

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2235837	(X3) Date Survey Completed 01/10/2024
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 5750 W Capitol Dr Ste B, Milwaukee, WI	
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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the center manager, the laboratory did not verify the accuracy of thirteen of thirteen total protein results from the three PT events in 2023 that were assigned a proficiency testing score that did not reflect laboratory test performance. Findings include: 1. The laboratory received reports from AAB-Medical Laboratory Evaluation PT program that included Total Protein results flagged with '#' for events one, two and three in 2023. Comparison of the laboratory reported result with the expected range showed the reported results were not within the range expected from the PT program. The reported total protein results and expected ranges for the '#' flagged results were: Event one: Sample number / reported result / expected range: 1 / 3.7 / 2.9 - 3.5 2 / 6.3 / 5.0 - 6.1 4 / 9.9 / 7.8 - 9.6 Event two: 6 / 8.7 / 6.5 - 7.9 7 / 4.4 / 3.2 - 3.9 8 / 10.2 / 7.8 - 9.5 9 / 7.8 / 5.8 - 7.1 10 / 5.7 / 4.2 - 5.1 Event three: 11 / 9.9 / 7.5 - 9.2 12 / 5.3 / 3.9 - 4.8 13 / 8.7 / 6.5 - 8.0 14 / 7.8 / 5.9 - 7.2 15 / 7.0 / 5.2 - 6.4 Further review of the records showed event one was scored by the PT program as 80% with sample 3 marked as unacceptable. The laboratory performed an evaluation of the results for sample 3 but the review did not show evaluation of the results of the three samples flagged with '#'. The laboratory director signed the second and third event reports, but the reports showed no evidence the laboratory evaluated the results for the flagged samples. The third event included the measurement units as grams / deciliter (g/dL). 3. Interview with the center manager (staff A) on January 10, 2024, at 10:00 AM</p>

revealed the PT program documentation stated the '#' flag indicated the result was ungraded by the PT program due an insufficient number of peer providers, was given a score of 100%, and required review. Further interview at 10:05 AM confirmed the laboratory had not evaluated the flagged results to verify their accuracy as part of their review of the events.