Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D1023301	07/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Urology Associates Of Green Bay Sc	720 S Van Buren St Ste 301, Green Bay, WI	

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
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 surveyor review of Proficiency Testing (PT) records and interview with a testing person (Staff A), the laboratory did not verify the accuracy of unscored analytes in five of five events from event three in 2022 through event one in 2024. Findings include: 1. Review of the American Proficiency Institute (API) reports for microbiology events 2022-03 through 2024-01 showed each of the five events included results that the PT program had not evaluated. The reports stated, "Laboratories ... must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." The 2022 Microbiology third event included ten not graded results in the Molecular Resistance Genes - Urine section. The 2023 Microbiology first event included not graded results for Sample UTI-05 for Enterobacter cloacae and sample UTI-01 for Candida tropicalis and thirty-three not graded results in the Molecular Resistance Genes - Urine section. The 2023 Microbiology event two included twenty-five not graded results in the Molecular Resistance Genes - Urine section. The 2023 Microbiology event three included a not graded result for Ureaplasma urealyticum sample UTI-14 and thirty not graded results in the Molecular Resistance Genes - Urine section. The 2024 Microbiology event one included twenty-seven not graded results in the Molecular Resistance Gene - Urine section. The records showed no evidence the laboratory reviewed any of the not graded results. 2. Interview with Staff A on July 3, 2024, at 11:35 AM confirmed the laboratory did not review the not graded results to verify accuracy.

D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyor review of procedures, observation of the centrifuge in the laboratory, and interview with a testing person (Staff A), the laboratory did not perform a function check to verify one of three centrifuge settings to ensure the revolutions per minute (rpm) achieved for urine sample preparation for microscopic analysis was acceptable. Findings include: 1. Review of the procedure for urine microscopic analysis showed the laboratory required urine sample centrifugation at 1500 rpm prior to microscopic examination. 2. Observation of the laboratory centrifuge on July 3, 2024, at 10:15 AM showed the centrifuge had three settings with setting C identified for use with urine samples. The centrifuge had a label dated June 25, 2024, with function check results for one setting that showed the rpm target was 3622 rpm and the actual reading was 3702 rpm. The label did not identify which of the three centrifuge settings produced the documented reading. 3. Interview with Staff A on July 3, 2024, at 10:20 AM confirmed a contractor had checked the centrifuge speed recently. Further interview confirmed Staff A used setting C to centrifuge urine samples and confirmed the function check did not show the rpm required for urine microscopic testing was acceptable.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with a testing person

	(Staff A), records for the calibration verification of the PSA (Prostate Specific Antigen) test performed on the Tosoh AIA analyzer were not available for three of the last four scheduled verifications. Findings include: 1. Review of laboratory records revealed personnel performed PSA calibration verification testing in June 2024. Further review showed no records of the calibration verifications due in December 2022, June 2023, or December 2023. 2. Interview with Staff A on July 3, 2024, at 12: 30 PM confirmed they did not know where to find the records of calibration verification from December 2022 or the two events in 2023 for the PSA test.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with testing personnel (Staff A), the laboratory director did not ensure the laboratory created and followed an approved corrective action plan for three of three events with unacceptable PT results from event three in 2022 through event one in 2024. Findings include: Review of reports from the American Proficiency Institute (API) from event three in 2022 through event one in 2024 showed three of the events included results API graded as unacceptable. The unacceptable results for each event are shown as: Sample / reported result / expected result. Event 2022-03 UTI-05 / Escherichia coli detected / not detected. Event 2023-02 UTI-06 / Escherichia coli detected / not detected. UTI-06 / Resistance Gene KPC not detected / detected. UTI-06 / Resistance Gene qnr / detected / not detected. UTI-09 / Candida glabrata not detected / detected. Event 2024-01 UTI-03 / Streptococcus agalactiae not detected / detected. Further review of the records showed no evidence the laboratory reviewed the unacceptable results. 2. Interview with Staff A on July 3, 2024, at 11:35 AM confirmed the laboratory did not review the unacceptable results and did not develop or follow an approved corrective action plan for the unacceptable PT results.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on surveyor review of CMS (Centers for Medicare and Medicaid Services) forms and competence evaluation records, and interview with staff, the laboratory did not provide academic credentials for three of three new testing personnel to show they were qualified to perform moderate complexity testing. Findings include: 1. The laboratory did not show three of three new testing personnel met the academic qualification requirements for moderate complexity testing. See D6065.

D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form CMS-209 'Laboratory Personnel Report (CLIA)' and competence evaluation records, and interview with a testing person (Staff A) and the Practice Manager (Staff B), three of three new non-waived testing personnel did not have documentation that showed they met the academic qualification requirements to perform moderate complexity testing. Findings include: 1. Review of the Form CMS-209 submitted for this survey and signed by the laboratory director on July 2, 2024, showed the laboratory had one non-waived testing person (Staff A). 2. Review of competence evaluation records showed the laboratory had evaluated competence for three additional staff (Staff C, D, and E) for testosterone and PSA (Prostate Specific Antigen) testing using the Tosoh AIA analyzer. The laboratory documented the evaluation of competence for Staff C on October 24, 2023, and April 24, 2024, Staff D on January 3, 2024, and Staff E on March 26, 2024. 3. Interview with Staff A on July 3, 2024, at 12:15 PM confirmed Staff C, D, and E currently performed testing on the Tosoh AIA analyzer. 4. Interview with Staff B on July 3, 2024, at 12:45 PM confirmed academic credentials were not available to show the three testing personnel met the academic requirements for moderate complexity testing personnel.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on surveyor observation of supplies in the laboratory, review of test procedures and interview with a testing person (Staff A), one of one testing person that performed microscopic urinalysis used potassium hydroxide (KOH) solution for yeast identification and did not follow the laboratory's procedure. Findings include: 1. Observation of testing supplies in the laboratory on July 3, 2024, at 10:00 AM revealed a bottle of KOH solution (EDM3 brand) near the microscope. 2. Review of the urine microscopic procedure showed no instructions for testing personnel to use KOH solution for microscopic urinalysis. 3. Interview with Staff A on July 3, 2024, at 10:15 AM revealed they used the KOH for evaluation of yeast in urine samples.

	Further interview confirmed the procedure did not direct staff to use KOH and confirmed they had not followed the procedure as written.