Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1091566	(X3) Date Survey Completed 12/09/2024
Name of Provider or Supplier Urology Group Of Florida Llc	**Street Address, City, State** 3399 Pga Blvd, Ste 230, Palm Beach Gardens, FL	
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
D0000	A recertification survey was conducted on 11/21/2024 to 12/09/2024. Urology Group of Florida LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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 record review and interview, the laboratory failed to create a policy on when and who to perform competency assessments on. The laboratory failed to perform annual competency on 1 of 5 TP (testing personnel) (TP#E) in 2022 and 2023. Finding Include: Review of Laboratory Personnel Report revealed TP#E was a testing person for moderate complexity. The review of Policy and Procedure signed by the laboratory director on 5/31/2024 revealed no documentation of a policy on how and when initial, six months and annual competency assessments would be performed. Review of Personnel Competency Attestation revealed TP#E had no annual competency assessments in 2022 and/or 2023. Review of Patient Reports revealed TP#E performed urinalysis microscopy testing on 11/4/2024 and 12/7/2023 On 11/21 /2024 at 2:31 PM, the clinical manager confirmed TP#E did not have competency assessments performed in 2022 and 2023.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and

	test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to store blood specimen tubes at -20 Celsius(C) or colder past 24 hours for prostate-specific antigen (PSA) and testosterone (Testo) testing. Findings Included: On 11/21/2024 at 11:40 AM, a lab tour revealed blood tubes were stored in freezer #2 to be tested at a later date. Review of Patient Reports revealed: 1. PT#1 specimen was collected on 7 /19/2023 and reported 7/21/2023 for PSA testing. 2. PT#2 specimen was collected on 7 /19/2023 and reported 7/21/2023 for PSA testing. 3. PT#3 specimen was collected on 9 /11/2024 and reported 9/12/2024 for PSA testing. 4. PT#4 specimen was collected on 9 /11/2024 and reported 9/12/2024 for Testo testing. 5. PT#5 specimen was collected on 9/11/2024 and reported 9/12/2024 for Testo testing. Review of the PSA reagent package insert read, "serum samples is to be assayed within 24 hours after collection, the specimen should be stored in refrigerator at 2 to 8C. Specimens held for longer times (up to 5 months) should be frozen at -20C or colder." Review of Temperature policy read," Freezer temperature changes in January 2024 from -20 to -27 to -0 to -20." Review of Temperature Logs revealed from January 2024 to November 2024 temperature logs were recording temperatures of -0 to -20C. On 11/21/2024 at 1:30 PM, testing personnel stated they store blood tubes in freezer #2 for two days for PSA and Testo testing.