

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2094125	(X3) Date Survey Completed 07/28/2023
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 2983 S Chicago Ave, South 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) 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. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the quality manager, testing personnel and the laboratory director did not sign the attestation statements documenting the routine integration of the PT samples into the patient workload for two of two events in 2023. Findings include: 1. Review of the first two proficiency testing events in 2023 from the American Association of Bioanalysts (AAB) showed no evidence the director and testing personnel signed the attestation statements from the proficiency testing provider. The attestation statements for the first and second events showed the name of the director printed on the form with a 'performed on' date. The analyst section of the form is blank. No signatures were evident on the form. 2. Interview with the quality manager (staff A) on July 28, 2023, at 10:50 AM confirmed the director and testing personnel did not sign the PT provider's attestation statement for events one and two in 2023 to document that testing personnel tested the PT samples in the same manner as patient samples.</p>