Chemistry (Events 1, 2, and 3) in 2022, the the testing personnel (TP) and Laboratory Director (LD) failed to sign Attestation Statements confirming the testing of PT samples were handled in the same manner as patient samples were tested. Based on review of the API PT documents for the Specialty Hematology (Events 1, 2, 3) and the Specialty Chemistry (Events 1, 2, 3) in 2023, the TP and the LD failed to sign Attestation Statements confirming the testing of PT samples were

	handled in the same manner as patient samples were tested. 2. Interview with the Laboratory Supervisor, on January 31, 2024, in the breakroom, at approximately 1:30 pm, confirmed the above aforementioned statements.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) provider, the laboratory failed to provide documentation that the testing for Specialties Hematology and Chemistry, had been performed in the same manner as their patient testing, and failure to submit the 1st event for Specialty Hematology 2022. The Laboratory failed to meet all Condition Level requirements. CONDITION LEVEL: 493.803 (a)(b)(c) REFERENCE: D-2009 Testing of Proficiency Testing Samples D-2123 Hematology
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) provider documents and staff interview the laboratory failed to submit sample results for the Speciality Hematology for the 1st event in 2022. Findings: 1. Review of the API PT documents for the Specialty Hematology for the 1st event in 2022, the

	laboratory received a score of 0% in 2022 for failure to return testing results. 2. Staff interview with the Laboratory Manager, on January 31, 2024, at approximately 1:15 pm, in the break room, confirmed the above aforementioned statement.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT), the Laboratory Director (LD) failed to meet the Condition level of overall management and direction with the submission of PT sample results, and documenting that the laboratory had performed the PT sample testing the same as patient testing. CONDITION: 493.1403 Laboratory Director Responsibilites REFERENCE: D-6017
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) provider documents and staff interview the Laboratory Director (LD) failed to verify the Laboratory submited sample results for the Speciality Hematology for the 1st event in 2022. Findings: 1. Review of the API PT documents for the Specialty Hematology for the 1st event in 2022, the laboratory received a score of 0% in 2022 for failure to return testing results. 2. Staff interview with the Laboratory Manager, on January 31, 2024, at approximately 1:15 pm, in the break room, confirmed the above aforementioned statement.