Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473725	07/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Urologic Specialists Of Oklahoma Inc	10901 E 48th St South, Tulsa, OK	

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
D0000	The recertification survey was performed on 07/16/19 and 07/17/19. The findings were reviewed with laboratory manager and the microbiology general supervisor at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
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 a review of records and interview with the laboratory manager, the laboratory director failed to sign proficiency testing attestation statements for 2 of 11 testing events. Findings include: (1) On the first day of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records and identified the following for 2 of 11 events: (a) First 2019 Chemistry Miscellaneous Event - The attestation statement had not been signed by the laboratory director; (b) First 2019 Microbiology Event - The attestation statement had not been signed by the laboratory director. (2) The surveyor reviewed the findings with the laboratory manager, who stated the attestation statements had not been signed by the laboratory director.

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 a review of records and interview with the laboratory manager, the laboratory failed to review and evaluate proficiency testing results for 1 of 11 testing events. Findings include: (1) On the first day of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2019 Chemistry Core Event (i) Alkaline Phosphatase - 5 of 5 results exhibited a negative bias (aa) CH-01 - SDI of -3.6 (bb) CH-02 - SDI of -3.4 (cc) CH-03 - SDI of -3.5 (dd) CH-04 - SDI of -2.2 (ee) CH-05 - SDI of -2.9 (2) The surveyor further reviewed the records and could not locate documentation verifying the biases had been identified and addressed; (3) The surveyor then reviewed the records with the laboratory manager, and asked if the biases had been addressed. The laboratory manager stated the biases had not been addressed.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and microbiology general supervisor, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results for 1 of 11 events. Findings include: (1) On the first day of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Microbiology (i) 2018 Second Event (aa) UR- 10 Urine Colony Count (A Quantitative Loop with any agar) (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded result; (3) The surveyor asked the laboratory manager and microbiology general supervisor if the result had been documented as evaluated. The laboratory manager and microbiology general supervisor reviewed the records and stated the non-graded result had not been documented as reviewed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or

	examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the laboratory manager, the laboratory failed to follow their written procedures. Findings include: HEMATOLOGY CALIBRATION (1) On the first day of the survey, the laboratory manager stated to the surveyor CBC (Complete Blood Count) testing was performed using the Beckman Coulter Act Diff 2 analyzer; (2) The surveyor reviewed the written procedure titled, "Calibration Guidelines" which stated: (a) "All moderate complexity analyzers must be calibrated at least every six months or more often it recommended by the manufacturer; (b) "Hematology - Our calibrators are shipped to us every six months on a standing order through Henry Schein". (3) The surveyor then reviewed 2017 through 2019 calibration records for the analyzer. There was no evidence a calibration had been performed every six months as required by policy. Calibration had not been performed: (a) Between 08/21/17 and 02/05/19 (due January 2019) (4) The surveyor reviewed the findings with the laboratory manager. The laboratory manager stated calibrations had not been performed every six months as indicated above. CENTRIFUGE FUNCTION CHECK FOR RPM (1) On the second day of the survey, the laboratory manager stated the following: (a) Urine Microscopic testing was performed as a PPM (Provider Performed Microscopy) procedure on the first floor of the facility at 11 stations, denoted as Pods (Pod A, Pod B, Pod C, Pod D, Pod E, Pod F, Pod G, Pod H, Pod J, Pod K, and the Procedure Area Pod); (2) The surveyor reviewed the written procedure title, "Centrifuge Use and Maintenance" which stated: (a) "After initial placement the lab will verify the speed every six months and the timer every three months or anytime the speed or time is questioned". (3) The surveyor then reviewed 2017 through 2019 centrifuge records and identified the following: (a) Speed - Checks had not been performed for each centrifuge in each pod between 07/17/17 and 04/29/19 (b) Time - Checks had not been performed for each centrifuge in each pod between 07/17/17 and 04/29/19 (4) The surveyor reviewed the findings with the laboratory manager. The laboratory manager stated the procedure had not been followed as indicated above. CENTRIFUGE FUNCTION CHECK FOR GENERAL LABORATORY (1) On the second day of the survey, the laboratory manager stated the laboratory performed Urine Microscopic testing; (2) The surveyor reviewed the written procedure title, "Centrifuge Use and Maintenance" which stated: (a) "After initial placement the lab will verify the speed every six months and the timer every three months or anytime the speed or time is questioned". (3) The surveyor then reviewed 2017 through 2019 centrifuge records and identified the following: (a) Speed - Checks had not been performed for each centrifuge in each pod between 07/17/17 and 04/29/19 (b) Time - Checks had not been performed for each centrifuge in each pod between 07/17/17 and 04/29/19 (4) The surveyor reviewed the findings with the laboratory manager. The laboratory manager stated the procedure had not been followed as indicated above.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental

	conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to have control procedures that monitored the accuracy and precision of the analytic process for Platelets 3 of 3 months. Findings include: (1) On the second day of the survey, the laboratory manager stated the following to the surveyor: (a) Platelet testing was performed using the Beckman Coulter Act Diff 2 analyzer; (b) Three levels (Low, Normal, high) of Coulter 4C-ES Cell control materials were performed each day of patient testing. (2) The surveyor reviewed quality control records for testing performed between 04/01/19 through 06/30/19. A bias was identified as follows: (a) Platelet (Normal Level lot#079500) - 57 out of 68 control results were consistently above the established mean. (3) There was no evidence in the records the control biases had been identified and addressed; (4) The surveyor reviewed the records with the laboratory manager and asked if there was documentation to prove the bias had been identified and addressed. The laboratory manager stated the bias had not been addressed; (5) Since the above bias had not been identified and addressed, the surveyor determined the laboratory failed to have control procedures that monitored the accuracy of testing for the above analyte.
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 a review of records, written policies, and interview with the laboratory manager and the microbiology general supervisor, the laboratory failed to follow their written quality control policy of the IQCP (Individualized Quality Control Plan). Findings include: (1) On the second day of the survey, the microbiology general supervisor stated to the surveyor the laboratory performed: (a) Urine culture testing, with presumptive identifications reported, using Remel TSA (Tryptic Soy Agar) 5% Sheep Blood/EMB (Eosin Metholylene Blue) Agar biplates; (b) AST (Antimicrobial Susceptibility Testing), using the Kirby-Bauer method and Remel Mueller Hinton Agar plates; (c) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP for the test system and identified the QCP (Quality Control Plan) stated the following: (a) "Testing of appropriate ATCC QC strains on each AST media type weekly". (3) The surveyor reviewed quality control records from 01/01/2018 through 07/07/19 (first day of the survey) and identified quality control testing had not been performed weekly as follows: (a) Escherichia coli ATCC (American Type Culture Collection) Strain 25922

	(i) Not performed between 01/06/19 and 01/20/19 (ii) Not performed between 04/20 /19 and 05/05/19 (b) Staphlococcus aureus ATCC Strain 25923 (i) Not performed between 07/12/18 and 07/22/18 (ii) Not performed between 11/18/18 and 12/02/18 (iii) Not performed between 04/14/19 and 04/21/19 (c) Pseudomonas aeruginosa ATCC Strain 27853 (i) Not performed between 04/21/19 and 05/05/19 (4) The surveyor reviewed the findings with the laboratory manager and microbiology general supervisor, who stated the QCP had not been followed 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 a review of records and interview with the laboratory manager and the microbiology general supervisor, the laboratory failed to have a policy for monitoring the effectiveness of their IQCPs. Findings include: (1) On the second day of the survey, the microbiology general supervisor stated to the surveyor the laboratory performed: (a) Urine culture testing, with presumptive identifications reported, using Remel TSA (Tryptic Soy Agar) 5% Sheep Blood/EMB (Eosin Metholylene Blue) Agar biplates; (b) Susceptibility testing, using the Kirby-Bauer method and Remel Mueller Hinton Agar plates. (c) An IQCP's (Individualized Quality Control Plan) had been developed for the test systems; (2) The surveyor reviewed the IQCP's (dated as approved 09/15/17). The QA (Quality Assessment) portion of the IQCP's did not include a schedule for evaluating the QCP's (Quality Control Plan) to ensure they continued to provide accurate and reliable results; (3) The surveyor reviewed the records with laboratory manager and microbiology general supervisor and asked if there was a policy to address how the laboratory will monitor the IQCP's, including the frequency of the reviews. The laboratory manager and microbiology general supervisor stated to the surveyor a policy had not been written.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director failed to ensure that a person performing moderate complexity testing had the appropriate training for 1 of 3 testing persons. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records. The following

	was identified: (a) Testing Person #2 - This person was hired to perform patient testing on 12/31/18. There was no documentation this person had been initially trained. A competency evaluation had not been documented as performed until 06/26 /19. (2) The surveyor reviewed the findings with the laboratory manager. The laboratory manager stated there was no additional documentation to prove the above person had been initially trained to perform moderate complexity testing.