| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 29D2268352 | 01/10/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Medical Laboratory Services Of Nevada | 2725 S Jones Blvd Suite 107, 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 |
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| **D0000** | This Statement of Deficiencies was created as a result of an on-site initial CLIA certification survey conducted at your facility on January 10, 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. |
| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.<br><br>This CONDITION is not met as evidenced by:<br>Based on the number and severity of the deficiency cited herein, the Condition: [Proficiency Testing] Enrollment and Testing of [Proficiency Testing] Samples was not met. The laboratory referred its College of American Pathologists (CAP) proficiency testing samples from the 2022 Urine Toxicology testing event C to Clarity Clinical Laboratory (CLIA number 11D2101175) for testing (see D2013). |
| **D2013** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(4)<br><br>The laboratory must not send proficiency testing samples or portions of proficiency |

testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:
Based on a self-report submitted by the laboratory on October 19, 2022, and an interview with the laboratory owner and the technical director on January 10, 2022, and email correspondence with the technical supervisor on January 17, 2023, the laboratory referred proficiency testing specimens to a reference laboratory for the 2022 College of American Pathologists (CAP) Urine Toxicology test event C (2022 UT-C) on October 17, 2022. Findings include: 1. The laboratory self-report submitted by the laboratory on October 19, 2022 stated that the College of American Pathologists (CAP) 2022 Urine Toxicology (UT) Proficiency Testing (PT) event C specimens were shipped by CAP to the laboratory on Monday, October 10, 2022. The specimens were expected to be received overnight, on October 11, 2022, according to email correspondence with the technical supervisor on January 17, 2023. When the specimens did not arrive as expected, the technical supervisor contacted CAP to re-order replacement samples on either October 12 or October 13, 2022. 2. The laboratory self-report submitted by the laboratory on October 19, 2022 stated that the original shipment of the CAP UT-C specimens were received on October 14, 2022. By the time the specimens were received, they were outside the acceptable temperature range and the lab was concerned about the specimen integrity. 3. The laboratory self-report submitted on October 19, 2022 stated that on October 18, 2022, Clarity Clinical Laboratory received CAP UT-C specimens UT-11, UT-12, UT-13, UT-14, and UT-15 from Medical Laboratory Services of Nevada. In a photograph submitted by the laboratory, the specimens were in aliquot tubes, and were labeled in black sharpie. Proficiency testing sample UT-11 is clearly identified as the sample number on one of the tubes in the photograph. On two of the tubes, the specimen number is not visible, but they are clearly labled "CAP", also in black sharpie. The biohazard bag that the aliquots were in also was labeled in black sharpie as "CAP". There also appears to be several requisitions folded and placed in the appropriate pocket in the biohazard bag. The requisition that is visible clearly states "CAP UT-11." 4. Clarity Clinical Laboratory notified the laboratory on October 18, 2022, and shipped the specimens back to the laboratory on October 19, 2022. The specimens were delivered to the laboratory on October 21, 2022. The owner of the laboratory stated during an interview at approximately 10:00 AM on January 10, 2023, that the specimens and the requisitions were discarded upon return receipt. 5. The replacement specimens ordered on October 12 or 13, 2022 were received on October 17, 2022. The specimens were tested by the laboratory on October 24, 2022 and submitted to CAP on November 4, 2022. The laboratory performs approximately 400,000 toxicology tests annually.

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| **D3027** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(1)<br><br>Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on a self-report submitted by the laboratory on October 19, 2022, and an interview with the laboratory owner and the technical supervisor, the laboratory failed to retain copies of the requisitions for the 2022 College of American Pathologists (CAP) Proficiency Testing (PT) specimens for test event UT-C that were sent to the reference laboratory. Findings include: 1. On October 19, 2022, the laboratory reported to the Nevada State Agency an incident of PT referral to a reference laboratory that occurred on October 17, 2022. Among the documents submitted by the laboratory was a photograph illustrating several requisitions folded together in the specimen bag labeled "CAP." The photograph clearly illustrated a requisition that identified a specimen as CAP UT-11. 2. During an interview with the laboratory owner and the technical supervisor conducted on January 10, 2023 at approximately 10:00 AM, it was confirmed that the laboratory did not retain copies of the requisitions sent to the reference laboratory with the proficiency testing specimens. The laboratory performs approximately 400,000 toxicology tests annually. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on the number and severity of the deficiency cited herein, the Condition: Laboratory Director [responsibilities] was not met. The director failed to ensure that proficiency testing samples were tested as required under subpart H. (refer to D6089) |
| **D6089** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(i)<br><br>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on a self-report submitted by the laboratory on October 19, 2022, and an interview with the laboratory owner and the technical supervisor on January 10, 2022, the director failed to ensure that the laboratory tested proficiency testing specimens as required under subpart H. Findings include: 1. The laboratory director failed to ensure that the proficiency testing was performed in accordance with 42 CFR 493.801(b). 2. The College of American Pathologists (CAP) Proficiency Testing (PT) Urine Toxicology test event C (2022 UT-C) specimens were sent to a reference laboratory on October 17, 2022. 3. The reference laboratory notified the submitting laboratory of |

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| | receipt of the PT specimens, and returned them without testing the samples. 4. The laboratory owner and the technical consultant confirmed the findings during an interview conducted on January 10, 2023 at approximately 10:00 AM. The laboratory performs approximately 400,000 toxicology tests annually. |