

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0672160	(X3) Date Survey Completed 05/15/2024
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 4901 Washington Ave, Suite 28, Racine, 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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory documents and interview and email correspondence with the center manager, staff A, the laboratory does not have a request from an authorized person for 89, 471 of 89, 471 total protein tests performed annually at this laboratory. Findings include: 1. Review of documents provided by the laboratory showed no evidence the laboratory director or other authorized person had approved an order for total protein testing. 2. Review of the "Application for Certification" CMS (Centers for Medicare and Medicaid Services) Form 116 signed by the laboratory director on May 13, 2024, showed the laboratory performed approximately 89, 471 chemistry tests annually. 3. Interview with staff A on May 15, 2024, at 2:35 PM confirmed the only chemistry testing the laboratory performed was total protein testing by refractometer. 4. Email correspondence from staff A on May 22, 2024 at 6:16 PM confirmed the laboratory did not have a standing order for the total protein testing performed on donors in the laboratory.</p>