

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2157494	(X3) Date Survey Completed 03/25/2025
Name of Provider or Supplier Optimumedicine	Street Address, City, State 175 E Reno Ave Ste C-6, 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 initial CLIA survey conducted at your facility on March 25, 2025. 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.
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapporitions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory personnel records, a review of the laboratory semi-annual and annual training and competency assessment records, a review of the director delegation of duties, and an interview with the laboratory personnel, the director failed to delegate the duty of training and competency assessments to personnel meeting the qualifications of a technical consultant as indicated in 42 CFR 493.1409. Findings include: 1. A review of the laboratory training and competency records between the dates of March 2023 and March 2025 for 11 of 35 testing personnel revealed that the initial, semi-annual and annual training and competency assessment records were signed by the personnel designated by the director in writing</p>

to perform the duty of training and competency assessments. 2. A review of the laboratory personnel records for the personnel designated by the director to perform training and competency assessment revealed that the personnel did not meet the minimum qualifications for a technical consultant as indicated in 42 CFR 493.1409. The personnel records revealed that the designee possessed a high school diploma. 3. The finding was confirmed during an interview with the personnel conducted on March 25, 2025 at approximately 10:30 AM and via email correspondence on March 26, 2025 at 12:00 PM. The laboratory performs approximately 53 routine chemistry tests and 5 hematology tests annually.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:
Based on a review of laboratory records for testing personnel training and competency assessment, and an interview with the laboratory personnel, the technical consultant failed to ensure that annual training and competency assessments during the first year of employment were completed timely. Findings include: 1. A review of the laboratory training and competency records between the dates of March 2023 and March 2025 for 11 of 35 testing personnel revealed that six of the 11 records reviewed indicated that the annual competency assessments were performed approximately one year after the semi-annual competency assessment rather than one year after the initial training and competency assessment was completed. 2. The laboratory personnel confirmed the findings during an interview conducted on March 25, 2025 at approximately 11:00 AM and the personnel indicated that the remaining records for all testing personnel who had been with the lab for one year or more would yield the same findings. The laboratory performs approximately 53 routine chemistry tests and 5 hematology tests annually.