Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0314894	05/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Urology Group, Pc, The	6029 Walnut Grove Road Suite 300, Memphis, TN	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with the technical consultant, the laboratory failed to test proficiency testing samples in the same manner as patient specimens in 2018 and 2019. The findings include: 1) Review of the laboratory's proficiency testing records revealed the following: 2018 Event Two Chemistry-Miscellaneous: Instrument printouts -- PSA, Free PSA and Testosterone performed multiple times for all three samples. 2018 Event Three Hematology /Coagulation Urinalysis Instrument printouts - Both samples were tested in duplicate-once on each instrument. 2019 Event One Hematology/Coagulation Urinalysis Instrument printouts -- Both samples were tested multiple times, by multiple personnel, on multiple dates and on multiple instruments. 2) Interview with the technical consultant on May 1, 2019 at 12:20 pm confirmed the laboratory failed to test proficiency samples the same as it tests patient samples when it performed repeat testing of proficiency testing samples. The laboratory does not routinely repeat patient testing. _____
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 review of patient test reports, laboratory records, and interview with the laboratory director, the laboratory failed to verify the accuracy of cytology and histopathology twice a year in 2017, 2018, and 2019. The findings include: 1) Review of patient numbers 17, 18, 19, 20, 22, 23, 24, 25 and 26 revealed patient testing performed for cytology and histopathology in 2017, 2018, and 2019. 2) Review of laboratory records revealed no records were available documenting accuracy twice a year in 2017, 2018, and 2019 for cytology and histopathology. 3) Interview with the laboratory director on May 1, 2019 at 12:15 pm confirmed no records were available documenting accuracy twice a year in 2017, 2018, and 2019. _____
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Citation number one Based on review of the laboratory procedure manual, calibration records, patient test report, quality control records and interview with the technical consultant, the laboratory failed to follow the procedure for quality control in 2019. The findings include: 1) Review of the laboratory procedure titled "QUALITY CONTROL ASSESSMENT" revealed that quality control is to be performed after "calibration of analyte." 2) Review of the calibration records revealed calibration of testosterone on 04.22.2019 at 01:12 pm. 3) Review of patient number twenty one test report revealed testosterone reported on 04.22.2019 at 4:24 pm. 4) Review of April 2019 quality control records for testosterone revealed that quality control was not performed following calibration of testosterone on 04.22.2019 with patient testing performed. 5) Interview with the technical consultant on May 1, 2019 at 4:00 pm confirmed the laboratory failed to follow the quality control procedure when it did not perform quality control after calibration in 2019. _____ Citation number two Based on observation of the laboratory, the laboratory procedure manual for urinalysis, and interview with the lead testing personnel, the laboratory failed to follow procedure for recording urine color and clarity in 2019. The findings include: 1) Observation of the laboratory on May 1, 2019 at 8:30 am revealed two Clinitek Advantus urinalysis instruments in use for patient testing. Testing personnel were observed performing urinalysis testing and did not enter color and clarity of the urine specimen into the urinalysis instrument. 2) Review of the laboratory procedure manual for urinalysis revealed "Enter the color and clarity of each specimen before dipping the urine strip." 3) Interview with testing personnel number one on May 1, 2019 at 8:45 am confirmed the laboratory personnel did not enter the color and clarity of the urine sample into the urinalysis instrument. The instrument is set to default to yellow and clear and testing personnel do not change the color and clarity to reflect the true urine color and clarity.

	Testing personnel number one stated they are too busy to enter the observations. The testing personnel failed to follow procedure for entering color and clarity of urine specimens in 2019. _____
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient test reports and laboratory records, and interview with the laboratory director, the laboratory failed to record stain quality control in 2019. The findings include: 1) Review of patient test reports for surgical pathology revealed the following: Patient number 18--prostate biopsy-reported on 4.26.19 Patient number 19--bladder biopsy-reported on 5.1.19 Patient number 20-surgical pathology for vas deferens-reported on 5.1.19 2) Review of laboratory records revealed no stain quality control documentation on 4.26.19 or 5.1.19. 3) Interview with the laboratory director on May 1, 2019 confirmed the laboratory does not document quality control for histology stain each day of use. _____
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of patient test report and interview with the laboratory director, the laboratory failed to document quality control for immunohistochemical (IHC) stains in 2019. The findings include: 1) Review of patient number 22 prostate biopsy test report revealed the use of IHC stains. 2) Review of laboratory records revealed no documentation of quality control for the IHC stain. 3) Interview with the laboratory director on May 1, 2019 at 12:15 pm confirmed the laboratory does not document IHC stain quality control. _____
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 review of patient test reports, laboratory records and interview with the laboratory director the laboratory failed to maintain workload records for cytology in 2017, 2018, and 2019. The findings include: 1) Review of patient number 17 test report revealed patient reporting for urine cytology on 4.29.19. 2) Review of laboratory records revealed no workload records for the individual examining the slide were maintained. 3) Interview with the laboratory director on May 1, 2019 at 12: 15 pm confirmed the laboratory director performs patient testing for cytology and failed to maintain cytology workload records. _____
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of instrument comparison records, and interview with the technical consultant, the laboratory failed to compare results between urinalysis instruments twice a year in 2017, 2018, and 2019. The findings include: 1) Observation of the laboratory on May 1, 2019 at 8:30 am revealed two moderately complex urinalysis instruments in use for patient testing: Clinitek Status Advantus serial numbers 85931526 and 02761628. 2) Review of instrument to instrument comparison records revealed no twice a year comparison in 2017, 2018, and 2019. 3) Interview with the technical consultant on May 1, 2019 at 1:30 pm confirmed the laboratory failed to compare results between the two moderately complex urinalysis instruments in 2017, 2018, and 2019. _____
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 review of the Clinitek Advantus Operator's Guide, patient test reports, and interview with the technical consultant, the final patient test report for urinalysis failed to include units of measure (UOM) in 2017, 2018, and 2019. The findings include: 1)

	Review of the Clinitek Advantus Operator's Guide and patient urinalysis test reports (#1 dated 4.29.19, #5 dated 11.6.18, #9 dated 2.14.18 and #13 dated 08.01.17) revealed the following: Glucose: Operator guide UOM = mg/dL, patient test reports=No UOM Protein: Operator guide UOM = mg/dL, patient test reports=No UOM Protein:Creatinine Ratio: Operator guide Correct UOM = mg/g, patient test reports =mg/dL 2) Interview with the technical consultant on May 1, 2019 at 4:00 pm confirmed the laboratory final patient urinalysis test report did not include UOM for glucose and protein and had incorrect UOM for protein:creatinine ratio in 2017, 2018 and 2019. _____