

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D2171182	<b>(X3) Date Survey Completed</b>  06/11/2024
<b>Name of Provider or Supplier</b>  Csl Plasma Inc	<b>Street Address, City, State</b>  8521 Geyer Springs Rd, Suite D, Little Rock, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6032</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</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. (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.</p> <p>This STANDARD is not met as evidenced by: Review of personnel files for thirteen testing personnel listed on the form CMS-209, lack of documentation, and interviews with laboratory staff, determined the laboratory director failed to authorize thirteen of thirteen testing personnel to perform testing without direct supervision. Survey findings include: A) During a review of personnel files for thirteen testing personnel (TP) listed on form CMS-209 (TP #'s one through thirteen) the surveyor determined all testing personnel one through thirteen (as listed on the form CMS-209) failed to have written authorization from the laboratory director, to perform moderate complexity testing without direct supervision. B) In an interview on 6/11/2024 at 12:01:00 p.m., laboratory center manager one and two (as listed on the form Entrance and Exit Conference Attendance Record) confirmed the lack of written authorizations to testing personnel one through thirteen (on form CMS 209).</p>