

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0862930	(X3) Date Survey Completed 01/31/2018
Name of Provider or Supplier Csl Plasma Of Columbia	Street Address, City, State 215 Assembly Street, Columbia, SC	
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
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 reappoints 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: During an onsite recertification survey on 1/31/2018, based on proficiency testing record review and personnel interview, the laboratory director failed to delegate duties related to total protein testing to another qualified individual for one of two years reviewed (2017). Findings include 1. Review of proficiency testing records revealed that an individual not listed on the CMS 209 (SN) had signed the attestation form as the director for the third testing event of 2017. This individual had also reviewed and signed the graded proficiency report for the same testing event. 2. During an interview with the center manager at 2:00 pm, the surveyor asked if there was a signed delegation from the director for SN to sign attestations and to review proficiency testing reports. The center manager presented the surveyor with documents that qualified SN as a laboratory director and a technical consultant, but a signed delegation of duties from the laboratory director on record was never produced. 3. During the exit interview at 3:35 pm, the center manager confirmed that the laboratory did not have a signed delegation of duties for SN to review proficiency testing reports or to sign proficiency attestations.</p>