

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  41D2105101	<b>(X3) Date Survey Completed</b>  06/28/2022
<b>Name of Provider or Supplier</b>  Urologic Specialists Of New England, Llc	<b>Street Address, City, State</b>  207 Quaker Lane, West Warwick, RI	
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>D2005</b>	<p><b>ENROLLMENT</b> CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to authorize the American Proficiency Institute (API) to release it's proficiency testing (PT) scores to HHS in the subspecialty of Bacteriology. Findings include: 1. Record review on 6/10 /2022 of the Casper 96D, CLIA Application and Survey Summary Report report revealed the report did not have the laboratory's PT scores listed. 2. Record review on 6/10/2022 of the laboratory's 2022 API reports revealed, the laboratory's CLIA number was not listed. 3. Staff interview with the Laboratory Director on 6/10/2022 at 12:30 PM confirmed the above findings. 4. The laboratory performs 20,000 tests annually in the subspecialty of Bacteriology</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the lab director (LD) failed to follow the laboratory competency policy to assess the competency of all laboratory personnel.</p>

Findings Include: 1. Record review of the laboratory's 'Quality Assurance Plan' on 6/10/2022 revealed: a. "Technical Supervisor competency must be filled out for Technical Supervisors." b. "General Supervisor competency must be filled out for General Supervisors." 2. Record review of the laboratory's 2020 and 2021 competency records on 6/10/2022 revealed the laboratory failed to document competency for 1 of 1 Technical Supervisor (TS) and 1 of 1 General Supervisor on their CLIA responsibilities. 3. Staff Interview on 6/10/2022 at 10:30 AM with the TS and the LD confirmed the above findings.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the technical supervisor failed to assure new testing personnel (TP) received training in order to perform high complexity testing in the subspecialty of Bacteriology. Findings include: 1. Record review of TP files on 6/10/2022 revealed the laboratory failed to provide evidence or documentation of training for 1 of 1 new TP who performed Microbiology Polymerase Chain Reaction (PCR) testing in 2020 and 2021. 2. Staff interview with the laboratory director on 6/10/2022 at 11:00 AM confirmed 1 of 1 new TP did not have training documentation available for PCR testing in 2020 and 2021. 3. The Laboratory performs 20,000 Bacteriology tests annually.