

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2227461	(X3) Date Survey Completed 02/05/2026
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 8 N Euclid Ave Ste 8-10, National City, CA	
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
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;</p> <p>This STANDARD is not met as evidenced by: Based on review of CSL Plasma document number DOC-000300698, titled, "Non-Licensed Testing Personnel Technical Consultant Observation Worksheet - California" and laboratory personnel training records titled, "CPU-MR-150 (CA Only), Non-Licensed Reception Technician - 5 Hour Training Certification"; and interview with laboratory personnel, it was determined that the laboratory failed to ensure personnel completed all the required training prior to receiving approval to perform Total Protein tests on patients specimens. Findings included: 1. The "Non-Licensed Testing Personnel Technical Consultant Observation Worksheet - California" documented Testing Person-17 [CMS209 Laboratory Personnel (CLIA), 2/05/26] was approved to perform Moderate Complexity testing, effective 11/06/25. 2. However, the "CPU-MR-150 (CA Only), Non-Licensed Reception Technician - 5 Hour Training Certification" for Testing Person-17 documented the required 5 hours of training was not completed until 11/12/25. 3. The Center Manager and the Assistant Manager of Quality affirmed (2/05/25 at 4:00 PM) the aforementioned documents dates and that it was routine practice to approve trainees to perform Total Protein testing on patients specimen prior to completing the required 5 hours of hands on training. 4. The "Non-Licensed Testing Personnel Technical Consultant Observation Worksheet - California" form failed to stipulate completion of the required 5 hours of hands on training as a prerequisite to receiving approval to perform testing on patients specimen. 5. The reliability and quality of Total Protein results reported by testing personnel prior to completing the 5 hours of required hands</p>

on training could not be assured during this Survey. Thirty-four testing personnel reported 71,519 results annually (CMS116 CLIA Application, 1/31/26). Records selected for review are, as follows: Date ID _____ 2/28/25
V12968478- 178 5/29/25 V13460753- 123 10/28/25 V12027257- 307 12/18/25
V14406748- 54 1/27/26 V12304003- 228 2/05/26 V13767901- 116.