Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520888	02/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Urology Associates Of Idaho Falls	2375 Coronado St, Idaho Falls, ID	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the NanoEntek FREND manufacturer user manual, a lack of laboratory room temperature and humidity records and an interview with testing personnel 1 (TP1) on 2/9/2026, the laboratory failed to monitor the testing temperature and humidity for the NanoEntek FREND since moving in September 2025. The findings include: 1. A review of the user manual for the NanoEntek FREND analyzer identified an operational room temperature of 18-20 C and a humidity of 20-80%. 2. A review of the laboratory temperature log identified the laboratory failed to monitor room temperature and humidity per the NanoEntek FREND manufacturer requirements 22 of 22 working days in September 2025, 23 of 23 working days in October 2025, 18 of 18 working days in November 2025, 16 of 16 working days in December 2025, 20 of 20 working days in January 2026 and 6 of 6 working days in Feburary 2026. 3. An interview with TP1 on 2/9/2026 at 2:14 pm confirmed that the laboratory failed to monitor room temperatures and humidity since moving in September 2025. 4. The laboratory reports performing 2,300 prostate specific antigen tests on the NanoEntek FREND annually.
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. This STANDARD is not met as evidenced by: Based on a lack of documentation and an interview with technical consultant 1 (TC1) on 2/9/2026, the laboratory failed to evaluate prostate specific antigen (PSA) results performed on their three (3) NanoEntek FREND analyzers twice annually to ensure that results were within the allowed acceptable difference between the analyzers since 9/11/2023. The finding include: 1. A lack of documentation for analyte result comparison between the laboratory's three (3) NanoEntek FREND analyzers identified that the laboratory failed to evaluate test results for PSA two (2) of two (2) times in 2024 and two (2) of two (2) times in 2025 to ensure that test results were within the allowed acceptable difference between the three (3) analyzers. 2. An interview with TC1 on 2/9/2026 at 2:57 pm confirmed that the laboratory failed to compare analyte results between analyzers to ensure accurate patient testing. 3. The laboratory reports performing 2,300 PSA tests annually.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of laboratory patient test reports and an interview with testing personnel 1 (TP1) on 2/9/2026, the laboratory failed to include the new address of the performing laboratory since September 1, 2025. The findings include: 1. A review of laboratory patient test reports for prostate specific antigen (PSA) identified that the laboratory failed to change the address of the performing laboratory since moving in September 2025. 2. An interview with the TP1 on 2/9/2026 at 3:19 pm confirmed that the address was not changed after the move. 3. The laboratory reports performing 2,300 PSA test annually.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

	This STANDARD is not met as evidenced by: Based on a review of laboratory patient test reports and an interview with the testing personnel 1 (TP1) on 2/9/2026, the laboratory failed to include the reference or normal range for all prostate specific antigen (PSA) results on final patient reports since the last inspection on 4/23/2023. The findings include: 1. A review of laboratory patient reports for PSA testing identified that the laboratory failed to include the reference or normal ranges since their last inspection on 4/23/2023. . 2. An interview with TP1 on 2/9/2026 at 3:19 pm confirmed that this was the report provided to patients. 3. The laboratory reports performing 2,300 PSA tests annually.
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 a review of temperature logs, Proficiency Testing (PT) documents, a lack of documentation, and interviews with testing personnel 1 and technical consultant 1 on 2 /9/2026, the laboratory director failed to ensure that the instrument testing environment was acceptable, that PT graded results were acceptable, that instrument verifications were performed after a laboratory move, that instrument comparisons were performed between the three (3) NanoEntek FREND analyzers to ensure accurate and reliable patient results, and that the laboratory had an adequate quality assurance plan. See D6013, D6018, D6020.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on a review of the NanoEntek FREND instrument verification documentation and an interview with technical consultant 1 (TC1) on 2/9/2026, the laboratory director failed to ensure that verification of instrument performance specifications were performed for three (3) of three (3) analyzers after the laboratory moved locations before beginning patient testing in September 2025. The findings include: 1. A review of the instrument verification documentation for the three (3) NanoEntek FREND analyzers identified that the laboratory director failed to ensure that manufacturer performance specifications were verified after moving to a new location before beginning patient testing on September 1, 2025. 2. An interview with TC1 on 2 /9/2026 at 3:23 pm confirmed that the laboratory director failed to ensure instrument verifications were performed on the three (3) NanoEntek FREND analyzers prior to patient testing. 3. The laboratory reports performing 2,300 tests on the NanoEntek FREND analyzers annually.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)

	(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation from the American Proficiency Institute (API) and an interview with testing personnel 1 (TP1) on 2/9 /2026, the laboratory director failed to review PT results for one (1) of three (3) events in 2024 and 2025. The findings include: 1. A review of PT documents for 2024 from API identified that the laboratory director failed to review graded results for the specialty of chemistry for event two(2). 2. A review of PT documents for 2025 from API identified that the laboratory director failed to review graded results for the specialty of chemistry for event two (2). 3. An interview with TP1 on 2/9/2026 at 1:45 pm confirmed that the laboratory director failed review the above PT results. 4. The laboratory reports performing 2,300 prostate specific antigen tests annually
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on a review the laboratory's Quality Assurance (QA) Policy, temperature logs, lack of instrument comparison documentation, lack of instrument performance specification verification documentation and interviews with testing personnel 1 (TP1) and technical consultant 1 (TC1) on 2/9/2026, the laboratory director failed to ensure that there was an adequate QA policy in place to ensure accurate patient testing in 2024 and 2025. The findings include: 1. A review of the QA policy identified that the policy was not adequate to detect and correct issues in general laboratory systems, preanalytic systems, analytic systems and postanalytic systems. 2. A review of temperature logs identified that the laboratory director failed to ensure that room temperature and humidity records were taken from September 1, 2025 to February 9, 2026 and failed to ensure that the technical consultant had reviewed the logs monthly to identify and correct the error. See D5413 3. A lack of instrument comparison documentation identified that the laboratory director failed to ensure that the laboratory verified result consistency between the three (3) NanoEntek FREND analyzer twice annually since 9/11/2023. See D5775 4. A lack of instrument verification documentation identified that the laboratory director failed to ensure that performance specification verifications were performed after the laboratory move and before beginning patient testing September 1, 2025. See D6013 5. Interviews with TP1 and TC1 on 2/9/2026 confirmed the above findings. 6. The laboratory reports performing 2,300 tests annually.