

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2140718	(X3) Date Survey Completed 05/23/2025
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 16950 Ella Blvd Suite 320, Houston, TX	
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	An announced survey of the laboratory was conducted on 05/23/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D2014	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to retain all PT documentation for a minimum of two years for two of five PT testing events reviewed from 2023 and 2024. Findings included: 1. Review of laboratory's PT records from 2023 and 2024 revealed the laboratory used the AAB-Medical Laboratory Evaluation (AAB-MLE) as their PT provider. 2. Further review of the laboratory's PT AAB-MLE records revealed the laboratory did not retain the following documentation for a minimum of two years for two of five reviewed PT events from 2023 and 2024: PT event: AAB-MLE Chemistry M2 2023 Tested: May 2023 Missing documentation: There were no personnel attestation forms or result forms available for review. PT Event: AAB-MLE Chemistry M3 2023 Tested: September 2023 Missing documentation: There was no PT result evaluation</p>

documentation available for review. 3. In an interview on 05/23/2025 at 11:40 hours in the conference room, the facility's Center Manager (as indicated on the submitted Survey Entrance/Exit Conference document) confirmed the findings.