

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2152874	<b>(X3) Date Survey Completed</b>  12/04/2018
<b>Name of Provider or Supplier</b>  Csl Plasma, Inc	<b>Street Address, City, State</b>  471 Route 38 W, Maple Shade, NJ	
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>D6015</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)</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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) record and interview with the Assistant Manager of Quality (AMQ), the Laboratory Director failed to ensure that the laboratory was enrolled in an approved PT program from October 2018 to the date of the survey. The AMQ stated on 12/4/18 at 1:30 pm that the corporate has enrolled but there was no document provided for the enrollment.</p>
<b>D6020</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) documentation and interview with</p>

the Assistant Manager of Quality (AMQ), the laboratory director failed to establish QC trends or shifts monitoring procedure from October 2, 2018 to the date of survey. The AMQ confirmed on 12/4/18 at 2:30 pm that the above mentioned procedure was not established.