

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2130503	(X3) Date Survey Completed 12/17/2019
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 2297 Browns Bridge Road, Gainesville, 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 December 17, 2019. 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:
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the technical consultant (TC) failed to perform a semi-annual competency during the first year of moderate-complexity testing as required. Findings include: 1. TP competency document review revealed the TC did not perform a semi-annual competency for Staff #2 (CMS 209) in 2019. 2. An interview with the Assistant Quality Manager on 12/17 /2019 in a conference room at approximately 11:45 a.m. confirmed the lack of the aforementioned competency for Staff #2 (CMS 209).</p>