Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2173386	03/03/2026
Name of Provider or Supplier	**Street Address, City, State**	
Urology Specialist Group Llc	2140 W 68th St Suite 302, Hialeah, 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	An announced CLIA recertification survey was conducted at Urology Specialist Group LLC from 02/27/2026 to 03/03/2026. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6076 493.1441 Condition: Laboratory Director
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to provides overall management and direction by ensuring the laboratory enrolled in a CMS-approved Proficiency Testing (PT) program for Bacteriology and Mycology specialties while the laboratory did Patient testing in 2025. Refer to D6088.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on records review and staff interview, the Laboratory Director (LD) failed to ensure the laboratory enrolled in Proficiency Testing (PT) for the second event of 2025 when the laboratory tested 150 patients using Realtime Polymerase Chain reaction (PCR) test to detect bacteria and or fungal presence in urine samples.

	Findings included: 1-Review performance evaluation signed by the LD on 03/04 /2025, revealed that the laboratory approved a test using a Realtime Polymerase Chain reaction (PCR) test for the detection of the following microorganisms in urine samples: Acinetobacter Baumannii, Candida albicans, Candida auris, Candida glabrata, Candida krusei, Candida Lusitanae, Candida tropicalis, Citrobacter freundii, Enterobacter aerogenes, Enterococcus faecalis, Enterococcus faecium, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morgamii, Mycoplasma hominis, Proteus Mirabilis, Proteus vulgaris, Providencia stuartii, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Staphylococcus saprophyticus, Streptococcus agalactiae, Ureaplasma uralyticum, and the following gen resistance: tampc, CTX-M group1, CTX-M group 2, ErmA, ErmB, FemA, KPC, mecA, mefA, NDM, OVA-48, QNr A, QnrB, SHV, TEM, vanA1/2, vanB, VIM/IMP-7. 2- Record review of the laboratory American of Proficiency Institute (API) PT records for 2025, revealed that the laboratory had no records for 2025 1st and 2nd event and that the laboratory failed to do an external verification of the testing method or a split sample for the period of reference. 3-Patient records review revealed that the laboratory tested 150 patient samples from 05/29/2025 to 08/22/2025. 4- During an interview on 02/27/2026 at 2:15 PM the General Supervisor confirmed that LD failed to ensure the laboratory participated in Proficiency Testing in 2nd event of 2025 or participated in an alternative evaluation.