

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2190756	(X3) Date Survey Completed 07/06/2021
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 2621 N Clairemont Avenue, Eau Claire, 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
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Certification and Surveyor Provider Enhanced Reporting (CASPER) records and the American Association of Bioanalysts (AAB) proficiency testing (PT) order confirmation form, and interview with the assistant manager of quality, Staff A, the laboratory did not authorize the proficiency test program to release to Health and Human Services (HHS) the laboratory's PT results. Findings include: 1. Review of the CASPER report 0155D (Individualized Laboratory Profile) for Clinical Laboratory Improvement Amendments (CLIA) identification number 52D2190756 on July 6, 2021 shows no proficiency testing data was available for review. 2. Review of the AAB PT "2021 Order Confirmation" showed the order for the laboratory contained a CLIA identification number of 52D2190753. Further review showed the address to be 2621 North Clairemont Avenue, Eau Claire, WI 54703, which is the address for this laboratory. 3. Interview with Staff A on July 6, 2021 at 1:30 PM, confirmed the laboratory did not provide the correct CLIA identification number to the PT provider to authorize the program to release this laboratory's PT results to HHS.</p>