Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2243600	11/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Garden State Urology Llc	16 Eden Lane, Whippany, NJ	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (b)(7) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to maintain the Work Records (WR) and Comparative Evaluation (CE) for Mycobacteriology and Urinary Tract Infection (UTI) panel performed with American Proficiency Institute (API) in the calendar years 2024 and 2025 1. There were no WR for all PT events in the calendar years 2024 and 2025. 2. There was no CE for events 1 of 2024 and 1 and 2 of 2025. 3. The GS confirmed on 11/5/25 at 11:00am the the WR for PT were not maintained.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to review and evaluate PT results obtained from the American Proficiency Institute (API) for Microbiology in the calendar year 2024 . The findings include: 1. The laboratory did not evaluate "Not Graded 11", "See Data Summary" responses from API in event 3, 2024 for the following: a. Resistance Gene: AmpC, Samples UTI-11, 13, 14. and 15. b. Resistance Gene: CTX-M , Samples UTI-11, 13, 14. and 15. c. Resistance Gene: CTX-M Group

	1 Samples UTI-11, 13, 14. and 15. d. Resistance Gene: CTX-M Group 2 Samples UTI-11, 13, 14. and 15. e. Resistance Gene: dfrA Samples UTI-11, 13, 14. and 15. f. Resistance Gene: Emb Samples UTI-11, 13, 14. and 15. g. Resistance Gene: IMP Samples UTI-11, 13, 14. and 15. h. Resistance Gene: KPC Samples UTI-11, 13, 14. and 15. i. Resistance Gene: mecA Samples UTI-11, 12, 13, 14. and 15. j. Resistance Gene: qnrA Samples UTI-11, 13, 14. and 15. k. Resistance Gene: qnrS Samples UTI-11, 13, 14. and 15. l. Resistance Gene: sul1 Samples UTI-11, 13, 14. and 15. m. Resistance Gene: sul2 Samples UTI-11, 13, 14. and 15. n. Resistance Gene: vanA Samples UTI-11, 13, and 14. o. Resistance Gene: vanB Samples UTI-11, 12, 13, and 14. p. Resistance Gene: VIM Samples UTI-11, 13, 14. and 15. q. Aerococcus urinae: Sample UTI-15. 2. The laboratory did not evaluate "Not Graded 3", "See Data Summary" responses from API in event 2, 2024 for the following: a) Rifampin resistance (molecular): Samples MTM-06 and 08 3. The GS confirmed on 11/5/25 at 10:30 am. the laboratory failed to evaluate the above mentioned coded results. Note: This was previously cited 10/18/23.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to verify the accuracy of Microbiology test results obtained from the American Proficiency Institute (API) fro the 2nd and 3rd events of 2024. The findings include: 1. The PT program assigned an artificial score of 100%, results were reported with the comments "See data summary", "Not Graded 11", and "Not Graded 3" 2. The laboratory did not evaluate "Not Graded 11", "See Data Summary" responses from API in event 3, 2024 for the following: a. Resistance Gene: AmpC, Samples UTI-11, 13, 14. and 15. b. Resistance Gene: CTX-M , Samples UTI-11, 13, 14. and 15. c. Resistance Gene: CTX-M Group 1 Samples UTI-11, 13, 14. and 15. d. Resistance Gene: CTX-M Group 2 Samples UTI-11, 13, 14. and 15. e. Resistance Gene: dfrA Samples UTI-11, 13, 14. and 15. f. Resistance Gene: Emb Samples UTI-11, 13, 14. and 15. g. Resistance Gene: IMP Samples UTI-11, 13, 14. and 15. h. Resistance Gene: KPC Samples UTI-11, 13, 14. and 15. i. Resistance Gene: mecA Samples UTI-11, 12, 13, 14. and 15. j. Resistance Gene: qnrA Samples UTI-11, 13, 14. and 15. k. Resistance Gene: qnrS Samples UTI-11, 13, 14. and 15. l. Resistance Gene: sul1 Samples UTI-11, 13, 14. and 15. m. Resistance Gene: sul2 Samples UTI-11, 13, 14. and 15. n. Resistance Gene: vanA Samples UTI-11, 13, and 14. o. Resistance Gene: vanB Samples UTI-11, 12, 13, and 14. p. Resistance Gene: VIM Samples UTI-11, 13, 14. and 15. q. Aerococcus urinae: Sample UTI-15. 3. The laboratory did not evaluate "Not Graded 3", "See Data Summary" responses from API in event 2, 2024 for the following: a) Rifampin resistance (molecular): Samples MTM-06 and 08 4. The GS confirmed on 11/5/25 at 11:20 am that the accuracy of the PT results were not verified and the PT program assigned an artificial score of 100%. Note: This was previously cited 10/18/23
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of reagents, review of the Procedure Manual (PM) and interview with the General Supervisor (GS) the laboratory failed to discard expired reagents used for Urinary Tract Infection Polymerase Chain Reaction (UTIPCR) testing from 10/19/23 to 11/5/25. The findings include: 1. The PM stated "All expired reagents, solutions, control materials and other supplies will be discarded and not used passed the expiration date." 2. Surveyor observation of the reagents revealed the following to be expired: a) One box of Taqman Master Mix lot 2791378 expired on 8 /31/24. b) One box of 20x SSC Lot 504627 expired on 9/30/24. c) One Quantstudio Digital PCR plate Lot 4619025 expired on 3/7/24. d) One box of Quantstudio 12k flex open array accessories kit lot 2211969 expired on 6/21/25. e) Two boxes of Quantstudio 12k flex open array accessories kit- starter lot 2208388 expired on 9/15 /23. f) Two boxes of Empty Array Card Kit-4pk lot 59313 expired on 7/23/22. 3. The GS stated "the reagents were kept but not used." 4. The GS confirmed on 11/5/25 at 1: 20 pm, the laboratory failed to discard expired reagents used for UTIPCR testing.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: A) Based on the lack of Maintenance Records (MR) for pipettes, observation of pipettes, review of the Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to perform and document maintenance on pipettes used for specimen preparation for Urinary Tract Infection Polymerase Chain Reaction (UTIPCR) testing from 10/19/23 to 11/5/25. The findings include: 1. The PM stated " Maintenance checks of all equipment will be performed as defined by the manufacturer and with at least the frequency specified by the manufacturer." 2. Two Thermoscientific Pipettes had calibration stickers with due dates of 1/4/21 and 7/4/21. 3. Two Tacta Mechanical Pipettes did not have calibration dates on them. 4. The GS confirmed on 11/5/25 at 1:00 pm, the laboratory did not perform and document maintenance on the pipettes. B) Based on the lack of Maintenance Records (MR) for fume hoods, observation of fume hoods, review of the PM and interview with the General Supervisor (GS), the laboratory failed to perform and document maintenance on fume hoods used for specimen preparation for UTIPCR testing from 10/19/23 to 11 /5/25. The findings include: 1. The PM stated " The fume hoods are to be verified for function yearly. If the units use filters these are to be changed according to manufacturers guidance." 2. There were was do documented evidence the laboratory changed the filters on two Air Clean 600 fume hoods. 3. The GS confirmed on 11/5

	/25 at 1:05 pm, the laboratory did not perform and document maintenance on the two fume hoods.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Reports (TR) for Urine Cytology tests and interview with the General Supervisor (GS) the laboratory failed to have all the required information from 10/19/23 to 11/5/25. The findings include: 1. TR for Urine Cytology did not include the address of the laboratory where the technical component was being performed. 2. The GS confirmed on 11/5/25 at 1:30 pm, the laboratory did not have all the required information on Urine Cytology TR.