Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2097023	12/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Urology Associates Of Green Bay, Sc	2720 Cahill Rd, Marinette, WI	

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
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory refrigerator, review of temperature records from 2024, and interview with the Clinic Manager (Staff A), the laboratory did not document corrective actions taken when the refrigerator temperatures were not within the acceptable range for proper storage of reagents on three days in twelve months. 1. Observation of the laboratory refrigerator on December 19, 2024, at 10:00 AM revealed reagent packs and controls for the Qualigen FastPack system stored in the refrigerator. The reagent packs and controls boxes showed the manufacturer storage requirement was between 2 - 8 degrees Celsius (C). 2. Review of 'Laboratory Duties' logs from 2024 that included documentation of the refrigerator temperature showed out of range temperatures recorded on February 1 (0 C), October 7 (10 C), and December 2 (0 C). The logs showed no corrective actions taken. 3. Interview with Staff A on December 19, 2024, at 10:30 AM confirmed the temperatures were not in range on the noted days and confirmed staff did not document corrective actions taken.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on surveyor review of Centers for Medicare and Medicaid Services (CMS) forms, personnel records, and test records, and interview with the Clinic Manager (Staff A), the Laboratory Director, who is also the Technical Consultant, did not evaluate the competency of two of five new testing personnel semiannually during the first year the individuals tested patient specimens. Findings include: 1. The CMS Form 209, Laboratory Personnel Report (CLIA) submitted for this survey and signed by the laboratory director on December 10, 2024, identified five individuals, including Staff B and C, as new testing personnel who were not identified as testing personnel on the CMS Form 209 from the previous survey (signed by the Laboratory Director on February 2, 2023). 2. Review of personnel records from 2022, 2023, and 2024 showed the Laboratory Director signed 'Personnel Evaluation Checklist for FastPack' forms showing completion of annual evaluations for Staff B on February 5, 2024, and Staff C on December 5, 2024. No earlier records of competence evaluation were available for Staff B or Staff C. 3. Review of patient test records from 2024 showed Staff B performed a patient test on April 15, 2024, further review showed Staff C performed testing since March 2024. 4. Interview with Staff A at 10:30 AM confirmed records were not available showing the Laboratory Director completed semi-annual competence evaluations for Staff B or C during the first year of patient testing.