Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0099671	07/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Urological Associates Of Bridgeport Pc	160 Hawley Ln, Ste 002, Trumbull, CT	

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
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 record review and staff interview, the laboratory failed to verify the accuracy bi-annually for semen analysis in the specialty of hematology. Findings include: 1. Record review of the laboratory proficiency testing and verification records on 7/25/19 revealed the laboratory did not have biannual verification for accuracy of semen analysis testing. 2. Staff interview with the practice manager on 7 /25/19 at 3:15 PM confirmed the above finding. 3. The laboratory performs 391 semen analysis tests annually.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to provide evidence that the laboratory evaluated the Hematoxylin & Eosin (H&E) stain for acceptable staining characteristics daily in the subspecialty of histopathology. Findings include: 1. Record review of the laboratory quality manual procedure 2.2.2 'Analytic Histology

	/Cytology Quality Processes', Quality Control (QC) Section on 7/25/19 revealed: a. The pathologist QC review of H&E stain on each day of use. b. For routine H&E, controls are the internal controls provided by normal tissue present in all cases. 2. Record review of the Daily Stain Quality Control Logs From July 2017 through July 2019 on 7/25/19 revealed a. Documentation of a 'check mark' is done weekly based on the week of the year (1-52 weeks) not daily. b. The laboratory did not have documentation of the actual date the stain quality is examined and check mark was recorded. c. Ledger/key notating definition of the check mark was not indicated. 3. Staff interview with the laboratory director (LD) on 7/25/19 at 11:00 AM confirmed the above. In addition, the LD stated: a. The laboratory receives batch shipments of H&E stains from their technical component reference laboratory several times per week. b. Examination of H&E slides by the LD occurs 2 to 3 times per week on average. 4. The laboratory performs 1,410 histopathology tests annually.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to provide evidence that the laboratory evaluated the immunohistochemical (IHC) stains for positive and negative reactivity each time of use in the subspecialty of histopathology. Findings include: 1. Record review of the laboratory quality manual procedure 2.2.2 'Analytic Histology/Cytology Quality Processes', Quality Control (QC) section on 7/25/19 revealed: a. The pathologist quality control (QC) review of positive and negative controls for IHC stains on each day of use. b. Controls slides for IHC stains are stored with regular histology cases. 2. Record review of the Daily Stain Quality Control Logs From July 2017 through July 2019 on 7/25/19 revealed: a. Documentation of a 'check mark' is done weekly based on the week of the year (1-52 weeks) not daily. b. Documentation of the actual examination date and reactivity observed for the IHC stain QC notated by the check mark was not recorded. c. Ledger/key notating definition of the check mark was not indicated. d. 2018: IHC controls were documented by the checkmark 3 of 52 weeks (weeks 9, 20 and 40). 3. Staff interview with the laboratory director (LD) on 7/25/19 at 11:00 AM confirmed the above. In addition, the LD stated: a. The laboratory receives batch shipments of slides from their technical component reference laboratory several times per week. b. Examination of histopathology slides including IHCs by the LD occurs 2 to 3 times per week on average.
D5667	CYTOLOGY CFR(s): 493.1274(h) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to provide evidence

	that the laboratory evaluated the quality of the cytology stain from an outside laboratory for acceptable staining characteristics daily in the subspecialty of cytology. Findings include: 1. Record review of the laboratory quality manual procedure 2.2.2 'Analytic Histology/Cytology Quality Processes' Quality Control (QC) section on 7/25 /19 revealed: a. The pathologist daily or as slides are received and read will perform QC review. b. Cytology PAP stain controls are the internal controls provided by normal tissue present in all cases. 2. Record review of the Daily Stain Quality Control Logs From July 2017 through July 2019 on 7/25/19 revealed a. Documentation of a 'check mark' is done weekly based on the week of the year (1-52 weeks) not daily. b. The laboratory did not have documentation of the actual date the stain quality is examined and check mark is recorded. c. Ledger/key notating definition of the check mark was not indicated. 3. Staff interview with the laboratory director (LD) on 7/25 /19 at 11:00 AM confirmed the above. In addition, the LD stated: a. The laboratory receives batch shipments from their technical component reference laboratory several times per week. b. Examination of cytology slides by the LD occurs 2 to 3 times per week on average. 4. The laboratory performs 842 cytology tests annually.
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 record review and staff interview, the laboratory director failed to ensure new testing personnel (TP) received appropriate training to perform moderate complexity testing prior to reporting patient test results in the specialty of hematology and subspecialty of urinalysis. Findings include: 1. Record review of the laboratory's "Quality Manual, 1. Quality System Overview" Policy on 7/25/19 revealed the "Assessment of the Quality System" section states 'UAB personnel performing urine and semen testing are required to show proficiency on initial training and to verify continuing competency annually'. 2. Record review of TP files on 7/25/19 revealed the laboratory did not have training documentation for 2 of 2 new TP. 3. Staff interview with the practice manager on 7/25/19 at 1:30 PM confirmed the above findings. 4. The laboratory performs approximately 1,394 microscopic urinalysis and 391 semen analysis tests annually.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by:

	Based on record review and staff interview, the laboratory failed to assess new moderate complexity testing personnel (TP) twice in the first year of patient testing in the specialty of hematology and subspecialty of urinalysis. Findings include: 1. Record review of the laboratory's "Quality Manual, 1. Quality System Overview" Policy on 7/25/19 revealed the "Assessment of the Quality System" section states 'UAB personnel performing urine and semen testing are required to show proficiency on initial training and to verify continuing competency annually'. 2. Record review of employee competency assessment records on 7/25/19 revealed the laboratory did not have competency documentation for 1 of 1 new TP, hired August 2018. 3. Staff interview with the practice manager (PM) on 7/25/19 at 3:00 PM confirmed the new TP was not assessed. The PM stated he/she was unaware of the requirement of competency assessment twice in the first year of patient testing. 4. The laboratory performs 1,394 microscopic urinalysis and 391 semen analysis annually.
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 and staff interview, the laboratory failed to document annual competency of testing personnel (TP) to assess the knowledge and skills necessary to perform moderate complexity semen analysis testing in the specialty of hematology. Findings include: 1. Record review of the laboratory's "Quality Manual, 1. Quality System Overview" Policy on 7/25/19 revealed the "Assessment of the Quality System" section states 'UAB personnel performing urine and semen testing are required to show proficiency on initial training and to verify continuing competency annually'. 2. Record review of TP competency records on 7/25/19 revealed the laboratory did not have annual competency documentation for 4 of 4 TP performing semen analysis for 2017 and 2018. 3. Staff interview with the practice manager on 7 /25/19 at 3:15 PM confirmed the laboratory failed to document annual competency for semen analysis. 4. The laboratory performs 391 semen analysis annually in the specialty of hematology.