Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0424085	09/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Uropartners	1725 W Harrison St Ste 758, Chicago, IL	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observation, record and manual review, manufacturer's instructions, and an interview with the testing personnel (TP), the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 for performing Prostate Specific Antigen (PSA) testing in the laboratory, affecting 16 out of 16 patients. Findings Include: 1. The laboratory failed to meet the following analytic systems requirements: *Failed to ensure expired supplies are not to be used. See. D5417. *Failed to perform calibration verification procedures. See D5437. *Failed to perform control procedures. See D5445.
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 direct observation, manual review, and an interview with the testing

	personnel (TP), the laboratory failed to ensure supplies are not to be used when they have exceeded their expiration date. Findings Include: 1. On 09/06/2019 at 11:00 AM during a tour of the laboratory, the surveyor observed the following expired supplies in the laboratory: *One Sterile Urine collection tube with the expiration date of 02 /2019 and *Two Sterile Urine collection tube with the expiration date of 07/2019. 2. The laboratory's manual failed to include a written method that would ensure supplies are not used pass their expiration dates. 3. On a Recertification survey conducted on 09 /06/2019 at 11:30 AM, the laboratory director and TP confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on record review, manufacturer's instructions, and an interview with the testing personnel (TP), the laboratory failed to follow the manufacturer's instructions to perform calibration verification (CV) procedures every 6 months on the analyzer used for Prostate Specific Antigen (PSA) testing, during the years of 2018 and 2019. Findings Include: 1. The laboratory was using the Qualigen Analyzer for PSA testing. 2. The analyzer's manual and the PSA quality control (QC) test records were reviewed. 3. The manual instructs the laboratory to perform the following: *Calibration verifications are to be performed every 6 months. 4. The CV documents revealed the following: *The CV performed on 12/21/2017 was completed and signed by the laboratory director (LD); *The CV performed on 06/15/2019 failed to be reviewed and accepted by the LD; *The CV performed on 08/12/2019 was performed with 2 levels of controls instead of the required 3 levels; the calculations were not completed, and failed to be reviewed and accepted by the LD. 5. The laboratory repeatedly failed to perform CVs as instructed in the laboratory manual. 6. On a Recertification survey conducted on 09/06/2019 at 11:30 AM, the LD and TP confirmed the above findings.
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 record review, manual, and an interview with the testing personnel (TP); the laboratory failed to perform control procedures using the number and frequency established by the laboratory for Prostrate Specific Antigen (PSA) testing, affecting 16 out of 16 patients. Findings Include: 1. The laboratory's policies and procedures manual, quality control (QC) logs from the month of June and October of 2018, patient test printout results and patients' electronic medical records (EMR) were reviewed. 2. The laboratory failed to follow it's QC Plan which is to include two control materials of different concentrations each day of patient testing. 3. The QC log book, patients' results, and their EMR records revealed the following: *Patients SM & FS were tested and reported on 06/11/18 - QC were performed on 06/11/18; *Patients HS, AK, DG, JD, GP, & SK were tested and reported on 06/14/18 - No QC performed on 06/14/18; *Patients CR, RW, TT, WV, TS, & FC were tested and reported on 10/26 /18 - No QC performed on 10/26/18; *Patients RM, FC, JE, & MM were tested and reported on 10/29/18 - No QC performed on 10/29/18; 4. The laboratory failed to perform controls on 1 of 4 days of patient testing. 5. On a Recertification survey conducted on 09/06/2019 at 11:30 AM, the LD and TP confirmed the above findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the quality control (QC) records, patient test records, and an interview with the testing personnel (TP), the laboratory director (LD) failed to ensure that two control materials of different concentrations was perform 1 of 4 days of patient testing for Prostate Specific Antigen (PSA). Findings Include: 1. The laboratory was using the Qualigen PSA test system. 2. QC records were reviewed for the months of June 2018 and October 2018. 3. QC were not performed on 06/14/2018; 10/26/2018; and 10/29/2018. 4. Review of patient test records revealed 16 patients were reported on the above dates 5. On a Recertification survey conducted on 09/06 /2019 at 11:30 AM, the LD and TP confirmed the above findings. 6. Refer to D5445.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's manual, quality assessment (QA) records, and an interview with the testing personnel (TP), the laboratory director (LD) failed to ensure that QA procedures are maintained to assure the quality of laboratory services provided for Prostate Specific Antigen (PSA) testing.. Findings Include: 1. The laboratory was using the Qualigen PSA test system. 2. The laboratory's procedures manual require QA procedures to be performed monthly. 3. QA records showed that QA procedures were not performed during the years of 2018 and 2019. 4. On a Recertification survey conducted on 09/06/2019 at 11:30 AM, the TP confirmed the above findings and stated that the laboratory use perform the QA procedures monthly.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS 209), and an interview with the testing personnel (TP), the technical consultant (TC) failed to assess test performance through previously analyzed specimens, internal blind testing samples or testing external proficiency testing samples in the competency of each TP performing Prostrate Specific Antigen (PSA) testing in the laboratory, affecting 1 out of 2 TP. Findings Include: 1. The laboratory was enrolled in the American Proficiency Institute (API) proficiency testing (PT) program to fulfill their twice annual verification. 2. The CMS 209, employee files, and PT attestation sheets for 2017, 2018 and 2019 were reviewed. 3. The API-PT attestation sheets, CMS 209, and employee files revealed the following: *The CMS 209 listed TP1 and TP2 for performing patient testing in the laboratory. *TP1 and TP2 had been authorized by the laboratory director to perform PSA testing. *TP2 was not included in blind sample testing for 2017, 2018 and 2019 according to the attestation statement reviewed for 2017, 2018 and 2019.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS 209), lack of documentation, and an interview with the testing personnel (TP), the technical consultant (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually, after the first year, affecting 1 out of 2 TP. Findings Include: 1. The laboratory procedures manual, the CMS 209, and employee files, were reviewed. 2. The CMS 209 and employee files showed the following: *TP1 and TP2 were listed on the CMS 209 as TP performing patient testing in the laboratory. *TP2 competency was evaluated on 09/07/2018 and 08/27/2019. *TP1 had no documentation that their competency had been evaluated in

	2018 or 2019. 3. The laboratory failed to follow competency policy and procedure to assess TP1, at least annually. 4. On a recertification survey conducted on 09/06/2019 at 11:30 AM, the TP confirmed the above findings.