

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2225244	(X3) Date Survey Completed 02/13/2024
Name of Provider or Supplier Csl Plasma, Inc - Austin	Street Address, City, State 1800 E Parmer Ln, Austin, 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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records, policies and procedures, and interview, the laboratory director failed to specify in writing the responsibilities and duties of testing personnel responsible for performing total protein for 8 out of 14 testing personnel reviewed. Findings follow. A. Review of personnel records showed 8 out of 14 testing personnel were missing job descriptions or delegation of duties for the Tech Receptionist performing total protein: testing personnel # 1, 2, 4, 5, 6, 7, 11, and 12 (as listed on the CMS form 209). B. Review of the policy and procedure DOC-000936690 on page 25 at Storage and Maintenance of Training Files under Employee Position Job Descriptions and Education Records stated, "For Employee Position Descriptions All applicable position descriptions should be signed and filed in the binder for the duties the employee performs". C. Interview with the Assistant</p>

Manager of Quality on February 13, 2024 at 1145 hours acknowledged the personnel were "cross-trained employees who did not sign the duties and responsibilities for the cross-trained area".