

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D1023301	(X3) Date Survey Completed 09/16/2026
Name of Provider or Supplier Urology Associates Of Green Bay Sc	Street Address, City, State 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on surveyor review of the CMS (Centers for Medicare and Medicaid Services) Form 209 'Laboratory Personnel Report (CLIA)' and proficiency testing (PT) records, and interview with a testing personnel (Staff A), two of the four testing personnel who routinely perform patient testing did not perform PT sample testing in 2025 and 2026. Findings include: 1. Review of the CMS Form 209, signed by the laboratory director on September 8, 2026, showed four testing personnel (Staff A-D) perform moderate complexity testing in this laboratory. 2a. Review of proficiency testing records for API (American Proficiency Institute) surveys for PSA and testosterone testing showed Staff A performed the tests for the three events in 2025 and the first and second event in 2026. Records showed Staff B participated in analysis of the samples for the third event in 2026. There was no evidence Staff C and D participated in PT sample analysis. 2b. Review of proficiency testing records for API surveys for urine microscopy images showed Staff A performed the urine microscopy image identification for the two events in both 2025 and 2026. 3. During an interview with Staff A on September 16, 2026, at 10:15 AM, Staff A confirmed all four testing personnel on the CMS Form 209 routinely performed patient testing for PSA and testosterone, and Staff A and Staff B performed urine microscopy patient testing. The interview further confirmed Staff C and D did not perform PT sample analysis.
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 surveyor review of laboratory records and procedures and interview with a testing personnel (Staff A), the laboratory director did not delegate the responsibility for performing testing personnel (TP) competency assessments to two of two TP that performed assessments in 2026 and did not ensure the laboratory had policies to assess the performance of personnel who were delegated technical consultant responsibilities. Findings include: 1. Review of annual competency evaluation records for testing performed on the TOSOH AIA-360 documented on 'Testing Personnel Competency Evaluation Form' showed Staff B performed and evaluated Staff A's competency. Further review of records showed Staff A performed and evaluated annual competency of Staff B, Staff C, and Staff D in 2026. 2. Review of laboratory records showed no evidence that the director delegated the responsibility for performing testing personnel competency evaluation to Staff A and Staff B or that the laboratory director assessed these personnel to ensure they effectively performed the competency evaluations. 3. Review of procedure, 'Personnel Training and Competency Evaluation', showed no mechanism for assessing staff with delegated technical consultant responsibilities. 4. Interview with Staff A on September 16, 2026, at 12:10 PM confirmed the laboratory director did not delegate in writing the responsibility for performing testing personnel competency evaluations to Staff A and Staff B and confirmed the procedure did not address evaluation of delegated technical consultant responsibilities.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Item 1: Based on surveyor review of laboratory procedures and interview with a testing personnel (Staff A), the laboratory's two of two procedures for urine

	microscopic analysis failed to include step by step performance of the test. Findings include: 1. Review of the laboratory's procedure manual revealed a 'KOH procedure' and a 'Manual Urinalysis Microscopic Exam' procedure. Review of the procedures revealed the procedures did not include step by step performance of the urine microscopic test to show how the laboratory used the KOH reagent as part of the urine microscopic analysis. Further review of the KOH procedure revealed it did not include specimen type and the procedures did not reference each other. 2. Interview with Staff A on September 16, 2026, at 10:10 AM revealed the laboratory used KOH to identify yeast in urine and confirmed the procedures for urine microscopic testing did not include step by step performance of the urine microscopic test to show how the laboratory used the KOH reagent as part of the analysis. Item 2: Based on surveyor review of laboratory procedures and interview with a testing personnel (Staff A), the laboratory's two of two procedures for testing on the TOSOH AIA-360 failed to include the laboratory's system for entering results in the patient record and reporting patient results. Findings include: 1. Review of the laboratory procedures for prostate specific antigen (PSA) and testosterone, tests performed on the TOSOH AIA-360 revealed no evidence that the procedures contained the laboratory's system for entering results in the patient record and reporting patient results. 2. Interview with Staff A on September 16, 2026, at 2:20 PM confirmed the laboratory's procedures for PSA and testosterone testing did not include the laboratory's system for entering results into the patient record and reporting patient results.
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 surveyor review of procedures, observation of the centrifuge in the laboratory, and interview with a testing person (Staff A), the laboratory's function check of the one of one centrifuge used for urine sample preparation for microscopic analysis did not meet the requirements for revolutions per minute (rpm) as defined in the laboratory's procedure. 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 September 16, 2026, at 2:25 PM showed the centrifuge had three settings with setting C identified for use with urine samples. The centrifuge had three labels dated June 17, 2026, with function check results that showed the rpm actuals were 3626, 3321, and 1910 rpm. The labels did not identify which of the three centrifuge settings produced the documented readings. 3. Interview with Staff A on September 16, 2026, at 2:25 PM confirmed a contractor checked the centrifuge speed recently. Further interview confirmed testing personnel used setting C to centrifuge urine samples and confirmed the function check did not meet the rpm requirements in the procedure for urine microscopic testing. This is a repeat deficiency, previously cited on July 3, 2024.
D6010	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(2) (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by: Based on surveyor review of documented humidity readings in the laboratory and interview with a testing personnel (Staff A), the laboratory director did not ensure the laboratory met its established humidity range for 33 of 41 days in January and February 2026, two of two months reviewed. Findings include: 1. Review of the 'Temperature Log Daily' indicated the laboratory's acceptable humidity range was 20% to 80%. Review of the log records from January and February 2026, showed the laboratory documented daily humidity readings on working days. Testing personnel documented readings that were less than 20% for 33 of 41 days. 2. Interview with Staff A on September 16, 2026, at 11:00 AM confirmed the laboratory's acceptable humidity range was 20 to 80% and that the daily humidity readings were less than 20% for 33 of 41 days of the two months reviewed, and that the laboratory director did not ensure the laboratory met its humidity range.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) 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 a testing personnel (Staff A), the laboratory director did not ensure the laboratory followed an approved corrective action plan for one of three chemistry events in 2025 with unacceptable PT results. Findings include: 1. Review of reports from the American Proficiency Institute (API) PT program from event two in 2025 showed the laboratory received an unacceptable result on sample IA-10 for the testosterone test. 2. Review of the PT records showed the laboratory performed an investigation of the unacceptable result and documented it on the 'Proficiency Test Results Corrective Action Report'. There was no evidence that the laboratory director signed the 'Laboratory Director Evaluation' section of the form. 3. Interview with Staff A on September 16, 2026, at 1:50 PM confirmed the laboratory director did not sign the 'Laboratory Director Evaluation' section of the 'Proficiency Test Results Corrective Action Report' and the laboratory director did not ensure the laboratory followed an approved corrective action plan for the unacceptable PT results. This is a repeat deficiency previously cited on July 3, 2024.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on surveyor review of competency evaluations and interview with a testing personnel (Staff A), the technical consultant, who is also the laboratory director, did not evaluate testing personnel competency as defined in 42 CFR 493.1413(8)(i)-(vi) and 493.1413(9) for two of two testing personnel in performing microscopic analysis of urine samples. Findings include: 1. Review of laboratory records showed Staff A and B performed microscopic analysis of urine samples. 2. Review of competency evaluation records showed no documented evaluation of the six competency assessment procedures for Staff A and B for microscopic analysis of urine samples. 3. Interview with Staff A on September 16, 2026, at 10:10 AM confirmed the technical consultant did not evaluate and document competency evaluation for two of two testing personnel who performed microscopic analysis of urine samples. This is a repeat deficiency previously cited on October 17, 2022.