Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0519139	10/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Urological Associates Of Western Colorado	2373 G Road, Suite 200, Grand Junction, CO	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures manual, and an interview with the general supervisor (GS), the laboratory failed to establish policies and procedures to ensure laboratory safety from physical, chemical, biochemical, electrical, and biohazardous materials since the last recertification survey was conducted on January 27, 2022. Findings include: 1. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish policies and procedures to ensure laboratory safety from physical, chemical, biochemical, electrical, and biohazardous materials. 2. An interview with the GS on October 16, 2024, at approximately 2:15 PM, confirmed the laboratory failed to establish policies and procedures to ensure laboratory safety from physical, chemical, biochemical, electrical, and biohazardous materials. 3. The laboratory performs approximately 7,800 tests annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's policies and procedures manual, and an interview with the general supervisor (GS), the laboratory failed to include requirements in their policies and procedures manual for patient preparation, specimen collection, conditions for specimen transportation, specimen acceptability and rejection criteria, and specimen referral for their urine PCR and rectal PCR assays. The laboratory also failed to include the reportable range, interfering substances, reference range, and critical or panic values for their urine PCR and rectal PCR assays, and failed to establish a course of action to take if a test system because inoperable in their policies and procedures manual since the last recertification survey was conducted on January 27, 2022. Findings include: 1. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish and follow written policies and procedures for patient preparation for their urine PCR assay, or rectal swab PCR assay. 2. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish and follow written policies and procedures for specimen collection for their urine PCR assay, or rectal swab PCR assay. 3. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish and follow written policies and procedures for conditions for specimen transportation for their urine PCR assay, or rectal swab PCR assay. 4. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish and follow written policies and procedures for specimen acceptability and rejection criteria for their urine PCR assay, or rectal swab PCR assay. 5. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish and follow written policies and procedures for specimen referral for their urine PCR assay, or rectal swab PCR assay. 6. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to include or establish a reportable range for their urine PCR assay, or rectal swab PCR assay. 7. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to include or establish interfering substances for their urine PCR assay, or rectal swab PCR assay. 8. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to include or establish a reference range for their urine PCR assay, or rectal swab PCR assay. 9. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to include or establish critical, or panic values for their urine PCR assay, or rectal swab PCR assay. 10. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to include or establish a policy or procedure of what course of action to take if a test system is inoperable in the laboratory. 11. An interview with the GS, on October 16, 2024, at approximately 11:00 AM, confirmed that the laboratory failed to establish and follow written policies and procedures for patient preparation, specimen collection, conditions for specimen transportation, specimen acceptability and

	rejection criteria, and specimen referral for their urine PCR and rectal PCR assays, and also failed to include the reportable range, interfering substances, reference range, and critical or panic values for their urine PCR and rectal PCR assays, and failed to establish a course of action to take if a test system becomes inoperable in their policies and procedures manual.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality assessment (QA) plan, and an interview with the general supervisor (GS), the laboratory failed to follow or establish written policies and procedures for an ongoing mechanism to monitor, and when indicated correct problems identified in the postanalytic system since the last recertification survey was conducted on January 27, 2022. Findings include: 1. Based on a review of the laboratory's QA plan, the laboratory failed to follow or establish written policies and procedures for an ongoing mechanism to monitor their postanalytic system spreadsheet, which calculates quality control (QC) acceptability and patient results, and when indicated correct problems identified in the postanalytic system. 2. An interview with the GS, on October 16, 2024, at approximately 2:00 PM, confirmed that the laboratory failed to follow or establish written policies and procedures for an ongoing mechanism to monitor their postanalytic system spreadsheet, which calculates quality control (QC) acceptability and patient results, and when indicated correct problems identified in the postanalytic system. 3. The laboratory performs approximately 7,800 tests annually.
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 the deficiencies cited herein, the Condition of Laboratories Performing High Complexity Testing; Laboratory Director was not met. The laboratory director failed to ensure verification procedures used are adequate to determine the accuracy, precision, reference range, and interfering substances of the laboratory's laboratory developed test method (see D6086), failed to ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action (see D6091), and failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results (see D6107).

D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on a review of the laboratory's verification procedure for their laboratory developed test (LDT) rectal swab PCR assay, an observation of the materials used during the verification of their LDT for the rectal swab PCR assay, and an interview with the general supervisor (GS), the laboratory director failed to ensure the laboratory adequately verified the accuracy, precision, reference range, and interfering substances of their LDT rectal swab PCR assay. Findings include: 1. Based on a review of the laboratory's verification procedure for their LDT rectal swab PCR assay, the laboratory director failed to ensure the laboratory failed to adequately verify the accuracy, precision, reference range, and interfering substances of their LDT rectal swab PCR assay by failing to use the same sample matrix, or simulated sample matrix as the intended specimen type for the assay by utilizing swabs inoculated with urine and spiked with reference organisms during the performance of the verification procedure. 2. An observation on October 16, 2024, at approximately 2:45 PM, of the materials the laboratory used to perform the verification of accuracy, precision, reference range, and interfering substances of their LDT rectal swab PCR assay revealed the laboratory used swabs inoculated with urine spiked with reference organisms instead of feces or simulated fecal material during the performance of the verification procedure. 3. An interview with the GS on October 16, 2024 at approximately 2:50 PM, confirmed that the laboratory director failed to ensure the laboratory adequately verified the accuracy, precision, reference range, and interfering substances of their LDT rectal swab PCR assay by failing to use the same sample matrix, or simulated sample matrix as the intended specimen type for the assay by utilizing swabs inoculated with urine and spiked with reference organisms during the performance of the verification procedure.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, and an interview with the general supervisor (GS), the laboratory director (LD) failed to ensure that PT result evaluations were being evaluated for successful performance, and that any problems requiring corrective action were identified since the laboratory began the molecular UTI PT events in 2023. Findings include: 1. Based on a review of the laboratory's PT records, result evaluation forms were not being signed or reviewed by the LD for successful performance since PT began in 2023 for molecular UTI PT events. 2. Based on a review of the laboratory's PT results, when the laboratory had scores below 100% for their molecular UTI PT events, no corrective actions were documented by the LD. 3. An interview with the GS, on October 16,

	2024, at approximately 12:00 PM, confirmed that the LD had not signed, or reviewed the PT result evaluation forms for successful performance, and that any problems requiring corrective action were not identified or documented since the laboratory began the molecular UTI PT events in 2023.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures manual, a review of personnel records, and an interview with the general supervisor (GS), the laboratory director failed to specify, in writing the specific duties of each consultant, supervisor, and individual responsible for the performance of preanalytic, analytic, and postanalytic phases of testing, or what procedures each individual is authorized to perform, whether supervision is required during specimen processing, test performance, or result reporting and whether supervisory or director review is required prior to reporting patient test results since the laboratory's last recertification survey was conducted on January 27, 2022. Findings include: 1. Based on a review of the laboratory's policies and procedures manual, the laboratory director failed to specify, in writing the specific duties of each consultant, supervisor, and individual responsible for the performance of preanalytic, analytic, and postanalytic phases of testing, or what procedures each individual is authorized to perform, whether supervision is required during specimen processing, test performance, or result reporting and whether supervisory or director review is required prior to reporting patient test results. 2. Based on a review of the laboratory's personnel records, the laboratory director failed to specify, in writing the specific duties of each consultant, supervisor, and individual responsible for the performance of preanalytic, analytic, and postanalytic phases of testing, or what procedures each individual is authorized to perform, whether supervision is required during specimen processing, test performance, or result reporting and whether supervisory or director review is required prior to reporting patient test results. 3. An interview with the GS, on October 16, 2024 at Approximately 10:30 AM, confirmed that the the laboratory director failed to specify, in writing the specific duties of each consultant, supervisor, and individual responsible for the performance of preanalytic, analytic, and postanalytic phases of testing, or what procedures each individual is authorized to perform, whether supervision is required during specimen processing, test performance, or result reporting and whether supervisory or director review is required prior to reporting patient test results.