

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2047435	(X3) Date Survey Completed 04/07/2021
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 3430 E Tropicana Avenue Suite 69, 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 recertification survey conducted at your facility on April 7, 2021. 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.
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES 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 assessment records for 2018, 2019, 2020, and 2021, and an interview with the Plasma Center Manager, Assistant Center Manager, and Assistant Quality Manager, and a telephone conversation with the Assistant Quality Manager, the Technical Consultant failed to ensure that the semi-annual training and competency assessments of testing personnel were performed and documented. Findings include: 1. A random audit of 39 of 54 testing personnel records revealed that the semi-annual training and competency assessment was not performed and documented for four of the testing personnel in 2019. 2. This was confirmed during an interview with the Center Manager, the Assistant Center Manager, and the Assistant Quality Manager conducted on April 7, 2021 at approximately 4:15 pm., and during a telephone conversation with the Assistant Quality Manager on April 8, 2021 at approximately 1:15 pm. The laboratory performs approximately 102,245 Chemistry tests annually.</p>
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a review of laboratory training and competency assessment records for 2018, 2019, 2020, and 2021, and an interview with the Plasma Center Manager, Assistant Center Manager, and Assistant Quality Manager, the Technical Consultant failed to ensure that the annual training and competency assessments of testing personnel were performed and documented. Findings include: 1. A random audit of 39 of 54 testing personnel records revealed that the annual training and competency assessment was not performed and documented for four of the testing personnel during 2019. 2. This was confirmed during an interview with the Center Manager, the Assistant Center Manager, and the Assistant Quality Manager conducted on April 7, 2021 at approximately 4:15 pm. The laboratory performs approximately 102,245 Chemistry tests annually.