

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2119636	(X3) Date Survey Completed 07/28/2022
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 3975 S Buffalo Dr, Suite C-101, 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	<p>This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on July 28, 2022. 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.</p>
D6064	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory personnel records, a review of the CSL Plasma policy entitled, "Nevada State Requirements, and an interview with the Associate Director of Operations and Quality and the Center Manager, the laboratory director failed to ensure that the testing personnel obtained or maintained the personnel certification as required by the State of Nevada. Findings include: 1. Nine of 38 testing personnel listed on the CMS-209 form failed to either obtain or maintain personnel certification as an Office Laboratory Assistant, as required by the State of Nevada prior to performing donor testing. 2. Personnel listed on the CMS-209 form identified by numbers 7, 9, 10, 19, 20, and 26 continued to perform donor testing for total protein test after failing to maintain current Office Laboratory Assistant Certification as required by the State of Nevada. The Office Laboratory Assistant Certification for personnel number 7 expired on November 14, 2021 and was not reinstated until May 12, 2022. The Office Laboratory Assistant Certification for personnel number 9 expired on December 18, 2021 and was not reinstated at the time of the survey. The Office Laboratory Assistant Certification for personnel number 10 expired on April 24, 2021, and was not reinstated at the time of the survey. The Office</p>

Laboratory Assistant Certification for personnel number 19 expired on February 25, 2022, and was not reinstated at the time of the survey. The Office Laboratory Assistant Certification for personnel number 20 expired on January 19, 2022, and was not reinstated until April 12, 2022. The Office Laboratory Assistant Certification for personnel number 26 expired on March 15, 2022, and was not reinstated until July 23, 2022. 3. Personnel listed on the CMS-209 form identified by numbers 21 and 35 performed plasma donor testing for the total protein test prior to applying for the Office Laboratory Assistant Certification as required by the State of Nevada. An application was not submitted to the State of Nevada for the Office Laboratory Assistant Certification by personnel number 21 prior to beginning performing donor testing for total protein on March 13, 2020, and had not been submitted at the time of the survey. An application was not submitted to the State of Nevada for the Office Laboratory Assistant Certification by personnel number 35 prior to beginning performing donor testing for total protein on July 7, 2021, and the application was not submitted until March 17, 2022. 4. Personnel listed on the CMS-209 form identified by number 11 continued to perform plasma donor testing for total protein after the initial application for the Office Laboratory Assistant Certification was denied due to failure to submit all of the required documents for certification. An initial application for the Office Laboratory Assistant Certification was submitted on July 13, 2020, and the certification was denied on November 30, 2021 for failure to complete the application. The personnel continued to perform donor testing, but did not submit a second application for certification until May 13, 2022, and the certification was issued on June 7, 2022. 5. The CSL Plasma policy entitled, Nevada State Requirements stated, "Individuals performing in any technical capacity within the center must be certified as an Office Laboratory Assistant. this includes members of Management and Quality who, on occasion, perform functions in the operational areas." 6. The findings were confirmed during an interview with the Associate Director of Operations and Quality and the Center Manager on July 28, 2022 at approximately 12:00 PM. The laboratory performs approximately 94,819 chemistry tests annually.