

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0923908	(X3) Date Survey Completed 11/04/2019
Name of Provider or Supplier Urologic Surgical Associates Pc	Street Address, City, State 4720 Fort Hamilton Parkway, Suite 1, Brooklyn, NY	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the pathology laboratory's procedure manual and interview with the pathologist/laboratory director, the laboratory failed to establish written procedures for: 1. The retention of FISH images; 2. The retention and storage of both cytology and pathology slides; 3. The computer system is inoperable.</p>
D5633	<p>CYTOLOGY CFR(s): 493.1274(d)(1)</p>

(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 surveyor's review of laboratory policies and procedures, lack of documentation and interview with the pathologist/laboratory director/technical supervisor, the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established and implemented. FINDINGS: The pathologist/laboratory director/technical supervisor confirmed on November 4, 2019 at approximately 1:30 PM, that the laboratory failed to establish written policies procedures to include the maximum workload limits for the pathologist who performs the primary evaluation of non-gynecologic cytology slides.

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 surveyor's review of the laboratory's cytology procedure manual, laboratory records and an interview with the pathologist/laboratory director/technical supervisor, the laboratory failed to established written policies and procedures to ensure that workload limits would be reassessed at least every 6 months and adjusted when necessary for the pathologist who performs the primary screening of non-gynecologic cytology slides. FINDINGS: The pathologist/laboratory director/technical supervisor, confirmed on November 4, 2019 at approximately 1:30 PM, that the laboratory failed to established written policies and procedures to ensure that workload limits would be reassessed at least every 6 months and adjusted when necessary for the pathologist who performs the primary screening of non-gynecologic cytology slides.

D5639

CYTOLOGY

CFR(s): 493.1274(d)(2)(i)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the Following: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;

This STANDARD is not met as evidenced by:

Based on surveyor's review of the cytology procedure manual and an interview with the pathologist/laboratory director, the laboratory failed to establish written policies and procedures to ensure that the maximum number of slides examined in a 24-hour period does not exceed 100 slides regardless of the site or location. FINDINGS: 1. The pathologist/laboratory director confirmed on November 4, 2019 at approximately

2:00 PM, that the laboratory failed to establish written policies and procedures that ensure the maximum number of slides examined in a 24-hour period does not exceed 100 slides regardless of the site or location.

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 surveyor's review of the Cytology procedure manual lack of workload records and an interview the pathologist/laboratory director, the pathologist failed to record the number of hours spent examining the cytology slides from January 1, 2018 through survey date. FINDINGS: 1. The pathologist/laboratory director confirmed on November 4, 2019 at approximately 1:30 PM, the surveyor's findings that the pathologist, as the primary reader, failed to record the total number of slides examined in a 24-hour period and the number of hours spent examining slides from January 1, 2018 through survey date. 2. The pathologist stated, " that the number of slides screened and the hours screened were not documented for this location."