Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2062835	06/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Urologic Surgeons Of Arizona, Plc	1234 S Power Rd Ste 102, Mesa, 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
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 lack of quality control (QC) documentation for review and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency established by the laboratory. Findings include: 1. The laboratory began patient testing in the sub-specialty of Bacteriology on May 7, 2019, with an estimated annual test volume of 25,974. The laboratory utilizes the Life Technologies Quant Studio 3 to perform a lab-developed test (LDT) to test for 18 UTI Pathogens and 8 ABX Resistance Markers on urine samples. 2. It is the practice of the laboratory to perform weekly and daily QC. The laboratory's established policy for weekly QC states, "An analytical run begins with a weekly calibration plate containing: 1) One set of positive controls (each one containing Taq polymerase, reverse transcriptase, Primers and probe for each pathogen and the endogenous control containing known amounts of DNA and RNA templates); 2) One set of no template controls (containing Taq polymerase, reverse transcriptase, Primers and probe for each pathogen and the endogenous control, no template DNA or RNA is included). 3. No weekly QC documentation (as described above in #2) was provided for review during the survey conducted on June 30, 2021 to indicate the laboratory performed weekly QC procedures for the week of 8/4/2019 through 8/11/2019.

	Approximately 13 patient samples were tested during this time period. 4. One patient report reviewed during the survey from testing that occurred on 8/06/2019 (Specimen# A19-260) and lack of the corresponding weekly QC records confirmed that the weekly QC was not performed during the week of 8/04/19 through 8/11/19. 5. The facility personnel confirmed that the laboratory failed to perform and document weekly QC during the time period 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 review of Quality Assessment (QA) documentation, Quality Control (QC) records, and interview with the facility personnel, the laboratory failed to identify and correct problems associated with Quality Control performance. Findings include: 1. The laboratory began patient testing in the sub-specialty of Bacteriology on May 7,2019, with an estimated annual test volume of 25,974. The laboratory utilizes the Life Technologies Quant Studio 3 to perform a lab-developed test (LDT) to test for 18 UTI Pathogens and 8 ABX Resistance Markers on urine samples. 2. The laboratory's established QA policy states, "Quality Control results should be monitored daily for out-of-limits results by the person performing the assay. If any problem is noted, the Laboratory Director and/or qualified personnel must review it and corrective action must be appropriately documented....A summary of the monthly quality control performance (mean, SD, CV) will be prepared and cumulative control data is reviewed by the Laboratory Director or qualified laboratory personnel." 3. During the survey conducted on June 30, 2021, the laboratory presented evidence of a Corrective Action Documentation Log completed on 8/13/19 by laboratory staff to identify the failure found with the lack of weekly QC results from the week of 8/04/19 through 8 /11/19, see D5445 for specific findings. The log listed the problem as resolved with the resolution recorded by the laboratory as "ensure weekly QC is done by the end of the week by setting reminder", however the corrective action log and the error was not reported to or reviewed by the laboratory director and/or qualified personnel as indicated in laboratory policy and the corrective action submitted for review did not address patient outcome associated with the failure to perform weekly QC. 4. The QA policies and procedures reviewed during the survey failed to include a mechanism to monitor, assess, and correct problems identified with QC performance, specifically to identify whether or not daily and weekly QC was performed in accordance with established laboratory policy each day of patient testing, rather than only assessing the acceptability of results from QC that was performed by the laboratory. 5. The facility personnel acknowledged that the corrective action referenced above failed to address patient outcome and the laboratory's QA process at the time of the survey failed to identify whether or not QC was performed each day of patient testing.
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 lack of quality control records and review of control procedures, the laboratory director failed to ensure that quality control programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5445 for findings.