Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2044511	02/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Csl Plasma Inc	300 N Valley Mills, Suite B, Waco, 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	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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. This STANDARD is not met as evidenced by: Based on review of personnel records, regulations, and interview, the laboratory director failed to specify in writing the duties and responsibilities of 16 of 16 testing personnel engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing. Finding follow. A. Review of the form Position Description for "Tech Reception" under "Responsibilities List current duties and responsibilities" stated, "Performs finger stick to obtain sample to obtain donor's hematocrit and total protein levels" for testing personnel #1-16 (as listed on the CMS Form 209). No other duties and responsibilities of the testing personnel are mentioned. B. Review of the regulations for testing personnel responsibilities at 493.1425 (b) stated, "Each individual performing moderate complexity testing must- (b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting

	and maintaining records of patient test results; (b)(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples; (b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed; (4) Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance; (5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and (6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications." C. Interview with the Assistant Manager of Quality on February 22, 2024 at 1000 hours confirmed the findings.