Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	44D0314894	06/09/2022
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
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 the laboratory procedure manual, document request, and staff interview, the laboratory failed to follow the procedure for verification of accuracy of cytology procedures in November 2021 and May 2022 resulting in the laboratory not verifying the accuracy of cytology procedures twice a year in 2021 and 2022. The findings include: 1. Review of the laboratory procedure manual revealed that verification of the accuracy of cytology procedures would be accomplished by splitting five samples with another laboratory twice a year in May and November for case review for concurrent diagnosis. 2. Request for documentation of the twice a year verification of accuracy of cytology procedures on 06/09/2022 at 1 pm to the laboratory lead testing person revealed no records were available for the verification due in November 2021 and May 2022. 3. Interview with the laboratory lead testing person on 06.09.2022 at 1:30 pm confirmed the laboratory failed to follow the laboratory procedure for verification of accuracy of cytology procedures in November 2021 and May 2022, resulting in the laboratory not verifying the accuracy of cytology procedures twice a year in 2021 and 2022.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, patient test records and email communication, and staff interview, the laboratory director failed to approve the procedures used in the molecular laboratory prior to patient testing which began on 07.16.2021 with approximately 4,430 patient reported from 07.16.2021 until the date of the survey on 06.09.2022. The findings include: 1. Observation of the laboratory on 06.09.2022 at 9 am revealed molecular based high-complexity laboratory-developed testing being performed in suite 110 for bacterial identification and bacterial antibiotic resistance. 2. Review of the laboratory procedure manual revealed the procedures for the molecular laboratory had not been approved the laboratory director. 3. Review of patient test records revealed the first patient was reported on 07.16.2021 (patient accession #175204.07162021). Review of email communication received on 06.14.2022 from the general supervisor of the molecular laboratory revealed approximately 4,430 patients have been reported since testing began on 07.16.2021 without procedures that were approved by the lab director. 4. Interview with the general supervisor of the molecular laboratory on 06.09.2022 at 2: 30 pm confirmed the laboratory director failed to review and approve procedures used for molecular testing prior to patient testing with the first patient reported on 07.16.2021.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of quality control (QC) records, patient test records and staff interview, the laboratory failed to verify the QC limits used for Lot 125467-Level three for the p2Prostate Specific Antigen (p2PSA) resulting in the use of incorrect QC limits from 03.30.2022 to 05.27.2022 with approximately 403 patients reported during the period the incorrect ranges were in use (one of nineteen lots reviewed for QC limits). The findings include: 1. Observation of the laboratory on 06.09.2022 at 8:30 am revealed the Beckman Coulter UniCel DxI 600 Access Immunoassay System (serial #901338) instrument in use for performing p2PSA patient testing. 2. Review of the laboratory's quality control records revealed the use of incorrect QC limits for p2PSA as follows: Lot 125467 - level three - manufacturer stated assay range = 958.15 +/- 143.72, range in use = 985.15 +/- 143.72. The incorrect ranges for p2PSA level three were in use from 03.30.2022 until 05.27.2022. 3. Review of patient # 127417 revealed p2PSA reported during the period the incorrect QC ranges were use. Further review of the laboratory activity report for the p2PSA test revealed approximately 403 patients were reported during the period when

	the incorrect ranges were in use. 4. Interview with the lead testing person on 06.09.2022 at 4:30 pm confirmed the laboratory failed to verify the QC ranges in use for p2PSA for lot 125467-level three in 2022 with approximately 403 patients reported during the period the incorrect ranges were in use (one of nineteen lots reviewed for QC limits).
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the molecular laboratory alternative proficiency testing assessment records, and interview with the general supervisor, the laboratory director failed to review the alternative proficiency testing assessment records for 11.17.2021 (one of one reports) in 2021. The findings include: 1. Review of the laboratory's report titled "Alternative Proficiency Testing' with an assessment date of 11.17.2021 revealed the report had not been reviewed. 2. Interview with the general supervisor of the molecular laboratory on 06.09.2022 at 4 pm confirmed the laboratory director failed to review the "Alternative Proficiency Testing" assessment dated 11.17.2021 for testing performed in the molecular laboratory (one of one reports).