Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0419129	09/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Uropartners Llc - Riverboat	1541 Riverboat Center Dr, Joliet, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #2; the laboratory failed to enroll in proficiency testing challenges in 2017 through 2019 in the sub-specialty of bacteriology for gram staining. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "Gram Stain", which outlined the test procedure for the determination of gram negative and/or gram positive organisms. 2. Review of American Proficiency Institute proficiency testing records revealed the laboratory failed to enroll in PT for gram staining. 3. Interview with TP#2, on 9-05-2019, at 3:10 pm, confirmed the laboratory will occasionally performs gram stains as part of the work-up for urine culture testing. 4. Review of test volume records revealed from July of 2018 through July of 2019 that 2,818 urine cultures were performed. 5. During the survey on 9-05-2019 at 4:50 pm, the surveyor's findings were confirmed by TP#2.
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the

	laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to perform bi-annual method accuracy evaluations for histopathology testing. See D5217, part A.
D5032	CYTOLOGY CFR(s): 493.1221 If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to perform bi-annual method accuracy evaluations for urine cytology testing. See D5217, part B. 2. The laboratory failed to have a procedure in place for identifying nongynecologic specimens that have a high potential for cross-contamination and the staining of those samples separately. See D5619. 3. The laboratory failed to establish and follow procedures to evaluate annual statistics for the number of cytology cases examined by specimen type and by diagnosis, including the number of cases reported as unsatisfactory for diagnostic interpretation. See D5629. 4. The laboratory failed to establish and follow procedures to evaluate 4 of 4 testing personnel who performed cytologic examinations against the laboratory's overall statistics. See D5631. 5. The laboratory failed to maintain cytology workload records for the total number of slides examined by each individual during each 24 hour period and the total number of hours spent examining those slides in a 24 hour period irrespective of the site or laboratory for 19 of 23 dates reviewed and failed to document workloads all together from 11-17-2018 to 11-30-2018. See D5645.
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 review of laboratory records and interview with testing personnel (TP) #2; the laboratory failed to verify the accuracy of urine culture identification and microscopic urinalysis analyte performance, which does not reflect the performance of the laboratory for proficiency testing (PT) event 1 of 2019. Findings Include: 1.

	Proficiency testing records for 2017 through 2019 were reviewed. 2. Review of American Proficiency Institute (API) Hematology/Coagulation PT documentation for event 1 of 2019 revealed the laboratory's performance was not graded for 1 of 2 urine sediment sample, sample US-02. 3. Review of the performance summary documentation for Hematology/Coagulation PT event 1 of 2019 revealed the laboratory failed to evaluate the accuracy of urine sediment PT performance. 4. Review of American Proficiency Institute (API) Microbiology PT documentation for event 1 of 2019 revealed the laboratory's performance was not graded for 1 of 5 urine culture identification samples, sample UR-03. 5. Review of the performance summary documentation for Microbiology PT event 1 of 2019 revealed the laboratory failed to evaluate the accuracy of urine culture identification PT performance. 6. On survey date 09-05-2019, at 4:50 pm, TP#2 confirmed the laboratory fail to verify the accuracy of urine sediment and bacteriology PT scores for event 1 of 2019.
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: A. Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to perform bi-annual method accuracy evaluations for histopathology testing in 2017 through 2019. Findings Include: 1. Proficiency testing records for 2017 through 2019 were reviewed. 2. Review of the laboratory's proficiency testing records revealed the laboratory failed to evaluate the accuracy of histopathology testing performed by the laboratory in 2017 through the date of survey (9-5-2019) in 2019. 3. Review of the test volume worksheet for July of 2018 through July of 2019 indicated 6,499 specimen blocks were tested for histopathology. 4. Interview with the LD on 9-05-2018, at 11:57 am confirmed the laboratory failed to perform the bi-annual method accuracy evaluations for histopathology slide evaluations in 2017 through 2019. B. Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to perform bi-annual method accuracy evaluations for urine cytology testing in 2017 through 2019. Findings Include: 1. Proficiency testing records for 2017 through 2019 were reviewed. 2. Review of the laboratory's proficiency testing records revealed the laboratory failed to evaluate the accuracy of urine cytology testing performed by the laboratory in 2017 through the date of survey (9-5-2019) in 2019. 3. Review of the test volume worksheet for July of 2018 through July of 2019 indicated 372 urine cytology cases were performed. 4. Interview with the LD on 9-05-2018, at 11:57 am confirmed the laboratory failed to perform the bi-annual method accuracy evaluations for urine cytology evaluations in 2017 through 2019.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the

	manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observations, and interview with testing personnel (TP) #2; the laboratory failed to check each batch of Tryptic Soy Agar (TSA) with 5% Sheep Blood (SB) and Eosin Methylene Blue (EMB) plates for sterility, growth, inhibition, and biochemical response with initial use. Findings include: 1. Direct observation of laboratory testing supplies on 09-05-2019, at 9:43 am, identified Tryptic Soy Agar (TSA) with 5% Sheep Blood (SB) and Eosin Methylene Blue (EMB) plates used for urine culture testing. 2. Review of the test volume worksheet indicated from July 2018 to July 2019 that 2,818 urine cultures were performed with TSA 5% SB and EMB media when no quality controls to check for sterility, growth, inhibition, and biochemical response were performed with the initial use. 3. On survey date 09-05-2019, at 4:50 pm, TP#2 confirmed the laboratory failed to perform and document quality control testing for TSA with 5% SB and EMB plates.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #2; the laboratory failed to perform quality controls each day tests are performed for antimicrobial susceptibility testing in 2017 through 2019. Findings include: 1. Review of the laboratory policy and procedure manual identified the procedure, "Kirby Bauer Sensitivity Testing", which indicated that quality control testing for Kirby Bauer (KB) sensitivities are performed weekly. 2. Interview with TP#2 on survey date 09-05-2019, at 9:50 am, confirmed that susceptibility controls are performed weekly, however the laboratory had not implemented an individual quality control plan (IQCP) for the reduced quality control frequency. 3. Review of test volumes records found from July 2018 through July 2019 that 1,286 Kirby Bauer Sensitivities were performed when daily quality control testing was not performed and documented. 4. On survey date 09-05-2019, at 4:50 pm the surveyor's findings were confirmed by TP#2.
D5619	CYTOLOGY CFR(s): 493.1274(b)(3) (b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (b)(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following

	staining. This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews with testing personnel (TP) #2 and the laboratory director (LD); the laboratory failed to have a procedure in place for identifying nongynecologic specimens that have a high potential for cross-contamination and the staining of those samples separately. Findings include: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to have a procedure to identify nongynecologic specimens with a high potential for cross-contamination and how they will be processed by the laboratory. 2. Interview with the LD on survey date 09-05-2019, at 12:47 pm, confirmed no written procedure was in place to identify and stain separately nongynecologic specimens with a high potential for cross-contamination. 3. Review of test volume records from July of 2018 through July of 2019 found the laboratory performed 372 nongynecological cytology slide examinations. 4. On survey date 09-05-2019, at 4:50 pm the surveyor's findings were confirmed by TP#2.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews with testing personnel (TP) #2 and the laboratory director (LD); the laboratory failed to establish and follow procedures to evaluate annual statistics for the number of cytology cases examined by specimen type and by diagnosis, including the number of cases reported as unsatisfactory for diagnostic interpretation. Findings include: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to have a policy in place to evaluate the annual cytology statistics by the number of cytology cases examined by specimen type and by diagnosis, including the number of cases reported as unsatisfactory for diagnostic interpretation. 2. Interview with the LD on survey date 09-05-2019, at 12:47 pm, confirmed no written procedure was established and followed to evaluate the annual cytology statistics by the number of cytology cases examined by specimen type and by diagnosis, including the number of cases reported as unsatisfactory for diagnostic interpretation. 3. Review of test volume records from July of 2018 through July of 2019 found the laboratory performed 372 nongynecological cytology slide examinations. 4. On survey date 09-05-2019, at 4:50 pm the surveyor's findings were confirmed by TP#2.

D5631	CYTOLOGY CFR(s): 493.1274(c)(6) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken. This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews with testing personnel (TP) #2 and the laboratory director (LD); the laboratory failed to establish and follow procedures to evaluate 4 of 4 testing personnel who performed cytologic examinations against the laboratory's overall statistics. Findings include: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to have a policy in place to evaluate personnel performing cytologic examinations against the laboratory's overall statics. 2. Review of the laboratory's cytology workload records for 2017 through the date of survey in 2019 (9-5-2019) 4 testing personnel were identified who had performed cytologic examinations. 3. Interview with the LD on survey date 09-05-2019, at 12:47 pm, confirmed no written procedure was established and followed to evaluate the annual cytology statistics against cases evaluated for 4 of 4 TP, who performed cytologic examinations in 2017 through 2019. 4. Review of test volume records from July of 2018 through July of 2019 found the laboratory performed 372 nongynecological cytology slide examinations. 5. On survey date 09-05-2019, at 4:50 pm the surveyor's findings were confirmed by TP#2.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews with testing personnel (TP) #2 and the laboratory director (LD); the laboratory failed to maintain cytology workload records for the total number of slides examined by each individual during each 24 hour period and the total number of hours spent examining those slides in a 24 hour period irrespective of the site or laboratory for 19 of 23 dates reviewed and failed to document workloads from 11-17-2018 to 11-30-2018. Findings include: 1. Review of the laboratory's policy and procedure manual identified the cytology workload records for 2017 through the date of survey, 9-5-2019. 2. Review of the cytology workload records revealed for 19 of 23 daily workload records reviewed the laboratory failed to document the amount of time and/or individual who performed the examinations in a 24 hour period irrespective of the site or laboratory. Date Missing documentation 12-20-2018 Time devoted to cytologic examination at other sites and at this location. 12-14-2018 Time devoted to cytologic examination at other sites and at this location. 12-04-2018 Who performed cytologic examinations, and time devoted to cytologic

	examination at other sites and this location. 11-16-2018 Time devoted cytologic examination at other sites. 11-09-2018 Time devoted to cytologic examination at this location. 11-06-2018 Time devoted to cytologic examination at this location. 11-02-2018 Time devoted to cytologic examination at this location. 10-30-2018 Who performed cytologic examinations, and time devoted to cytologic examination at other sites and this location. 10-25-2018 Who performed cytologic examinations, and time devoted to cytologic examination at other sites and this location. 10-23-2018 Who performed cytologic examinations, and time devoted to cytologic examination at other sites and this location. 10-19-2018 Who performed cytologic examinations, and time devoted to cytologic examination at other sites and this location. 10-16-2018 Who performed cytologic examinations, and time devoted to cytologic examination at other sites and this location. 10-11-2018 Who performed cytologic examinations, and time devoted to cytologic examination at other sites and this location. 10-04-2018 Who performed cytologic examinations, and time devoted to cytologic examination at other sites and this location. 10-02-2018 Who performed cytologic examinations, and time devoted to cytologic examination at other sites and this location. 09-06-2018 Who performed cytologic examinations, and time devoted to cytologic examination at other sites and this location. 08-23-2018 Who performed cytologic examinations, and time devoted to cytologic examination at other sites and this location. 05-15-2018 Who performed cytologic examinations. 12-07-2017 Who performed cytologic examinations, and time devoted to cytologic examination at other sites and this location. 3. Review of cytologic examination test records reviewed revealed the laboratory failed to have workload records for cytologic examinations performed between 11-17-2018 to 11-30-2018. 4. Review of test volume records from July of 2018 through July of 2019 found the laboratory performed 372 nongynecological cytology slide examinations. 5. On survey date 09-05-2019, at 4:50 pm the surveyor's findings were confirmed by TP#2.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #2; the laboratory director failed to identify, in writing, the responsibilities and duties of each person engaged in laboratory testing. Findings Include: 1. Review of the laboratory's policy and procedure manual revealed the laboratory director failed to specify, in writing, the responsibilities and duties of each person engaged in laboratory testing. 2. On survey date 9-05-2019, at 04:50 pm, the surveyor's findings were confirmed by TP#2.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification

	requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the technical supervisor (TS) failed to provide the technical supervision in accordance with 493.1451. Findings Include: 1. The TS failed to ensure annual competency assessments were completed for 4 of 4 testing personnel who performed histopathology and cytology testing. See D6128. 2. The TS failed to estabilish individual workload limits and reassess those limits at least every 6 months for 4 of 4 testing personnel who performed cytologic examinations. See D6130.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory's technical supervisor failed to ensure annual competency assessments were completed for 4 of 4 testing personnel who performed pathology and cytology testing in 2017 through the date of survey 9-5-2019. Findings Include: 1. Competency assessments records for 2017 through 9-5-2019 were reviewed. 2. Review of competency assessment documentation revealed no annual competency assessments were completed for 4 of 4 testing personnel performing histopathology and cytology testing. 3. On survey date 09-05-2019, at 12:50 pm, the LD confirmed annual competency assessments were not completed for 4 of 4 testing personnel performing histopathology and cytology testing.
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory's technical supervisor failed to establish workload limits and reassess those workload limits at least every 6 months for 4 of 4 testing personnel who performed cytologic examinations in 2017 through the date of survey, 9-5-2019. Findings include: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to have a policy in place to evaluate individual workload limits for personnel performing primary cytology screenings. 2. Review of the laboratory's cytology workload records for 2017 through the date of survey in 2019 (9-5-2019)

	identified 4 testing personnel who performed primary cytology screenings. 3. Review of the laboratory's personnel records revealed the technical supervisor failed to establish individual workload limits for 4 of 4 testing personnel (TP) identified. 4. Review of test volume records from July of 2018 through July of 2019 found the laboratory performed 372 nongynecological cytology slide examinations. 5. Interview with the LD on survey date 09-05-2019, at 12:47 pm, confirmed the technical supervisor failed to establish workload limits and reassess the workload limits at least every 6 months for 4 of 4 TP, who performed cytologic examinations in 2017 through 2019.