

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2148148	(X3) Date Survey Completed 08/22/2023
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 1530 W Jefferson St, Joliet, IL	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of American Association of Bionalysts (AAB) proficiency testing records, CSL Plasma Document No. "CPU-QI-000171814" titled "CLIA Oversight, Proficiency Testing Performance Guide", CSL Plasma event detail report "PR#1223723", and personnel interviews with the assistant manager of quality (AMQ) and testing personnel (TP) #3; the laboratory failed to test AAB proficiency testing (PT) samples in the same manner as patient specimens for six of six proficiency testing events performed in 2021 through 2023. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the CSL Plasma policy document, "CPU-QI-000171814, Title: CLIA Oversight, Proficiency Testing Performance Guide", which stated on page 35 of 49, "Test samples in the same manner as donor samples". 2. AAB PT records from event three of 2021 through event two of 2023 (6 total events) were reviewed. The laboratory received a score of 80% for total protein testing for event one of 2022. 3. Review of the CSL "Plasma - Event - Detail Report, PR#1223723" for the less than 100% score for total protein for event one of 2022 stated in the investigation summary "Proficiency testing was performed under the direction of the AMQ (name redacted) and LD...the testing personnel (name redacted) performed proficiency testing in a secluded, quiet environment to minimize distractions and interruptions and to allow for adequate time to complete testing." Additionally, the investigation summary documented the following concern by the testing personnel performing the PT event, "nervous due to the presence of both the AMQ and LD". 4. Interview with the AMQ on 8-22-23 at 11: 15 am, confirmed the laboratory director (LD) watches the performance of all PT</p>

samples and PT samples are only performed when the LD is on site. 5. Review of AAB PT records identified TP#3 performed the PT samples for event two of 2023. 6. Interview with TP#3 on 8-22-23, at 11:56 am, confirmed the AMQ and LD watched her perform the event two of 2023 PT samples in a private booth and checked the results of the total protein PT samples as they were performed. 7. Interview with the AMQ on 8-22-23 at 2:10 pm, confirmed the AMQ and LD do not watch all total protein testing performed for donors.