Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2172591	01/25/2022
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
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of established performance specification documentation for the Laboratory Developed Test (LDT), Urinary Tract Infections (UTI) by PCR, used to test patient urine specimens and interview with the facility personnel, the laboratory failed to demonstrate the effects of the patients' clinical conditions, disease states, and medications as interfering substances that may effect the analytical specificity of the test system. Findings include. 1. During the survey conducted on January 25, 2022, no documentation was included in the establishment of performance specifications for the UTI PCR test indicating if the patients' clinical conditions, disease states, and any common medications may effect and/or inhibit the analytical specificity of the test system. 2. The facility personnel acknowledged that there was no specific analysis performed that included the effects of the patients' clinical conditions, disease states and common medications as possible interfering substances that may effect analytical specificity of the test system. 3. The laboratory started patient testing using the LDT, UTI by PCR in March 2020 and has an approximate annual test volume of 54,000.

D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's established IQCP (Individualized Quality Control Plan) for the UTI PCR lab-developed test, review of Quality Control (QC) documentation, review of the UTI PCR test procedure and interview with the Laboratory Director, (A) the laboratory's Quality Control Plan (QCP) does not reflect the QC procedure performed by the laboratory; (B) the IQCP does not include a Quality Assessment (QA) plan. Findings include: 1. The laboratory started patient testing using the Lab-Developed Test (LDT), UTI by PCR, in March 2020 and has an approximate annual test volume of 54,000. The laboratory developed and implemented an IQCP for this test. A2. Review of the laboratory's QCP listed in the IQCP indicated that QC on the UTI Taqman Array Card includes a negative control performed on each card run and a Positive (B. atrophaeus) control with every sample. A3. Review of the Quality Control section located in the laboratory's test procedure titled, "Extraction Procedure for UTI qPCR Analysis" stated, "Taqman Urinary Tract Microbia Amplification Control contains a linearized multi-target plasmid with target sequences for each available urinary tract microbiota profiling assay. It can be included in profiling experiments as a positive control and for troubleshooting. It will be included on the first UTI card run monthly, after background calibration, as a stand alone sample at real-time PCR and carried through the remainder of the workflow." A4. No evidence was presented for review to indicate the monthly positive control indicated above was included in the laboratory's QCP, as part of the IQCP. A5. During an interview with the laboratory director, it was confirmed that the laboratory was performing the monthly positive control referenced above and the laboratory failed to include the monthly control requirement in the QCP. B1. The laboratory chose to develop an IQCP for UTI PCR testing performed on the ThermoFisher Quant Studio 12K Flex analyzer. As required in the CLIA regulations, an IQCP must include three parts: a Risk Assessment (RA), a Quality Control Plan (QCP), and a Quality Assessment (QA) plan. B2. The IQCP presented for review during the survey conducted on 1/25/2022 failed to include a QA plan. B3. The laboratory director acknowledged that the IQCP developed by the laboratory failed to include a QA plan.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 review of IQCP documents and procedures specific to the laboratory's established Quality Control Plan for testing performed on the ThermoFisher Quant Studio 12K Flex instrument, the laboratory director failed to ensure that quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5445 for findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 lack of quality assessment (QA) policies and procedures required as part of the IQCP established by the laboratory, the laboratory director failed to ensure that a QA program is established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5445 for findings.