Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0314894	03/20/2024
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
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory policy, lack of records, and staff interviews, the laboratory failed to perform function checks for the centrifuges used to process patient blood samples for chemistry testing in 2023 and 2024. The findings include: 1. Observation of the laboratory on 03/20/2024 at 10:00 am revealed three Druker Diagnostics 642E centrifuges used to centrifuge patient blood samples for serum chemistry testing on the Beckman Coulter Unicel 600 (Serial# 901338) instrument. 2. A review of the laboratory policy titled "Specimen Collection and Handling" section "Serum Samples" revealed patient blood samples would be centrifuged for 10 minutes at 3000 revolutions per minute (RPM) for chemistry testing. 3. Documentation of centrifuge timer and RPM function checks were not available on the date of the survey (03/20/2024) for 2023 or 2024. 4. An interview with the technical consultant and laboratory lead on 03/20/2024 at 11:00 am confirmed the laboratory used the Druker Diagnostics 642E centrifuges to process patient serum samples for chemistry testing on the Beckman Coulter Unicel 600 chemistry instrument and did not have documentation for centrifuge timer and RPM function checks for 2023 or 2024.

D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Aspen Web 116 database specialties, the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), lack of records, and staff interview, the laboratory director failed to ensure compliance with 493.51(c) which requires laboratories to notify the state agency of deletions or changes in test methodologies included in a specialty or subspecialty, or both, within six months of the change, when the laboratory stopped patient testing for the bacteriology and mycology sub-specialties in December 2022 and failed to notify the state agency of the change. The findings include: 1. Review of the Aspen Web 116 database revealed the laboratory's CLIA certification included the sub-specialties of bacteriology and mycology. 2. A review of the Form CMS 116 submitted for the survey on 03/20/2024 did not include bacteriology and mycology as specialties. 3. Documentation of state agency notification for the deletion of bacteriology and mycology was not available on the date of the survey (03/20/2024) 4. An interview on 03/20/2024 with the technical consultant and laboratory lead at 11:00 am confirmed the laboratory ceased testing for bacteriology and mycology in December 2022 and failed to notify the state agency of the changes.