

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2079194	(X3) Date Survey Completed 10/31/2018
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 3201 South Cobb Drive, Suite A, Smyrna, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on October 31, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapporitions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on technical consultant (TC) document review and staff interview, the laboratory director (LD) failed to ensure the competency of moderate-complexity laboratory personnel as required. Findings include: 1. TC (Staff #3 CMS 209) document review revealed there was no annual competency performed for 2017 and 2018 thus far. 2. An interview with the Assistant Manager of Quality on 10/31/2018 in a conference room at approximately 3:00 p.m. confirmed an annual competency was not performed for the TC (Staff #3 CMS 209) for 2017 and 2018 thus far.</p>