

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2243600	<b>(X3) Date Survey Completed</b>  10/18/2023
<b>Name of Provider or Supplier</b>  Garden State Urology Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2003</b>	<p><b>ENROLLMENT</b> CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to establish and maintain the accuracy of Microbiology tests from 11/19/21 to the date of survey. This findings include. 1. The PT provider used by the laboratory American Proficiency Institute (API) did not include all analytes run on the Urinary Tract Infection (UTI) panel performed by the laboratory. 2. 1st event 2023 did not include C. Amalonaticus, C. trachomatis, CMV, E. aerogenes, HHV6, HBKV-VP2, G. Vaginalis, M. tuberculosis, N. gonorrhoeae, S. enterica, S. Haaemolytics, T. Gaginalis, U. parvum. 3. The TS confirmed on 10/18/23 at 12:45 pm not all analytes for microbiology PT were performed.</p>
<b>D3011</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory reagents, reagent refrigerator and interview with the Technical Supervisor (TS), the laboratory failed to ensure</p>

protection from chemical and physical hazards from 5/31/22 to the date of survey. The findings include: 1. All flammable and inhalation risk reagents were not kept in a flammable cabinet. 2. One case of 100% alcohol reagent and one case of 80% alcohol reagent were observed on a wire rack. 3. The laboratory stored a beverage in a refrigerator that was labeled No Food or Drink. 4. The TS confirmed on 10/18/23 at 12:00 pm that the laboratory did not ensure protection from chemical and physical hazards.

**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 Technical Supervisor (TS), the laboratory failed to review and evaluate PT results obtained from the American Proficiency Institute (API) for Microbiology in the calendar year 2023 . The findings include: 1. The laboratory did not evaluate "Not Graded 11", "See Data Summary" responses from API in event 1, 2023 for the following: a. Resistance Gene: CTX-M Group 1 Samples UTI-01,02,03 and 04. b. Resistance Gene: CTX-M Group 2 Samples UTI-03 and 04. c. Resistance Gene: Emb Samples UIT-01, and 05 d. Resistance Gene: IMP Samples UTI-01,03 and 04. e. Resistance Gene: KPC Samples UTI-01,03 and 04. f. Resistance Gene: OXA Samples UTI-01,03 and 04. g. Resistance Gene: qnrA Sample UTI-01,03 and 04. h. Resistance Gene: qnrS Samples UTI-01,03, and 04. i. Resistance Gene: vanA Samples UTI-01,02,03,04 and 05. j. Enterobacter Sample UIT-5. 2. The laboratory did not evaluate "Not Graded 11", "See Data Summary" responses from API in event 2, 2023 for the following: a.. Resistance Gene: AmpC, Samples UTI-07 and 09. b. Resistance Gene: CTX-M Samples UTI-07 and 09. c. Resistance Gene: CTX-M Group 1 Samples UTI-07 and 09. d. Resistance Gene: CTX-M Group 2 Samples UIT-07 and 09. e. Resistance Gene: dfrA Samples UIT-07 and 09. f. Resistance Gene: EmB Samples UTI-06,07, 09,a and 10. g. Resistance Gene: IMP Samples UTI-07, and 09. h. Resistance Gene: OXA Samples UTI-07, and 09. i. Resistance Gene: qnr Samples UTI-07, and 09. j. Resistance Gene: qnrA Samples UTI-07, and 09. k. Resistance Gene: qnrS Samples UTI-07, 09 and 10. l. Resistance Gene: sul Samples UTI-07 and 09. m. Resistance Gene: sul1 Samples UTI-07 and 09. n. Resistance Gene: sul2 Samples UTI-07 and 09. o. Resistance Gene: vanA Samples UTI-06, 08, 09 and 10. p. Resistance Gene: vanB Samples UTI-06, 08, 09 and 10. 3. The TS confirmed on at 10: 30 am on 10/18/23 that the laboratory failed to evaluate the above mentioned coded results.

**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 Technical Supervisor (TS), the laboratory failed to verify the accuracy of Microbiology test results obtained from the American Proficiency Institute (API) 2nd event of 2022 and 1st event 2023. 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". 2. There was no documented evidence the laboratory verified the following for event 1st event 2023. a. Resistance Gene: CTX-M Group 1 Samples UTI-01,02,03 and 04. b. Resistance Gene: CTX-M Group 2 Samples UTI-03 and 04. c. Resistance Gene: Emb Samples UIT-01, and 05 d. Resistance Gene: IMP Samples UTI-01,03 and 04. e. Resistance Gene: KPC Samples UTI-01,03 and 04. f. Resistance Gene: OXA Samples UTI-01,03 and 04. g. Resistance Gene: qnrA Sample UTI-01,03 and 04. h. Resistance Gene: qnrS Samples UTI-01,03, and 04. i. Resistance Gene: vanA Samples UTI-01,02,03,04 and 05. j. Enterobacter Sample UIT-5. 3. There was no documented evidence the laboratory verified the following for the 2st event of 2023. a.. Resistance Gene: AmpC, Samples UTI-07 and 09. b. Resistance Gene: CTX-M Samples UTI-07 and 09. c. Resistance Gene: CTX-M Group 1 Samples UTI-07 adn 09. d. Resistance Gene: CTX-M Group 2 Samples UIT-07 adn 09. e. Resistance Gene: dfrA Samples UIT-07 and 09. f. Resistance Gene: EmB Samples UTI-06,07, 09,a adn 10. g. Resistance Gene: IMP Samples UTI-07, and 09. h. Resistance Gene: OXA Samples UTI-07, and 09. i. Resistance Gene: qnr Samples UTI-07, and 09. j. Resistance Gene: qnrA Samples UTI-07, and 09. k. Resistance Gene: qnrS Samples UTI-07, 09 and 10. l. Resistance Gene: sul Samples UTI-07 and 09. m. Resistance Gene: sul1 Samples UTI-07 and 09. n. Resistance Gene: sul2 Samples UTI-07 and 09. o. Resistance Gene: vanA Samples UTI-06, 08, 09 and 10. p. Resistance Gene: vanB Samples UTI-06, 08, 09 and 10. 3. The TSD confirmed on 10/18/23 at 11:20 am that the accuracy of the PT results were not verified and the PT program assigned an artificial score of 100%,

**D5401**

**PROCEDURE MANUAL**  
 CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
 Based on surveyor review of the Procedure Manual (PM) and interview with Technical Supervisor (TS) the laboratory failed to follow the procedure for "General QA Plan" from 5/31/22 to the date of survey. The findings include: 1. The PM states "Monthly the Medical Director (or his designee) is to review the following report: Monthly Quality Assessment Report (MQAR)." 2. There was no documented evidence the aforementioned report was reviewed. 3. The TS confirmed on 10/18/23 at 10:45 am the laboratory failed to follow the above mentioned procedure.

**D5805**

**TEST REPORT**  
 CFR(s): 493.1291(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 Bacteriology, Mycology, Parasitology and Virology tests performed on the Quantstudio 12 Flex Real- Time PCR System and interview with the Technical Supervisor (TS) the laboratory failed to ensure the TR included all the required information from May 2022 to the date of survey. The findings include: 1. 10 out of 10 TR did not indicate the address of the laboratory location where the test was performed. 2. 10 out of 10 TR did not indicate the specimen source. 3. 10 out of 10 TR did not include the required statement for tests that have not been FDA-cleared or approved, "The performance characteristics of this test were determined by Garden State Urology LLC." 4. The TS confirmed on 10/18/23 at 12:00 pm, the laboratory failed to ensure the TR included all the required information.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under 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 Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure that PT samples were tested for Microbiology tests in the calendar year 2022. The TS confirmed on 10/18/23 at 11:45 pm that the LD did not ensure PT Microbiology PT samples were tested.

**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 a interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from May 2022 to the date of the survey. 1. The LD failed to ensure that PS were adequate . Cross refer to D6086. 2. The LD failed to ensure that Proficiency Testing results were reviewed and evaluated. Cross refer to D6091. 3. the LD failed to

ensure to specify in writing the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing. Cross refer to D6107.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure that PS were adequate to perform Bacteriology, Virology, Mycology and parasitology tests performed on the Applied bioscience Quantstudio 12K Flex analyzer from May 2022 to the date of survey. The findings include: 1. There was no documented evidence a carryover study was performed. 2. There was no documented evidence of a stability study. 3. There were no Manufactures Packet Inserts (MPI) for any materials used to perform the PS. 4. There were no final reports for patients results used in the PS. 5. There were no original raw data reports with time and date. 6. There was no Comment for Sample P2317950 when the the validation run failed. 7. There was no Comment for Sample P2317027 when the validation run failed. 8. Clinical Validation Run Sample P2318014 Microbiology results were reported as *S. agalactiae* but the Original Run results and Validation run results reported *A. Urinae*. The Polymerase Chain Reaction (PCR) results did not match. 9. The TS confirmed on 10/18/23 at 12pm the LD failed to ensure that PS were adequate.

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical supervisor (TS), the Laboratory Director failed to ensure that Microbiology results performed with the American Proficiency Institute (API) were reviewed and evaluated by the appropriate staff. The findings include: 1. There was no documented evidence the laboratory reviewed PT events 1 and 2 of 2023. Cross refer 5211. 2. The TS confirmed on 10/18/23 at 11:50 pm that the LD did not ensure all PT reports were reviewed.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether

supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor observation of the Personnel Files and interview with the Technical Supervisor (TS) the Laboratory Director (LD) failed to specify in writing the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, from 5/31/22 to the date of the survey. The TS confirmed on 10/18/23 at 1:00 pm that the LD failed to specify in writing the responsibilities and duties of the aforementioned staff.