

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2222281	(X3) Date Survey Completed 07/08/2025
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 3690 East Bay Drive Unit N, Largo, FL	
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 CLIA recertification survey was conducted at CSL Plasma Inc on 07/08 /2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
D6005	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c)</p> <p>(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the lab director failed to develop a policy or provide evidence of the required onsite visits for one of one six month period reviewed (01/2025 - 06/2025). Findings included: Review of records revealed no policy regarding the lab director being onsite every 6 months and no evidence of an onsite visit for 01/2025 to 06/2025. Interview with the Quality Manager on 07/08 /2025 at 1:30 p.m. confirmed the above.</p>