

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 29D2140510	<b>(X3) Date Survey Completed</b> 01/29/2024
<b>Name of Provider or Supplier</b> Csl Plasma, Inc	<b>Street Address, City, State</b> 3220 S Nellis Blvd, 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 January 29, 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>D6053</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory training and competency records, and an interview with the Center Manager and the Assistant Manager of Quality, the technical supervisors failed to ensure that semiannual competency assessment was completed during the first year of employment for new personnel. Findings include: 1. A review of the laboratory training and competency assessment records revealed that there were no records of semiannual competency assessment for total protein testing for one of seven testing personnel employed by the laboratory for at least six months, and less than one year. 2. The Center Manager and the Assistant Manager of Quality confirmed the findings during an interview conducted on January 29, 2024 at approximately 1:30 PM. The laboratory performs approximately 67,847 chemistry tests annually.</p>
<b>D6064</b>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1423(a)</p>

Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory personnel records, consultation with the Nevada Division of Public and Behavioral Health (DPBH) Laboratory Personnel database, and an interview with the Center Manager and the Assistant Quality Manager, the director failed to ensure that the testing personnel obtained or maintained their personnel certification prior to performing patient testing, as required by the State of Nevada. Findings include: 1. A review of the laboratory personnel records and consultation with the Nevada DPBH database revealed that seven of 30 testing personnel either failed to obtain or failed to maintain active Office Laboratory Assistant (OLA) certification prior to performing patient testing, as required by the State of Nevada. 2. Testing personnel identified on the CMS-209 form as number 7 continued to perform patient testing after the expiration of the OLA between the dates of March 27, 2023 and issuance of a new OLA certification effective January 11, 2024. 3. Testing personnel identified on the CMS-209 form as number 9 continued to perform patient testing after the expiration of the OLA between the dates of June 28, 2022 and the reinstatement of the certificate on August 2, 2022. 4. Testing personnel identified on the CMS-209 form as number 11 continued to perform patient testing after the expiration of the OLA between the dates of February 26, 2023 and issuance of a new OLA certification effective January 11, 2024. 5. Testing personnel identified on the CMS-209 form as number 20 continued to perform patient testing after the expiration of the OLA between the dates of June 11, 2022 and the reinstatement of the certificate on August 2, 2022. 6. Testing personnel for identified on the CMS-209 form as number 22 performed patient testing prior to applying for the OLA certification as required by the State of Nevada. The personnel completed initial training and competency assessment on October 9, 2023. The personnel failed to apply for the OLA certification until January 17, 2024. The certificate was issued on January 19, 2024. 7. Testing personnel identified on the CMS-209 form as number 27 continued to perform patient testing after the expiration of the OLA between the dates of March 9, 2023 and issuance of a new OLA certification effective January 12, 2024. 8. . Testing personnel for identified on the CMS-209 form as number 28 performed patient testing prior to applying for the OLA certification as required by the State of Nevada. The personnel completed initial training and competency assessment on January 26, 2023. The personnel failed to apply for the OLA certification until June 29, 2023. The certificate was issued on June 30, 2023. 9. The findings were confirmed during an interview with the Center Manager and the Assistant Quality Manager on January 29, 2024 at approximately 11:15 AM. The laboratory performs approximately 67,847 chemistry tests annually.