Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0110154	02/22/2019
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Clinical Consultant (CC), the laboratory failed to maintain attestation statements for PT provided by the American Associations of Bioanalysts (AAB) for Q2 NonChemistry and Q3 Chemistry 2018. The CC confirmed on 2/20/19 at 10:30 am that the above attestation statements were not maintained.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by:

	Based on surveyor review of the Competency Assessment (CA) records and interview with the Clinical Consultant (CC), the laboratory failed to perform CA correctly on one of three Testing Personnel and the General Supervisor (GS) from 3/8/17 to the date of survey. The finding includes: 1. The CA did not include how assessment was done and what records were reviewed. 2. The CC confirmed on 2/20/19 at 10:00 am that CA was not done correctly.
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 surveyor review of the Procedure Manual and interview with the Laboratory Director (LD), the laboratory failed to establish a written procedure which included number of cytology cases examined, specimens processed by type and patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) from 3/8/17 to the date of the survey. The LD confirmed on 2/20/19 at 10:30 am the laboratory did not have the above procedure.
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 surveyor review of the Procedure Manual (PM), review of laboratory records, and interview with the Laboratory Director (LD), the laboratory failed to establish written policies and procedures to ensure that the LD/Technical Supervisor (TS) established a maximum workload limit for two of two Testing Personnel who performed the primary screening of cytology specimens from 3/8/17 to the date of the survey. The LD confirmed on 2/20/19 at 10:45 am that there were no written procedures to establish individual workload limits and no workload limits established by the TS/LD.
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 the surveyor review of the Procedure Manual (PM), review of laboratory records, and interview with the Laboratory Director (LD), the laboratory failed to establish a written procedure to ensure that the workload limit is reassessed at least every 6 months and adjusted when necessary from 3/8/17 to the date of the survey. The LD confirmed on 2/20/19 at 10:40 am the above procedure was not established.
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 review of the Procedure Manual and interview with the Laboratory Director (LD), the laboratory failed to establish a written procedure which ensures the maximum number of slides read in an 8 hour period does not exceed 100 regardless of the location from 2/2/19 to the date of the survey. The LD confirmed on 2/20/19 at 10: 15 am the laboratory did not establish the above procedure.
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 3/8/17 to the date of the survey. The LD confirmed on 2/20/19 at 10:50 am that the above mentioned procedure was not established.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and

	identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Reports (FR) and interview with the Clinical Consultant (CC), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR for Urine Culture and Sensitivity tests from 3/8/17 to the date of survey. The CC confirmed on 2/20/19 at 2:15 pm that the TRD was not on the FR.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the surveyor review of the Final Reports (FR) and interview with the Clinical Consultant (CC), the laboratory failed to have a Reference Range (RR) for Urine Culture and Sensitivity tests on the FR from 3/8/17 to the date of the survey. The CC confirmed on 2/20/19 at 2:20 pm that the above tests did not have a RR on the FR.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Clinical Consultant (CC), the laboratory failed to have a procedure to verify manually entered Urine Culture and Sensitivity test results into the Patient's Medical Record for accuracy from 3/8/17 to the date of the survey. The LD confirmed on 2/20/19 at 2:15 pm that the laboratory did not have the procedure mentioned above.