Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0110154	08/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Urology Group, Pa	4 Godwin Avenue, Midland Park, 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
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 surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to enroll in an approved PT program for Gram Stain and Antibiotic Susceptibility tests from 2/22/19 to the date of survey. The TC confirmed on 8/12/21 at 2:40 pm the laboratory was not enrolled in PT for the above test..
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to review and evaluate coded PT results obtained with the American Association of Bioanalysts (AAB) Chemistry tests

	in the calendar year 2020 and 2021. The findings include: 1. The laboratory did not evaluate the asterisk (*) (out of grading range or incorrect response) for Urine Sediment Educational in event Q3 - 2020 and Q1 - 2021. 2. The TC confirmed on 8/12 /21 at 2:30 pm that the laboratory failed to evaluate coded results for PT events above.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Laboratory Director (LD), the laboratory failed to establish a detailed procedure for Biannual Assessment (BA) from 2/22/19 to the date of survey. The findings include: 1. The BA procedure did not include the name of the referring pathologist or how discrepancies will be documented. 2. The laboratory included the diagnosis when sending out the slides for review but the diagnosis is part of the BA. 2. The LD confirmed on 8/12/21 at 3:15 pm that the BA procedure was not in detail.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturers Package Insert (MPI), Microbiology work records and interview with the General Supervisor (GS), the laboratory failed to follow the MPI for BD BBL Sensi-Disc Antimicrobial Susceptibility Test Discs used for Urine Culture Sensitivity tests from 2/22/19 to the date of the survey. The finding includes: 1. The MPI stated to perform a Gram Stain before plating organism but there was no documented evidence Gram Stains on Gram Negative organisms were performed. 2. The TP #3 listed on CMS form 209 confirmed on 3/14/19 at 2:10 pm the laboratory did not follow the MPI. .
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 the lack of Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to check each new lot number and shipment of Mueller Hinton Agar, MacConkey/Blood Agar plates and Uricults for sterility, ability to support growth and select or inhibit organisms from 2/22/19 to the date of the survey. The GS confirmed on 8/12/21 at 1:50 pm the laboratory did not perform the above QC.
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 Laboratory Director (LD), the laboratory failed to establish written policies and procedures for the evaluation and comparison of three of three required statistics for nongynecologic cytology from 2/22/19 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 LD confirmed on 8/12/21 at 2:50 pm the laboratory did not have the above procedure. This was cited on the previous survey performed on 2/22/21.
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 interview with the Laboratory Director (LD), the laboratory failed to establish workload limits for personnel reading nongynecology slides from 2/22/19 to the day of the survey. The LD confirmed on 8/12/21 at 3:00 pm 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 Laboratory Director (LD), the laboratory failed to establish a procedure for maintaining records of the total number of slides reviewed in 24 hours from 2/22/19 to the date of the survey. The LD confirmed on 8/12/21 at 3:05 pm that the above mentioned procedure was not established. This was cited on the previous survey performed on 2/22/21.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. This STANDARD is not met as evidenced by: Based on surveyor review of the Individual Quality Control Plan (IQCP), Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to follow written procedures for QC performed on the Remel Rapid One System from 2/22/19 to the date of survey. The findings include: 1. The IQCP stated QC was to be performed with each new lot number and monthly there after but the laboratory performed QC once on each new lot number. 2. The GS confirmed on 8/12 /21 at 2:45 pm that the laboratory did not follow written procedures.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure that PT samples were tested for Gram Stain and Antibiotic Sensitivity tests from 2/22/19 to the date of the survey. The TC confirmed on 8/12/21 at 2:35 pm that the LD did not ensure PT samples were tested for all tests performed in the laboratory.