Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472947	08/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Urology Center Of Southern Oklahoma, Pc	1119 Walnut Dr, Ste 2, Ardmore, 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 08/03/2021. The findings were reviewed with the office manager and nurse supervisor at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the office manager and nurse supervisor, the laboratory failed to verify the accuracy of urinalysis testing, urine sediment examinations, and post vasectomy analysis at least twice annually. Findings include: (1) On 08/03/2021 at 10:10 am, the nurse supervisor stated the following to the surveyor: (a) The laboratory performed routine urinalysis testing using the Clinitek Advantus analyzer; (b) The laboratory performed urine sediment examinations performed as a PPM (Provider Performed Microscopy) procedure; (c) The laboratory performed post vasectomy analysis (present or absent) performed as a PPM procedure. (2) The surveyor reviewed 2019, 2020, and 2021 records and identified the testing had not been verified for accuracy twice annually during the review period; (3) The records were reviewed with the office manager and nurse supervisor who both stated at 01:40 pm, the laboratory had not verified the accuracy twice annually as indicated above.
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 office manager and nurse supervisor, the laboratory failed to ensure quality control materials were stored as required by the manufacturer for 2 of 3 months. Findings include: (1) On 08/03/2021 at 10:10 am, the nurse supervisor stated to the surveyor: (a) The laboratory performed routine urinalysis testing using the Clinitek Advantus analyzer; (b) The laboratory used two levels of Premium Liquid Urine Controls to perform QC (quality control) each day of patient testing. (2) The surveyor reviewed the manufacturer's storage requirements for the QC materials: (a) The package insert for the QC materials required storage at 2-8 degrees C (Celsius) or 36 - 46 degrees F (Fahrenheit). (3) The surveyor reviewed laboratory refrigerator records for 3 months (December 2020 through February 2021) and identified that for 2 of 3 months the refrigerator temperatures were colder than the manufacturer's storage requirements as follows: (a) December 2020 - 3 of 21 days (i) 12/14/2020 - The refrigerator temperature had been documented at 34 degrees F; (ii) 12/17/2020 - The refrigerator temperature had been documented at 34 degrees F; (iii) 12/18/2020 - The refrigerator temperature had been documented at 34 degrees F. (b) January 2021- 2 of 18 days (i) 01/11/2021- The refrigerator temperature had been documented at 34 degrees F; (ii) 01 /21/2021- The refrigerator temperature had been documented at 34 degrees F. (4) The surveyor reviewed the records with the office manager and nurse supervisor who both stated to the surveyor on 01:55 pm, the laboratory did not store the QC material according to the manufacturer's requirements as indicated above.
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 a review of records and interview with the office manager and nurse supervisor, the laboratory failed to use materials that had not expired for 2 of 7 months. Findings include: (1) On 08/03/2021 at 10:10 am, the nurse supervisor stated the following to the surveyor: (a) The laboratory performed routine urinalysis testing using the Clinitek Advantus analyzer; (b) The laboratory used two levels of Premium Liquid Urine Controls to perform QC (quality control) each day of patient testing. (2) The surveyor reviewed 8 months of QC records (December 2020 through July 2021) and identified the following: (a) Lot# 150031 (level 1) and Lot#150032 (level 2) with an expiration date of 03/31/2021 were used to determine acceptability of patient testing from 04/01/2021 through 05/31/2021; (3) The surveyor asked the nurse supervisor if patients were tested between 04/01/2021 through 05/31/2021 using the expired QC material. The nurse supervisor and office manager reviewed the QC

	records and stated at 01:55 pm, the laboratory used the expired QC materials to determine acceptability of patient testing on 04/01,05,08,12,15,19,22,26,29/2021; and 05/03,05,06,10,13,14,17,20,24,27,28/2021.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the office manager and nurse supervisor the laboratory failed to perform function checks on the urine centrifuge, with at least the frequency specified by the manufacturer. Findings include: (1) On 08/03/2021 at 10:10 am, the nurse supervisor stated the following to the surveyor: (a) The laboratory performed urine sediment examinations as a PPM (Provider Performed Microscopy) procedure; (b) The specimens were processed in the Unico PowerSpin LX centrifuge. (2) The surveyor reviewed the centrifuge function check records that had been performed in 2019, 2020, and 2021. The RPM (revolution per minute) calibrations had been performed on 07/17/2019 and 12/07/2020; (3) The surveyor then reviewed the manufacturer's operation manual for the centrifuge. Page 5 of the manual under the heading, "Calibration" stated "It is recommended that your centrifuge's RPM be calibrated at least every 6 months"; (4) The surveyor reviewed the findings with the office manager and nurse manager who both stated at 01:45 pm the laboratory's policy to perform the RPM calibrations was on an annual basis and was not aware the manufacturer required the calibrations every 6 months.
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 and interview with the office manager and nurse supervisor, the laboratory failed to follow their function check protocol for ensuring the urine centrifuge was functioning properly. Findings include: (1) On 08/03/2021 at 10:10 am, the nurse supervisor stated the following to the surveyor: (a) The laboratory performed urine sediment examinations as a PPM (Provider Performed Microscopy) procedure; (b) The specimens were processed in the Unico PowerSpin LX centrifuge at a speed of 2000 rpm (Revolutions Per Minute) and a time of 3 to 5 minutes. (2) The surveyor asked the nurse supervisor to explain how often function checks (speed and

	timer checks) were performed on the centrifuge. The nurse supervisor stated at 10:15 am it was the laboratory's policy to check the speed and timer of the centrifuges annually; (3) The surveyor reviewed the centrifuge function check records that had been performed in 2019, 2020, and 2021. The centrifuge time had been checked as follows: (a) 07/17/2019 for 10 minutes; (b) 12/07/2020 for 10 minutes. (4) The surveyor reviewed the records with the office manger and nurse supervisor and asked if the timer had been checked at a time of 3 minutes and 5 five minutes according to the laboratory's policy for performing urine sediment examinations. Both stated at 01: 42 pm, the checks had not be checked at 3 minutes and 5 minutes.