Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2172589	01/06/2026
Name of Provider or Supplier	**Street Address, City, State**	
Urology Partners Of North Texas, Pllc	5005 S Cooper St Suite 250, Arlington, TX	

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	An onsite recertification survey was conducted on 01/06/2026. The facility was found to be out of compliance with CLIA regulations 42 CFR Part 493. CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.801 Enrollment and testing of samples 493.1441 Laboratory Director, high complexity
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the CMS (Center for Medicare & Medicaid Services) 116 form, API (American Proficiency Institute) 2025 catalog, 155 CASPER (Certification and Survey Provider Enhanced Reporting) report, proficiency testing records, and confirmed in staff interview, the laboratory failed to meet the requirements of enrollment in proficiency testing for one of one subspecialty (Virology) in 2025 and to the date of the survey in January 2026. Findings included: 1. Review of the CMS 116 form submitted on the day of the survey listed the subspecialty of virology to include molecular testing for the following viruses on their UTI (urinary tract infection) panel: BK Virus (Human Polyomavirus 1) JC Virus (John Cunningham /Human Polyomavirus 2) HSV 1/2 (Herpes Simplex Virus) Adenovirus CMV (Cytomegalovirus) 2. Review of the API 2025 catalog revealed the proficiency testing company offered a molecular virology program. The API catalog stated: "Laboratories

	enrolling in programs to satisfy CMS requirements for PT are responsible for ensuring they are testing five samples, three times per year." 3. Review of the 155 CASPER report and the laboratory's proficiency testing records revealed no proficiency testing scores for the virology subspecialty. 4. During an interview, in the office, on 01/06 /2026 at 10:54 a.m., the Laboratory Supervisor was asked to provide proficiency testing enrollment records for 2025. She stated that the UTI panel that the facility was enrolled in with the proficiency testing company did not include virology testing, confirming the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, patient records, and confirmed in interview, the laboratory failed to ensure hematology reagents did not exceed their expiration dates prior to patient CBC (complete blood count), hemoglobin and hematocrit testing for 2230 of 2230 patients from October 23, 2025, through January 6, 2026. Findings included: 1. During a tour of the laboratory on 01 /06/2026 at 2:30 p.m., the surveyor observed the following in a cabinet in the hematology section of the laboratory: One opened box containing eight Cellclean Auto tubes; lot #A4169 expiration date 10/22/2025. One unopened Cellclean Auto box; lot #A4169 expiration date 10/22/2025. 2. During an interview, in the laboratory, on 01/06/2026 at 2:38 p.m., Testing Person-4 was asked if the laboratory had any other Cellclean Auto reagents that were available for use. She stated that the Cellclean Auto in the cabinet were the only ones available for use in patient testing. 3. Review of laboratory records identified 2230 patients from October 23, 2025, through January 6, 2026, who had CBC, hemoglobin or hematocrit testing using the expired Cellclean Auto reagents. The following is a random sampling of patients who were tested for CBC, hemoglobin or hematocrit using Cellclean Auto reagents that had exceeded their expiration dates: Test date: 12/04/2025 Patient ID: 919000; test: CBC Test date: 12/08 /2025 Patient ID: 2311920; test: CBC Test date: 12/09/2025 Patient ID: 126390; test: CBC Test date: 12/10/2025 Patient ID: 898440; test: CBC Patient ID: 1475030; test: CBC Test date: 12/11/2025 Patient ID: 2346600; test: CBC Patient ID: 244190; test: hemoglobin and hematocrit Test date: 12/12/2025 Patient ID: 136850; test: hemoglobin and hematocrit Test date: 12/16/2025 Patient ID: 2353320; test: CBC Test date: 12/18/2025 Patient ID: 57020; test: CBC The laboratory failed to ensure hematology reagents did not exceed their expiration dates prior to patient testing. 4. During an interview, in the office, on 01/06/2026 at 2:42 p.m., the Laboratory Supervisor confirmed the laboratory failed to ensure hematology reagents did not exceed their expiration dates prior to patient testing.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that

	perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory's temperature log and confirmed in interview, the laboratory failed to document corrective action when refrigerator temperature ranges were not within the laboratory's specifications for 40 of 123 days in 2025 (January-June). Findings included: 1. Review of the laboratory's "TEMPERATURE MIN /CURRENT/MAX VERIFICATION AND PM LOG - BI-ANNUAL" from January 2025 through June 2025 revealed the laboratory had an established acceptable temperature range of 2 degrees C to 8 degrees C for the reagent refrigerator. Further review of the laboratory's temperature log revealed 40 of 123 days in 2025 when the refrigerator temperature exceeded the laboratory's acceptable range of 2 degrees C to 8 degrees C and no corrective action was documented as follows under the "Max" temperature column: 01/30/2025: 9 C 01/31/2025: 9 C 02/04/2025: 9 C 02/05/2025: 9 C 02/06/2025: 9 C 02/10/2025: 9 C 02/11/2025: 9 C 02/12/2025: 9 C 02/13/2025: 9 C 02/14/2025: 9 C 02/17/2025: 9 C 02/19/2025: 9 C 02/20/2025: 9 C 02/21/2025: 9 C 02 /24/2025: 9 C 03/14/2025: 9 C 03/17/2025: 9 C 04/14/2025: 9 C 04/15/2025: 9 C 04 /16/2025: 9 C 04/17/2025: 9 C 04/25/2025: 9 C 05/06/2025: 9 C 05/07/2025: 9 C 05 /12/2025: 9 C 05/16/2025: 9 C 05/19/2025: 9 C 05/23/2025: 9 C 05/29/2025: 9 C 05 /30/2025: 9 C 06/02/2025: 9 C 06/03/2025: 9 C 06/04/2025: 10 C 06/05/2025: 9 C 06 /06/2025: 9 C 06/06/2025: 9 C 06/16/2025: 9 C 06/17/2025: 9 C 06/20/2025: 9 C 06 /23/2025: 9 C 2. During an interview, in the office, on 01/06/2026 at 2:42 p.m., the Laboratory Supervisor, after a review of records, confirmed the laboratory failed to document corrective action when room temperature ranges were not within the laboratory's specifications for 40 of 123 days in 2025 (January-June). Word Key: MIN - minimum MAX - maximum PM - preventative maintenance C - Celsius
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 review of Centers for Medicare and Medicaid Services (CMS) 209 form, laboratory testing personnel competency in 2024 and 2025, and confirmed in interview, revealed the Technical Consultant (TC-1) failed to evaluate the competency of one of four testing persons performing moderate complexity testing in 2024 and 2025. Findings Included: 1. Review of CMS-209 form submitted at time of survey, 01 /06/2026, revealed the following laboratory personnel performing moderate complexity testing: a. Technical Consultant 1 (TC-1) b. Testing Person 1 (TP-1) c. Testing Person 2 (TP-2) d. Testing Person 3 (TP-3) e. Testing Person 4 (TP-4) 2. Review of laboratory personnel annual competencies in 2024 and 2025, revealed TC-1 failed to evaluate the annual competency of one of four testing personnel (TP-1) performing moderate complexity testing. 3. In an interview on 01/06/2025 at 10:25

	AM in the facility office space, the laboratory director confirmed the Technical Consultant (TC-1) failed to evaluate the competency of one of four testing persons performing moderate complexity testing in 2024 and 2025.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS (Center for Medicare & Medicaid Services) 116 form, API (American Proficiency Institute) 2025 catalog, 155 CASPER (Certification and Survey Provider Enhanced Reporting) report, proficiency testing records, and confirmed in staff interview, laboratory director failed to enroll in a proficiency testing program for one of one subspecialty (Virology) for which it seeks certification in 2025 and to the date of the survey in January 2026. Refer to D6088.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on review of the CMS (Center for Medicare & Medicaid Services) 116 form, API (American Proficiency Institute) 2025 catalog, 155 CASPER (Certification and Survey Provider Enhanced Reporting) report, proficiency testing records, and confirmed in staff interview, the laboratory director failed to enroll in a proficiency testing program for one of one subspecialty (Virology) for which it seeks certification in 2025 and to the date of the survey in January 2026. Refer to D2000.