Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473725	10/25/2023
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 10/25/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager and the administrator at the conclusion of the survey.
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 failed to ensure a proficiency testing attestation statement had been signed by the laboratory director for one of six events reviewed during 2021, 2022, and to date in 2023. Findings include: (1) A review of the third 2021; first, second, and third 2022; and first and second 2023 Chemistry Core proficiency testing records identified the following for one of six events: (a) Third 2022 Event - The attestation statement had not been signed by the laboratory director. (2) The findings were reviewed with the laboratory manager who stated on 10/25/2023 at 10:45 am, the attestation statement had not been signed by the laboratory director.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES

	CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the laboratory manager, the laboratory director failed to assess the competency of the technical consultant based on the position responsibilities as listed in subpart M. Findings include: (1) A review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the technical consultant, including the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of October 2021 through the current date identified competencies, based on job responsibilities, had not been performed for the technical consultant listed on the CMS-209; (3) The findings were reviewed with the laboratory manager on 10/25/2023 at 11:30 am there was no policy and competencies were not performed for the technical consultant during the review period of October 2021 to the current date.
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 a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to ensure the humidity was maintained as required by the manufacturer of the Beckman Coulter Access 2 analyzer for four of nine months reviewed in 2023. Findings include: (1) On 10/25/2023 at 10:00 am, the laboratory manager stated PSA, Free PSA, and Testosterone testing were performed using the Beckman Coulter Access 2 analyzer; (2) A review of the manual for the analyzer titled, "Instructions for Use" in Section 1.13 "System Overview" stated "Operational humidity should be in the range of 20% to 80%"; (3) A review of laboratory humidity records from January through September 2023 identified humidity readings were less than 20% for four of nine months as follows: (a) January - 15 of 21 humidity readings were documented as less than 20%; (b) February - Seven of 20 humidity readings were documented as less than 20%; (c) March - Three of 20 humidity readings were documented as less than 20%; (d) April - Two of 20 humidity readings were documented as less than 20%. (4) The records were reviewed with the laboratory manager who stated on 10/25/2023 at 03:10 pm, the laboratory humidity had not been maintained as required by the manufacturer as shown above. 48517 Based on observation and interview with the laboratory manager, the laboratory failed to ensure two of two types of blood collection tubes were stored as required by the

	manufacturer, in a room denoted as the central supply supply room. Findings include: (1) Observation of the central supply room and interview with the laboratory manager on 10/25/2023 at 10:05 am, identified the following: (a) 1300 BD Vacutainer EDTA tubes, lot # 3136174, storage temperature of 4-25 degrees Celsius; (b) 1650 Greiner Vacuette serum separator clot activator tubes, lot # B230333T, storage temperature of 4-25 degrees Celsius. (2) Interview with the laboratory manager on 10/25/2023 at 10: 05 am confirmed the laboratory was not monitoring the temperature of the central supply room.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory manager, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the laboratory on 10/25/2023 at 09:30 am, identified the following expired supplies that appeared to be available for use: (a) 50 Copan Eswab LQ - lot # N20336800 with an expiration date of 09/30/2023; (b) One gallon of Citronox - lot # C9EO with an expiration date of 05/2022; (c) One gallon of High purity reagent grade water - lot # 2124408 with an expiration date of 09/07/2022; (d) One liter of Contrad 70 - lot # 81911 with an expiration date of 05/04/2021; (e) One gallon of Cytorich - lot # 9120937 with an expiration date of 03/31/2022. (2) Interview with the laboratory manager on 10/25/2023 at 09:30 am confirmed the expired supplies were available for use.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, maintenance records, and interview with the laboratory manager, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures during the review period of 01/01/2022 through 09/30/2023. Findings include: (1) On 10/25/2023 at 10: 00 am, the laboratory manager stated PSA, Free PSA, and Testosterone testing were performed using the Beckman Coulter Access 2 analyzer; (2) A review of the manual for the analyzer titled, "Instructions for Use" in Section 6.6 "Weekly Maintenance Steps" stated the following required maintenance procedures: (a) "Clean the Instrument Exterior" (b) "Inspect the Liquid Water Bottle for Wear" (c) "Check for Fluid in the Waste Filter Bottle" (d) "Inspect and Clean the Primary Probe" (e) "Replace and Clean the Aspirate Probe" (f) "Run Daily Maintenance" (g) "Run System Check" (3) A review of maintenance logs from on 01/01/2022 through 09/30 /2023 identified no documentation weekly maintenance had been performed between 11/2/2022 and 01/05/2023; (4) The records were reviewed with the laboratory

	manager who stated on 10/25/2023 at 03:12 pm, weekly maintenance had not been documented as performed as shown above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager, the laboratory failed to follow their written protocol for ensuring the urine centrifuges were functioning properly for two of two annual function checks performed during the review period of October 2021 through the current date. Finding include: (1) On 10/25/2023 at 2:00 pm, the laboratory manager stated the following: (a) Urine sediment examinations were performed as a PPM (Provider Performed Microscopy) procedure in areas denoted as pods; (b) The specimens were processed in Unico centrifuges at a speed of 1800 rpm (revolutions per minute) +/- 100 RPM for 5 minutes; (2) A review of the centrifuge function check records confirmed the centrifuge speed and timer were last checked on 01/10/2021; (3) A review of the procedure titled, "Centrifuge use and maintenance", stated "After initial placement the lab will verify the speed every year and the timer every year or anytime the speed or time is questioned"; (4) A review of centrifuge function check records during 2021 through the current date identified the centrifuge speed and time had not been checked for nine of nine Unico centrifuges since 01/10/2021; (5) The records were reviewed with the laboratory manager, who stated on 10/25/2023 at 2:00 pm, the laboratory had not followed their policy.
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 complete analytic process for seven of seven months reviewed. Findings include: LEVEY JENNINGS NOT PRINTED (1) On 10/25/2023 at 10:00 am, the laboratory manager stated the following: (a) The laboratory performed PSA, Free PSA, and Testosterone testing using the Beckman Coulter Access 2 analyzer; (b) Two levels of QC (quality control) materials were tested each day of patient testing. (2) On 10/25/2023 a review of records from January 2023 through July 2023 identified no evidence, such as Levey-Jennings graphs and cumulative statistical data, to prove that QC results had been monitored for variances (i.e., biases, shifts, trends) between 03/31 /2023 through 05/01/2023; (3) Interview with the laboratory manager on 10/25/2023 at 3:12 pm confirmed that QC data to include Levey-Jennings graphs and cumulative statistical data had not been printed and reviewed for the period stated above. BIASES NOT IDENTIFIED (1) On 10/25/2023 at 10:00 am, the laboratory manager stated the following: (a) The laboratory performed PSA, Free PSA, and Testosterone testing using the Beckman Coulter Access 2 analyzer; (b) Two levels of QC (quality control) materials were tested each day of patient testing. (2) A review of quality control records for testing performed between 01/01/2023 through 03/01/2023 and between 05 /01/2023 through 07/31/2023 identified the following biases: (a) Free PSA (Level 3 lot # 85303) - 69 out of 83 control results were consistently above the established mean; (b) PSA (Level 3 lot # 85303) - 94 out of 98 control results were consistently above the established mean; (c) Testosterone (Level 1 lot # 85301) - 55 out of 60 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 records were reviewed with the laboratory manager who stated the biases had not been identified and addressed. 48517 Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for three of three months reviewed for testing performed using the the Ortho Vitros 350 analyzer. Findings include: (1) On 10/25/2023 at 2:30 pm, the laboratory manager stated the following: (a) The laboratory used the OrthoVitros 350 to perform Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase, AST (Aspartate Aminotransferase), BUN, Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin, Total Protein, and Direct Bilirubin; (b) Three levels of QC (quality control) materials were tested each day of patient testing. (2) A review of records from July 2023 through September 2023 identified the following biases; (a) Aspartate Aminotransferase (AST) (control level NPV1N1) - 80 of 93 control results were consistently below the established mean; (b) Glucose (GLU) (control level NPV1N1) - 54 of 61 control results were consistently below the established mean; (c) Potassium (K+) (control level NPV1N1) - 61 of 66 control results were consistently below the established mean. (3) There was no evidence in the records the control biases had been identified and addressed; (4) The records were reviewed with the laboratory manager who stated on 10/25/2023 at 2:30 pm, the biases had not been identified and addressed.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboaratory manager, the laboratory director failed to ensure proficiency testing reports were reviewed for 1 of 6 Chemistry Core events. Findings include: (1) On 10/25/2023 a review of Chemistry Core proficiency testing revealed the Performance Evaluations included a space for the laboratory director or designee signature and date (indicating review of the graded evaluation). The following events had not been signed and dated as reviewed by the laboratory director or designee: (a) Third 2023 Chemistry Core Event (2) The surveyor reviewed the records with the laboratory manager, who stated the graded evaluation, as indicated above, had not been signed and dated as reviewed by the laboratory director or designee.