Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2154506	05/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Florida Bladder Institute	1890 Sw Health Pkwy, Ste 202, Naples, 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 FLORIDA BLADDER INSTITUTE from 05/07/2026 to 05/18/2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiency cited as follows:
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 record review and staff interview, the laboratory failed to verify the accuracy of testing method at least twice annually for 21 out of 82 tests performed by the laboratory for detection of Urinary Tract Infection (UTI) or Vaginal Infection since 01/01/2025. Findings included: 1-Review of the test menu provided with the form CMS-116 Clinical Laboratory Improvement Amendment (CLIA) Application for Certification signed by the Laboratory Director on 04/06/2026 listed the detection of Vaginal microorganism and gene resistance markers using a Reverse Transcription-Polymerase Chain Reaction (RT-PCR) laboratory developed test (LDT) that included: Acinetobacter baumanii, Atopium vaginae, Bacterial Vaginosis-Associated Bacterium 2 (BVAB2), Candida albicans, Candida auris, Candida glabrata, Candida krusei, Candida lusitaniae, Candida parapsilosis, Candida tropicalis, Chlamydia trachomatis, Citrobacter freundii, Enterobacter aerogenes, Enterobacter cloacae Enterococcus faecalis, Enterococcus faecium, Escherichia coli, Gardnerella vaginalis, Haemophilus ducreyi, HSV I, HSV II, Klebsiella oxytoca, Klebsiella pneumoniae, Lactobacillus crispatus, Lactobacillus gasseri, Lactobacillus iners, Lactobacillus jensenii, Megasphaera I, Megasphaera II, Mobiluncus curtisii, Mobiluncus Mulieris, Morganella morganii, Mycoplasma genitalium, Mycoplasma hominis, Neisseria gonorrhea, Prevotella bivia, Proteus mirabilis, Proteus vulgaris, Providencia stuartii, Pseudomonas aeruginosa, Serratia marcescens, Staph. Saprophyticus, Staphylococcus

	aureus, Strep. Agalactiae (Group B), Treponema pallidum, Trichomonas vaginalis, Ureaplasma parvum, Ureaplasma urealyticum, ampC, ant2, Antla, aph2, aph3, CTX-M Group1, CTX-M Group2, DfrA, DfrA1, DfrA5, ErmA, ErmB, femA, fosA, GyrA, KPC, mecA, mefA, NDM, OXA-48, ParC, PVL, QNrA, QnrB, SHV, Sul1, Sul2, TEM, TetB, TetM, TetO, Van1/2vanB, VI /IMP7. 2- Review of American Proficiency Institute (API) Proficiency Testing (PT) worksheet for 2026 first event of Microbiology Vaginal and Urinary Tract Infection (UTI) panels, revealed that the following microorganisms and resistance markers were not listed: Candida auris, Lactobacillus crispatus, Lactobacillus gasseri, Lactobacillus iners, Lactobacillus jensenii, Megasphaera I, Megasphaera II, Mobiluncus curtisii, Mobiluncus Mulieris, Morganella morganii, ant2, Antla, aph2, aph3, DfrA, DfrA1, DfrA5, fosA, GyrA, ParC, TetO, 3-The laboratory did not have any records of a twice a year accuracy verification for: Candida auris, Lactobacillus crispatus, Lactobacillus gasseri, Lactobacillus iners, Lactobacillus jensenii, Megasphaera I, Megasphaera II, Mobiluncus curtisii, Mobiluncus Mulieris, Morganella morganii, ant2, Antla, aph2, aph3, DfrA, DfrA1, DfrA5, fosA, GyrA, ParC, TetO. 4-The laboratory tested 935 patients from 01/01/2025 to 05/07/2026. 5-During an interview on 05/07/2026 at 02: 00 PM, the Laboratory Director confirmed that the laboratory failed to do twice a year verification for Candida auris, Lactobacillus crispatus, Lactobacillus gasseri, Lactobacillus iners, Lactobacillus jensenii, Megasphaera I, Megasphaera II, Mobiluncus curtisii, Mobiluncus Mulieris, Morganella morganii, ant2, Antla, aph2, aph3, DfrA, DfrA1, DfrA5, fosA, GyrA, ParC, TetO during the period of reference.