

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 07D0099671	<b>(X3) Date Survey Completed</b> 06/12/2019
<b>Name of Provider or Supplier</b> Urological Associates Of Bridgeport Pc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5032</b>	<p><b>CYTOLOGY</b> CFR(s): 493.1221</p> <p>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.</p> <p>This <b>CONDITION</b> is not met as evidenced by: Based on review of laboratory policies and procedures, record review and interview it was determined that the laboratory failed to establish individual workload limits (refer to D5633); failed to establish written policies and procedures to reassess workload limits every six months (refer to D5637) and failed to establish written policies and procedures to prorate workload limits (refer to D5641). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This <b>STANDARD</b> is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and an interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of one of one Laboratory Director/Technical Supervisors that performed microscopic evaluations of cytology specimens during the years 2017 and 2018 and to the date of the survey in 2019. Findings include: 1. The</p>

Survey Team requested and the laboratory failed to provide written policies and procedures for the competency assessment of one of one Laboratory Director /Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessment for one of one Laboratory Director /Technical Supervisors during the years 2017 and 2018 and to the date of the survey in 2019. 3. During an interview with the Survey Team at 1:30 PM on June 11, 2019, the Laboratory Director/Technical Supervisor confirmed that there were no written policies and procedures for competency assessments of the Laboratory Director /Technical Supervisor.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
Based on review of three laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for one laboratory process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the electronic entry and reporting of final cytology test results. 2. During an interview with the Survey Team at 4:15 PM on June 10, 2019, the Laboratory Director/Technical Supervisor confirmed this finding.

**D5633**

**CYTOLOGY**  
CFR(s): 493.1274(d)(1)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

This STANDARD is not met as evidenced by:  
Based on the review of laboratory policies and procedures, lack of documentation and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established by the

Laboratory Director/Technical Supervisor for one of one Laboratory Director /Technical Supervisors during the years 2017 and 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that maximum workload limits were established by the Laboratory Director/Technical Supervisor for the Laboratory Director/Technical Supervisor who performed the primary evaluation of nongynecologic cytology specimens. 2. The Survey Team requested and the laboratory failed to provide documentation of an individual workload limit for one of one Laboratory Director/Technical Supervisors. 3. During an interview with the Survey Team at 10:05 AM on June 10, 2019, the Laboratory Director/Technical Supervisor confirmed that there were no procedures for assigning workload limits or documentation of workload limits.

**D5637**

CYTOLOGY  
CFR(s): 493.1274(d)(1)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limits for one of one Laboratory Director /Technical Supervisors were reassessed at least every six months and adjusted when necessary during the years 2017 and 2018, and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written policy and procedure for the reassessment of workload limits at least every six months for one of one Laboratory Director/Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of a reassessed workload limit for one of one Laboratory Director/Technical Supervisors during the years 2017 and 2018 and to the date of the survey in 2019. 3. During an interview with the Survey Team at 10:05 AM on June 10, 2019, the Laboratory Director /Technical Supervisor confirmed that the laboratory did not have a policy and procedure for the reassessment of workload limits every six months.

**D5641**

CYTOLOGY  
CFR(s): 493.1274(d)(2)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;

This STANDARD is not met as evidenced by:  
Based on review of laboratory polices and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limits for one of one Laboratory Director

/Technical Supervisors, when examining slides in less than an 8-hour workday and with duties other than slide examination, would be prorated using a period of eight hours to determine the number of slides that may be examined. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies or procedures to prorate the workload limits for one of one Laboratory Director /Technical Supervisors when examining slides in less than an 8-hour day. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for one of one Laboratory Director/Technical Supervisors during the years 2017 and 2018 and to the date of the survey in 2019. 3. During an interview with the Survey Team at 10:05 AM on June 10, 2019, the Laboratory Director/Technical Supervisor confirmed that the laboratory did not have policies and procedures for prorating the workload limits.

**D5643**

CYTOLOGY  
CFR(s): 493.1274(d)(2)(iii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(iii) Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide; and (d)(2)(iv) Technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100 slide workload limit.

This STANDARD is not met as evidenced by:  
Based on the review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to designate how nongynecologic ThinPrep slide preparations were counted for workload recording purposes. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written policy and procedure to designate how nongynecologic ThinPrep slides (cell dispersion over one-half or less of slide) were counted for workload recording. 2. During an interview with the Survey Team at 10:45 AM on June 11, 2019, the Laboratory Director/Technical Supervisor confirmed that the laboratory did not have a policy and procedure for how nongynecologic slides were counted for workload recording.

**D5655**

CYTOLOGY  
CFR(s): 493.1274(e)(4)

(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory. a. The laboratory statistics for 2018 documented 21

	<p>unsatisfactory slide preparations. 2. During an interview with the Survey Team at 10:45 AM on June 11, 2019, the Laboratory Director/Technical Supervisor confirmed that the laboratory did not have a policy and procedure specifying the criteria for an unsatisfactory nongynecologic slide preparation.</p>
<p><b>D5791</b></p>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic phases of cytology testing. Cross refer to D5633, D5637, D5641, D5643 and D5655</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director/Technical Supervisor failed to fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations (refer to D6079); failed to ensure quality assessment programs were established (refer to D6094) and failed to establish and follow policies and procedures to evaluate the competency and training needs for one of one Laboratory Director/Technical Supervisors (refer to D6103). The cumulative effect of these systemic problems resulted in the Laboratory Director/Technical Supervisor's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.</p>
<p><b>D6079</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(a)(b)</p> <p>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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his</p>

or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and interviews it was determined that the Laboratory Director/Technical Supervisor failed to be responsible for the overall operation and administration of the laboratory, to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director/Technical Supervisor were performed. Cross refer to D5403, D5633, D5637, D5641, D5643 and D5655

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and interviews it was determined that the Laboratory Director/Technical Supervisor failed to ensure that quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur. Cross refer to D5791

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on the review of laboratory policies and procedures and interview it was determined that the Laboratory Director/Technical Supervisor failed to establish policies and procedures to evaluate the competency and training needs for one of one Laboratory Director/Technical Supervisors who performed microscopic evaluations of nongynecologic cytology results during the years 2017 and 2018 and to the date of the survey in 2019. Cross refer to D5209

**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 procedures, lack of laboratory records and interview it was determined that the Laboratory Director/Technical Supervisor failed to establish individual workloads limits for one of one Laboratory Director/Technical Supervisors. The Laboratory Director/Technical Supervisor also failed to reassess the workload limits at least every six months and make adjustments when necessary during the years 2017 and 2018 and to the date of the survey in 2019. Cross refer to D5633 and D5637

**D9999**

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