

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0887993	(X3) Date Survey Completed 10/11/2021
Name of Provider or Supplier Las Vegas Urology-Smoke Ranch	Street Address, City, State 7500 Smoke Ranch Road Suit 200, Las Vegas, NV	
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	<p>This Statement of Deficiencies was created as a result of an on-site initial CLIA certification survey conducted at your facility October 11, 2021. 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>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2021 Event 2 American Proficiency Institute (API) Microbiology proficiency testing (PT) results, a review of the director approved laboratory procedure entitled, "Proficiency Testing," a review of the results of a comparison study with an outside laboratory evaluated on October 7, 2021, and an interview with the laboratory Technical Supervisor, the laboratory failed to establish a step-by-step policy and procedure for the performance and evaluation of the split sample analysis performed to verify the accuracy of the polymerase chain reaction testing for the urine pathogen identification. Findings include: 1. A review of the API 2021 Microbiology PT Event 2 test results revealed that the laboratory received a score of 63% for the urine organism identification. 2. The laboratory performed a study of ten specimens on September 28, 2021, and sent the ten specimens to another laboratory, which analyzed the specimens on September 30, 2021. The results of the split sample analysis to determine the accuracy of the urine identification test by PCR were evaluated on October 7, 2021. 3. The director approved policy entitled, "Proficiency Testing," did not include step by step instructions on the performance of a split sample analysis that specified the number of specimens to be tested, and the</p>

criteria for acceptability for the results of the evaluation in order to verify the accuracy of the test. 4. The technical supervisor confirmed the findings during an interview conducted on October 11, 2021 at approximately 10:30 AM. The laboratory performs approximately 2500 microbiology tests annually.