Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2105499	(X3) Date Survey Completed 02/05/2018
Name of Provider or Supplier Csl Plasma, Inc	**Street Address, City, State** 1050 Westbank Expressway, Westwego, LA	

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	A Certification Survey was conducted on February 5, 2018 at CSL Plasma, INC-CLIA ID # 19D2105499. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6053.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant(s) failed to evaluate and document the performance of individuals at least semi-annually during the first year for two (2) of eleven (11) testing personnel reviewed. Findings: 1. Review of the laboratory's policies and procedures revealed "Only trained personnel with approval of the Technical Consultant may independently perform regulated testing. Competency is evaluated during initial training, at six months and annually thereafter or whenever testing methodology changes." 2. Review of personnel records revealed the laboratory utilizes a competency assessment form for laboratory personnel which includes the six (6) competency assessment criteria required by CLIA. 3. Review of personnel records for laboratory personnel revealed the laboratory did not have documentation of performance of a semi-annual competency assessment for the following two (2) personnel: Personnel 5 (due January 2018) Personnel 8 (due January 2018) 4. In interview on February 5, 2018 at 3:33 pm, Personnel 10 confirmed Personnel 5 and Personnel 8 did not have semi-annual competency assessments performed. Personnel 10 stated the identified personnel were waiting for Personnel 1 to perform their assessments.