Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0112337	(X3) Date Survey Completed 10/05/2021
Name of Provider or Supplier Urologic Specialties Pa	**Street Address, City, State** 177 North Dean Street, 3rd Floor, South Tower,, Englewood, NJ	
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 surveyor review of the Biannual Assessment (BA) records and interview with the Physicians Office Owner (POO), the laboratory failed to verify the accuracy of Histopathology and Cytology testing from 5/3/19 to the date of survey. The finding includes: 1) Biannual assessment has not been performed since 5/3/19. 2) The POO confirmed on 10/5/21 at 11:00 pm that the laboratory did not perform BA for Histopathology and Cytology since 5/3/19.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on lack of maintenance records and interview with the Physicians Office Owner (POO), the laboratory failed to perform and document annual maintenance on the microscope used in laboratory testing from January 2020 to the date of the survey. The POO confirmed on 10/5/21 at 10:30 am there was no documented evidence that annual maintenance was performed on the microscope from January 2020 to the date of the survey.

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 policies and procedures, lack of laboratory records and interview with the Physicians Office Owner (POO), the laboratory failed to establish written policies and procedures for the evaluation and comparison of three of three required statistics for nongynecologic cytology from 1/31/19 to the date of the survey. Findings include: 1. The laboratory failed to provide written policies and procedures for an annual statistical evaluation of three required statistics for nongynecologic specimens. 2. The laboratory failed to provide an evaluation of three of three required statistics. Statistics include: a. The number of cytology cases examined. b. The number of specimens processed by specimen type. c. The number of patient cases reported by diagnosis to include unsatisfactory. 3. The POO confirmed on 10/5/21 at 10:50 am the laboratory did not have the above procedure.
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 surveyor review of the Procedure Manual (PM) and Work Load log and interview with the Physicians Office Owner (POO), the laboratory failed to establish workload limits for personnel reading nongynecology slides from 6/5/19 to the day of the survey. The POO confirmed on 10/5/21 at 11:00 am that workload limits were not established.
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 review of the Procedure Manual and interview with the Physicians Office Owner (POO) the laboratory failed to establish a procedure for maintaining records of the total number of slides reviewed in 24 hours from 1/31/19 to the date of the survey. The POO confirmed on 10/5/21 at 10:15 am that the above mentioned procedure was not established.