Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2172591	11/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Arizona State Urology Llc	6525 W Sack Drive Suite 201, Glendale, AZ	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on lack of proficiency testing (PT) attestation statements for review from 2022 to 2024 and interview with the laboratory director (LD), the laboratory failed to provide evidence of the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens. Findings include: 1. The laboratory performs testing under the speciality of Microbiology with an annual test volume of 15,000. 2. The laboratory participates in three PT events annually for all testing performed under the specialty of Microbiology. 3. During the survey on 11/06 /24, the laboratory failed to provide evidence of the signed PT attestation statements for the first and second PT events of 2024, and third event of 2023. 4. The lab director or designated technical consultant failed to sign the attestation statement from the first PT event of 2022. 5. The LD interviewed on 11/06/24 at 12:30 PM confirmed the attestation statements indicated above were either not available for review or did not contain the appropriate signatures at the time of the survey.

D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of Proficiency Testing (PT) records and interview with the laboratory director (LD), the laboratory failed to retain PT records for the third event of 2022 for testing performed under the specialty of Microbiology. Findings include: 1. No documentation for the third PT event of 2022 was presented including PT worksheets, instrument print outs, signed attestation statements, and final PT results and scores 2. The LD interviewed on 11/6/24 at 12:30 PM confirmed that the documentation indicated above could not be located.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records from 2022 through 2024 and interview with the laboratory director (LD), the laboratory failed to provide a documented review of PT results from the 2nd testing event of 2024, 3rd testing event of 2023, and 1st and 2nd testing events of 2022. Findings include: 1. The laboratory participates in PT for all testing performed under the specialty of Microbiology. The laboratory performs 1,500 tests annually. 2. No evidence, either by written comment or signature, was presented during the survey conducted on 11/6/2024 to indicate the laboratory director or other laboratory personnel reviewed the PT results for the 2nd testing event of 2024. 3. No evidence, either by written comment or signature, was presented during the survey conducted on 11/6/2024 to indicate the laboratory director or other laboratory personnel reviewed the PT results for the 3rd testing event of 2023. 4. No evidence, either by written comment or signature, was presented during the survey conducted on 11/6/2024 to indicate the laboratory director or other laboratory personnel reviewed the PT results for the 1st and second testing events of 2022. 5. The LD interviewed on 11/26/24 at 12:30 PM confirmed the PT results indicated above were not reviewed by laboratory personnel.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of established quality assessment (QA) policies and procedures and interview with the laboratory director (LD), the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the general

	laboratory systems requirements specified at 493.1231 through 493.1236. Findings include: 1. No QA documentation was provided for review during the survey conducted on 11/6/2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the general laboratory system requirements specified at 493.1231 through 493.1236, including but not limited to Proficiency Testing. 2. The LD interviewed on 11/6/2024 at 1:00 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the general laboratory systems requirements.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 review of temperature records from 2022 to 2024, review of the manufacturer's specifications for the Quantstudio 5 analyzer and interview with the laboratory director (LD), the laboratory failed to monitor and document the temperature of the room where testing is performed for 2 of 3 days of patient testing. Findings include: 1. The laboratory utilizes the Quantstudio 5 analyzer to perform high-complexity Polymerase Chain Reaction (PCR) testing on patient specimens under the specialty of Microbiology with an annual test volume of 15,000. 2. The manufacturer's specifications for the Quantstudio 5 reviewed during the survey listed an operating room temperature range of: 15C to 30C (59F to 86F) 3. The laboratory failed to provide documention demonstrating the room temperature where the Quantstudio 5 analyzer is utilized was monitored and recorded on 2 of 3 testing dates reviewed during the survey: 6/27/22 and 7/23/24. 4. The number of patients tested on the dates indicated above could not be determined at the time of the survey. 5. The LD interviewed on 11/6/2024 at 1:30 PM confirmed the laboratory failed to monitor and document the room temperature as indicated above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures and interview with the laboratory director (LD) the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1256 and 493.1281 through

	493.1289. Findings include: 1. No QA documentation was provided for review during the survey conducted on 11/6/2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the analytic systems specified at 493.1251 through 493.1256 and 493.1281 through 493.1289. 2. The LD interviewed on 11/6/2024 at 2:00 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the analytic systems.