Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0607216	(X3) Date Survey Completed 10/03/2025
Name of Provider or Supplier Urology Associates Of Silicon Valley	**Street Address, City, State** 2460 Samaritan Dr, San Jose, CA	

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
D3003	FACILITIES CFR(s): 493.1101(a)(2) (a)(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's workspace and workflow, and interview with the laboratory testing person on October 3, 2025, at 12:04 p.m., the laboratory failed to minimize sample contamination. The findings include: 1. The laboratory performed PCR test to detect various microorganisms in the patients' urine sample. The test method utilizes manual sample preparation, nucleic acid extraction and signal detection with the PCR instrument. The laboratory's equipment and spaces are poorly arranged and that prevents a unidirectional workflow to minimize contamination. Therefore, patients' samples may have potentially cross contaminated and affected patient care. 2. The laboratory director on October 3, 2025, at 12:04 p.m., affirmed that the laboratory's work process has the potential of sample cross contamination. 3. The laboratory's testing declaration form, signed by the laboratory director on 9/26 /2025 stated that the laboratory performed approximately 1,500 tests, annually.
D3005	FACILITIES CFR(s): 493.1101(a)(3) (a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by:

	Based on Surveyor review of laboratory's workflow, and interview with the laboratory testing person on October 3, 2025, at 12:04 p.m., the laboratory failed to maintain a uni-directional workflow and use separate areas for specimen preparation, PCR amplification, product detection, and reagent preparation. The findings include: 1. The laboratory used Applied Biosystem's Taqman microbial array PCR method to detect microorganisms in the patient's urine sample. The method includes nucleic acid extraction, reagent preparation, PCR amplification and signal detection. The laboratory performed all the steps in a single room that measured approximately 80 sq. ft. It extracted nucleic acid with the Kingfisher semi-automated instrument. It used the extracted nucleic acid with the amplification reagents to make PCR plate on the bench top. Then, it amplified the PCR plate using Quantstudio 12k flex instrument from ABI. The laboratory personnel moved the sample back and forth within the room throughout the procedure and did not maintain a unidirectional workflow. Unidirectional workflow refers to the manner in which testing personnel and patient specimens move through the molecular testing process to prevent cross-contamination, and consists of separate areas for the reagent preparation, pre-amplification area for specimen preparation and amplification reaction set up, and post-amplification area for specimen amplification, product detection, and storage or disposal of amplified products. Therefore, the quality of the patients' test results rendered by the laboratory cannot be assured and may have harmed patients. 2. The laboratory director on October 3, 2025, at 12:04 p.m., affirmed that the laboratory did not follow a unidirectional workflow for the PCR amplification procedure. 3. The laboratory's testing declaration form, signed by the laboratory director on 9/26/2025 stated that the laboratory performed approximately 1,500 tests, annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, workflow, patient test records and interview with the laboratory testing person on October 3, 2025, at 12:04 p.m., the laboratory director failed to assure laboratory's compliance with the applicable regulations and potentially harmed patients. The findings include: See D3003, and D3005.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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 laboratory's workflow and interview with the laboratory testing person on October 3, 2025, at 12:04 p.m., the laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory are appropriate for the test. The findings include: See D3005.