

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2087543	(X3) Date Survey Completed 07/12/2023
Name of Provider or Supplier Nevada Compassionate Pain Care	Street Address, City, State 7220 S Cimarron Rd Ste 270, 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	This Statement of Deficiencies was created as a result of an on-site CLIA validation survey conducted at your facility on July 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.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2021 and 2022 American Proficiency Institute (API) proficiency testing (PT) records, and an interview with the technical supervisor and the laboratory director, the laboratory failed to ensure that the attestations stating that the specimens were tested in the same manner as patients were signed by the testing personnel, and failed to ensure that the attestations retained were those for Nevada Compassionate Pain Care. Findings include: 1. The API 2021 Chemistry Miscellaneous attestation for test event one was not signed by the testing personnel who performed the test. 2. The API 2022 Chemistry Miscellaneous attestation for test</p>

event two was not the attestation for Nevada Compassionate Pain Care. The attestation retained in the records indicated that it was for a laboratory located in McKinney, Texas (45D2217503-Allay Spine and Pain). 3. The findings were confirmed during an interview with the technical supervisor and the laboratory director conducted on July 12, 2023 at approximately 10:30 AM. The laboratory performs approximately 74,999 chemistry, urinalysis and toxicology tests annually.

D3031

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:
Based on a random patient audit of five patients tested between the dates of December 22, 2021 and March 14, 2023, and an interview with the technical supervisor and the laboratory director, the laboratory failed to retain the LC/MS quality control records and the LC/MS chromatography records for a minimum of two years. Findings include: 1. A random patient audit of five patients tested between the dates of December 22, 2021 and March 14, 2023 revealed that the laboratory did not retain the quality control for the LC/MS toxicology testing for two of the five dates reviewed. There were no records for the dates of December 22, 2021 and November 21, 2022. 2. During an interview on July 12, 2023 at approximately 12:00 PM with the technical supervisor and the laboratory director, it was confirmed that the LC/MS chromatography files had been erased, and that the records could not be retrieved. The laboratory performs approximately 74,999 chemistry, urinalysis and toxicology tests annually.