

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  29D0945985	<b>(X3) Date Survey Completed</b>  08/02/2024
<b>Name of Provider or Supplier</b>  Urology Nevada, Ltd	<b>Street Address, City, State</b>  5560 Kietzke Lane Bldg A, Reno, NV	
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>D0000</b>	<p>This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on August 2, 2024. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.</p>
<b>D5215</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(2)</p> <p>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).</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) evaluations from 2023 and 2024, the laboratory's PT documentation, the laboratory's standard operating procedures (SOPs), and an interview with the laboratory manager, the laboratory director failed to ensure that all ungraded proficiency testing results were reviewed for accuracy. Findings include: 1. A review of API PT evaluations and laboratory PT documentation for 2023 and 2024 revealed that the director failed to review the ungraded results for microbiology PT events one and two in 2023. 2. The laboratory SOP titled "QM28 Proficiency Testing Results Evaluation and Documentation of Corrective Action", indicated that all results must be reviewed by the laboratory director or designee within one month. 3. These findings were confirmed by the laboratory manager in an interview at approximately 11:00 AM on August 2, 2024. The laboratory performs approximately 360 microbiology tests annually.</p>

**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 a review of the American Proficiency Institute (API) Proficiency Testing (PT) evaluations from 2023 and 2024, the laboratory's PT documentation, the laboratory's standard operating procedures (SOPs), and an interview with the laboratory manager, the laboratory director failed to ensure that all proficiency testing reports received were reviewed for accuracy and to identify any problems that require corrective action. Findings include: 1. A review of API PT evaluations and laboratory PT documentation for 2023 and 2024 revealed that the director failed to review the results for microbiology event one in 2024. 2. The laboratory SOP titled "QM28 Proficiency Testing Results Evaluation and Documentation of Corrective Action", indicated that all results must be reviewed by the laboratory director or designee within one month. The API PT evaluation for microbiology event one for 2024 was available on approximately March 20, 2024. 3. These findings were confirmed by the laboratory manager in an interview at approximately 11:00 AM on August 2, 2024. The laboratory performs approximately 360 microbiology tests annually.

**D6092**

**LABORATORY DIRECTOR RESPONSIBILITIES**

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

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) evaluations, the laboratory's PT documentation, and an interview with the laboratory manager, the laboratory director failed to ensure that an investigation was conducted and a corrective action plan was implemented for all unacceptable or unsatisfactory proficiency testing results. Findings include: 1. A review of API PT documentation from 2023 and 2024 revealed that for the third microbiology event of 2023, sample UTI-15 was unacceptable for the antibiotic resistance gene TET-B resulting in an overall microbiology antibiotic resistance score of 99%. There was no documented investigation or corrective action plan available. 2. The laboratory SOP titled "QM28 Proficiency Testing Results Evaluation and Documentation of Corrective Action", indicated that all results that do not match or have clinically significant differences must be investigated and corrective actions must be documented. 3. These findings were confirmed by the laboratory manager in an interview at approximately 11:00 AM on August 2, 2024. The laboratory performs approximately 360 microbiology tests annually.