

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D2159086	<b>(X3) Date Survey Completed</b>  02/20/2019
<b>Name of Provider or Supplier</b>  Csl Plasma, Inc	<b>Street Address, City, State</b>  4150 Grape Rd, Mishawaka, IN	
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: Based on document review and interview, the laboratory director failed to specify in writing the duties and responsibilities of ten of ten personnel reviewed (SP1 - SP10). Findings included: 1. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on 2-20-2019 indicated SP1 through SP10 were testing personnel. 2. Review of personnel records indicated the laboratory director did not assign duties and responsibilities, to include which tests each person was authorized to perform and whether or not supervision was required for specimen processing, test performance, and result reporting, for SP1 through SP10. 3. Review of patient records indicated the following: a. SP2 performed total protein testing for Patient #4 (2-14-2019). b. SP4 performed total protein testing for Patients #9 (2-15-2019) and #10 (2-8-2019). c. SP6 performed total protein testing for Patients #2 (2-19-2019), #3 (2-19-2019), and #7 (2-15-2019). d. SP8 performed total protein testing for Patients #1 (2-19-2019), #5 (2-15-2019), #6 (2-16-2019), and #8 (2-14-2019). 4. In interview on 2-20-2019 at 11:16 AM, SP12 (Assistant Manager of Quality) acknowledged the laboratory director did not assign duties and responsibilities to SP1</p>

through SP10. 5. Duties and responsibilities for SP1 through SP10 were not provided within seven days of the survey date.