Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0943757	10/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Prody Urology Pllc	575 S Wickham Rd Suite B, Melbourne, 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	Recertification survey was conducted from 8/15/2023 to 10/30/2023. Prody Urology PLLC clinical laboratory was not in compliance with 42 CFR Part 493, requirements for clinical laboratories. The following conditions were not met: 5400- Analytic Systems
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review, and interview, the laboratory failed to complete performance specifications for the following drug resistance targets :CTX-M -lactamases (CTX-M-Group 1), Vancomycin-Resistant Enterococci(VRE Van A), Staphylococcal chromosome cassette me (Mec A), Vancomycin-resistant enterococci (Vre Van B), dihydrofolate reductase (Dfra), quinolone resistance gene (Qnr) and Sulfonamide Resistance Genes (Sul) for urinary tract infection pathogens using Polymerase chain reaction(PCR) before patient testing on February 2022. (D5423)
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test

	system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to complete performance specifications for the following drug resistance targets :CTX-M -lactamases (CTX-M-Group 1), Vancomycin-resistant enterococci(VRE Van A),Staphylococcal chromosome cassette me(Mec A), vancomycin-resistant enterococci (Vre Van B), dihydrofolate reductase(Dfra), quinolone resistance gene(Qnr) and Sulfonamide Resistance Genes (Sul) for urinary tract infection pathogens using Polymerase chain reaction(PCR) before patient testing on February 2022. Findings Included: Review of Urinary Tract Infection Pathogens Using Realtime Reverse Transcriptase Quantitative Polymerase chain reaction (RT-PCR) signed by the previous laboratory director on 4 /29/2021 revealed no documentation of performance specifications in accuracy, precision, analytical sensitivity, analytical specificity and interfering substances for CTX-M- Group 1, VRE Van A, Mec A, Vre Van B, Dfra, Qnr and Sul. On 8/15/2023 at 11:00 AM, the lab's General Supervisor stated 736 patients were tested with the UTI PCR panel from February 1, 2022, to August 15th, 2023. On 8/15/2023 at 10:44 AM, the General Supervisor confirmed performance specifications were not completed for CTX-M- Group 1, VRE Van A, Mec A, Vre Van B, Dfra, Qnr and Sul drug resistance targets.