Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 29D0945985	**(X3) Date Survey Completed** 01/12/2023
Name of Provider or Supplier Urology Nevada, Ltd	**Street Address, City, State** 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.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D0000	This Statement of Deficiencies was created as a result of an on-site CLIA initial certification survey conducted at your facility on 1/12/2023. 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.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and an interview with the laboratory supervisor, the laboratory director failed to attest to the routine integration of the samples into the patient workload using the laboratory's routine methods for the third microbiology event in 2022. Findings include: 1. Review of the American Proficiency Institute (API) PT attestation forms from 2022 revealed that the laboratory director failed to sign the attestation form for the third microbiology PT event in 2022. 2. The laboratory supervisor confirmed these findings in an interview at approximately 11:00 AM on 1/12/2023. The laboratory performs approximately 360 microbiology tests annually.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on lack of competency assessment documentation, lack of a competency assessment policy, and electronic communication with the laboratory supervisor, the laboratory failed to establish and follow written policies and procedures to assess competency for employees performing provider performed microscopy (PPM) tests for sperm presence/absence and urine sediment. Findings include: 1. The laboratory failed to provide documentation of competency assessments for nine of nine mid-level practitioners performing provider performed microscopy (PPM) tests for sperm presence/absence and urine sediment. 2. The laboratory failed to provide documentation of a policy for assessing the competency of testing personnel performing PPM tests for sperm presence/absence and urine sediment. 3. The laboratory supervisor confirmed these findings by electronic mail on 1/23/2023 at 11: 29 AM. The laboratory performs approximately 300 PPM procedures annually.
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 review of the American Proficiency Institute (API) Proficiency Testing (PT) evaluation, the laboratory's PT documentation and an interview with the laboratory supervisor, the laboratory failed to ensure that the unacceptable results for Molecular Bacti-Urine and Molecular Mycology -Vaginal in the second event of 2022 and for Mycoplasma genitalium in the third event of 2022 were evaluated. Findings include: Review of API PT documentation from the second bacteriology PT event for 2022 revealed that sample UTI-04 had unacceptable results for two of fifty-six analyte targets, Staphyloccocus sp. and Staphylococcus epidermis, resulting in a score of 95% for Molecular Bacti - Urine. Review of API PT documentation from the second mycology PT event for 2022 revealed that sample VGP-04 had unacceptable results for two of six analyte targets, Candida albicans and Candida tropicalis, resulting in a score of 67% for Molecular Mycology -Vaginal. Review of API PT documentation from the third PT event for 2022 revealed that sample MPG-06 had unacceptable results for the analyte Mycoplasma genitalium. Review of the laboratory's PT documentation revealed that no investigations were documented for the unacceptable results for samples UTI-04, VGP-04, and MPG-06. The laboratory supervisor confirmed these findings in an interview at approximately 11:00 AM on 1/12/2023. The laboratory performs approximately 360 microbiology tests annually.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT)

	evaluations, lack of laboratory documentation, and an interview with the laboratory supervisor and clinic manager, the laboratory failed to verify the accuracy of Molecular Mycology-Vaginal and provider performed microscopy (PPM) tests for sperm presence/absence and urine sediment at least twice a year. Findings include: 1. Review of the API PT evaluations for Molecular Mycology-Vaginal revealed a score of 67% and 0% for the second and third events of 2022, respectively. 2. The laboratory supervisor confirmed these findings in an interview at approximately 11:00 AM on 1/12/2023. 3. Review of the API PT evaluations for PPM revealed a score of 0% for the first and third PPM events in 2022 for sperm presence/absence and urine sediment. 4. The laboratory was unable to provide evidence that additional verification of accuracy had been performed during 2022. 5. The clinic manager confirmed these findings in an interview at approximately 11:00 AM on 1/12/2023. The laboratory performs approximately 360 microbiology tests and approximately 300 PPM tests annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's standard operating procedures (SOPs) and an interview with the clinic manager, the laboratory failed to ensure that a written policy and procedure was established to monitor, assess, and, when indicated, correct problems identified in proficiency testing (PT) performance for provider performed microscopy (PPM) PT tests. Findings include: 1. The laboratory was unable to provide the SOP regarding review, verification, and corrective action of PPM PTs. 2. These findings were confirmed by the clinic manager in an interview at approximately 4:00 PM on 1/12/2023. The laboratory performs approximately 300 PPM tests annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 observation and an interview with the laboratory supervisor, the laboratory failed to ensure that laboratory reagents were discarded by their expiration dates. Findings include: 1. During the on-site survey on 1/12/2023, observation of reagents stored in the laboratory's refrigerator revealed the following expired reagents which were available for use: a. Zeptometrix Vaginal Panel controls with lot number 327613 and expiration date of 11/15/2022. b. Zeptometrix BCID Panel controls with lot number 327916 and expiration date of 9/28/2022. c. Zeptometrix BC/GN Panel controls with lot number 327964 and expiration date of 6/22/2022. d. Zeptrometrix Chlamydia trachomatis positive controls with lot number 326864 and expiration date

	of 9/2022. 2. The laboratory supervisor confirmed these findings in an interview at approximately 4:30 PM on 1/12/2023. The laboratory performs approximately 360 microbiology tests annually.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on review of the Laboratory Director Visitation Form, the laboratory's Quality Control (QC) logs, verification records, standard operating procedures (SOPs), and an interview with the laboratory supervisor, the laboratory failed to verify the performance specifications of the high and low semi-quantitative QCs for PCR testing of urine specimens when the frequency of QC testing was changed from daily to weekly. Findings include: 1. Review of the Laboratory Director Visitation Forms from July through December 2022 revealed that on 11/29/2022 the SOPs were to be updated to "reflect weekly and daily QC for semiquantitative testing." 2. Review of the laboratory's QC logs from July through December of 2022 revealed that the semiquantitative QCs listed as Amp-high and Amp-low were changed from being run daily to being run weekly in October 2022. 3. Review of the laboratory's SOP titled "166106.78 UN-TOP-02 TAC Preparation SOP (1)",shows that the SOP Section 6 Quality Control still states that "a high and low positive control should be run for every batch of master mix made per day." 4. The laboratory was unable to provide documentation of studies that verify the accuracy and reliability of patient test results when the high and low semi-quantitative QCs are run weekly rather than daily. 5. The laboratory supervisor confirmed these findings in an interview at approximately 12:00 PM on 1/12/2023. The laboratory performs approximately 360 microbiology tests annually.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of corrected and amended reports from September through December 2022 and an interview with the laboratory supervisor, the laboratory failed to generate corrected and amended reports that clearly defined what had been altered from the original report. Findings include: 1. Review of the corrected report from 10 /25/2022 for patient VK revealed a notes section on page 2 that stated, "Reviewed and reported as NOT DETECTED by supervisor. Below clinical threshold. jbecker 21:18: 26 10/14/2022; The organism detected expresses a gene associated with extended beta-lactamase production." 2. An interview with the laboratory supervisor at

	approximately 3:00 PM on 1/12/2023 revealed that the correction on the report was to add the comment, "The organism detected expresses a gene associated with extended beta-lactamase production," to page 1 of the report for greater visibility in addition to its original location on page 2. The notes section does not clearly state the reason for the corrected report. 3. The laboratory supervisor indicated the statement, "Reviewed and reported as NOT DETECTED by supervisor. Below clinical threshold. jbecker 21:18:26 10/14/2022," is an autogenerated comment when an analyte result requires manual review of additional acceptance criteria prior to the report being released. The autogenerated comment does not clearly define which analyte has been reviewed. 4. Review of the amended report from 9/28/2022 for patient AB revealed a notes section that stated, "The organism detected expresses a gene associated with extended beta-lactamase production." This statement is also in the comments section on page 1, but the report is described in the header as an amended report, rather than a corrected report. 5. An interview with the laboratory supervisor at approximately 3:00 PM on 1/12/2023 revealed that the amended information on the report was to update the collection date from 9/20/2022 to 9/26/2022. This change is not identified as the new information on the report. The laboratory performs approximately 360 microbiology tests annually.
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 review of the American Proficiency Institute (API) Proficiency Testing (PT) evaluation, the laboratory's PT documentation, the laboratory's standard operating procedures (SOPs), and an interview with the clinic manager, the laboratory director failed to ensure that 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. Findings include: 1. Review of API PT evaluations and laboratory PT documents for 2022 revealed that documentation was not available for the first PPM PT testing event of 2022 for sperm presence/absence and urine sediment. 2. Review of the API PT evaluations for the third PPM testing event of 2022 revealed a score of 0% for sperm presence/absence and urine sediment for the first PPM event in 2022. 3. The laboratory was unable to provide documentation that the laboratory results of the first PPM testing event of 2022 had been compared to the expected results from API to verify the accuracy of the PT results. 4. The laboratory was unable to provide documentation of the investigation and corrective action for the unsuccessful results of the first PPM testing event of 2022. 5. The laboratory was unable to provide the SOP regarding review and verification of PPM PTs. 6. These findings were confirmed by the clinic manager in an interview at approximately 4:00 PM on 1/12/2023. The laboratory performs approximately 300 PPM 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 review of the American Proficiency Institute (API) Proficiency Testing (PT) evaluations for Molecular Bacti-Urine, Molecular Mycology-Vaginal, and provider performed microscopy (PPM) tests for sperm presence/absence and urine sediment, the laboratory's PT documentation, and interviews with the laboratory supervisor and clinic manager, the laboratory director failed to ensure there was an approved corrective action plan to be followed when any proficiency testing result is found to be unacceptable or unsatisfactory. Findings include: 1. Review of API PT documentation from the second bacteriology PT event for 2022 revealed that sample UTI-04 had unacceptable results for two of fifty-six analyte targets, Staphyloccocus sp. and Staphylococcus epidermis, resulting in a score of 95% for Molecular Bacti-Urine. 2. Review of API PT documentation from the second mycology PT event for 2022 revealed that sample VGP-04 had unacceptable results for two of six analyte targets, Candida albicans and Candida tropicalis, resulting in a score of 67% for Molecular Mycology-Vaginal. 3. Review of API PT documentation from the third PT event for 2022 revealed that sample MPG-06 had unacceptable results for the analyte Mycoplasma genitalium. 4. Review of the laboratory's PT documentation revealed that no corrective actions were documented for the unacceptable results for samples UTI-04, VGP-04, and MPG-06. 5. The laboratory supervisor confirmed these findings in an interview at approximately 11:00 AM on 1/12/2023. 6. Review of API PT evaluations and laboratory PT documents for 2022 revealed that documentation was not available for the first PPM PT testing event of 2022 for sperm presence/absence and urine sediment. 7. Review of the API PT evaluations for the third PPM testing event of 2022 revealed a score of 0% for sperm presence/absence and urine sediment for the first PPM event in 2022. 8. The laboratory was unable to provide documentation of corrective action for the unsuccessful PPM PT results for sperm presence/absence and urine sediment for the first PT event of 2022. 9. These findings were confirmed by the clinic manager in an interview at approximately 4:00 PM on 1 /12/2023. The laboratory performs approximately 360 microbiology tests and approximately 300 PPM tests annually.