

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 29D2044859	<b>(X3) Date Survey Completed</b> 08/20/2024
<b>Name of Provider or Supplier</b> Osteopathic Medical Associates Of Nevada	<b>Street Address, City, State</b> 5410 W Sahara Ave, Las Vegas, 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>	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on August 20, 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.
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 2023 American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the lead medical assistant, the laboratory failed to ensure that the laboratory verified the accuracy of the MCH and MCHC results at least twice annually. Findings include: 1. A review of the 2023 API PT records revealed that the laboratory achieved unacceptable scores for the MCH. The MCH score for the 2023 test event numbers one and two was 40%. The MCH score for the 2023 test event number three was 60%. 2. A review of the 2023 API PT records revealed that the laboratory achieved unacceptable scores for the MCHC. The MCHC score for the 2023 test event number two was 40%. The MCHC score for the 2023 test event number three was 60%. 3. The findings were confirmed during an interview with the lead medical assistant conducted on August 20, 2024 at approximately 1:45 PM. The laboratory performs approximately 1000 hematology tests annually.</p>
<b>D5293</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(b)(c)</p>

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:

A review of the 2022, 2023 and 2024 American Proficiency Testing (API) Proficiency Testing (PT) corrective action for unacceptable results for analytes for which the laboratory achieved a score of less than 100%, and an interview with the lead medical assistant, the laboratory failed to ensure that corrective actions taken for proficiency testing failures were effective to improve performance and verify the accuracy of tests. Findings include: 1. A review of the 2022, 2023, and 2024 API PT records revealed that for each event in which unacceptable results were achieved, the same corrective action was documented each time. The proficiency testing failures were not corrected. 2. The corrective action for the 2022 API test event three MCHC score of 80% stated, "Will ensure proper mixture of samples being tested. Normal controls-date of testing (11-11-22). 1 pt sample run on testing date-all analytes WNL, analytes for pt WNL. Will monitor with next testing. second set of testing samples run-MCHC (HSY-12) WNL." 3. The corrective action for the 2023 API test event one MCH and MCHC scores of 60% stated, "Must ensure proficiency samples mixed and handled appropriately prior testing. Controls in range-all analytes normal. 2 pt sample run-both had normal analytes in results." 4. The corrective action for the 2023 API test event two MCH and MCHC scores of 40% stated, "Enforce proper mixing of samples prior proficiency samples testing-MAs counselled. Controls were normal 7-18-23-no analytes out of range. No patient samples run on that day. Will follow." 5. The corrective action for the 2023 API test event three MCHC score of 40% stated, "MCH analyte out of range in samples HSY-12, 13, 15. In a second set of sample run & not recorded these 3 analytes were in range. Must ensure proper temperature & proper mixing prior testing of proficiency samples. Controls completely normal. 3 pt samples run-all analytes WNL. 6. The findings were confirmed during an interview with the lead medical assistant on August 20, 2024 at approximately 1:45 PM. The laboratory performs approximately 1000 hematology tests annually.