

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2082894	<b>(X3) Date Survey Completed</b>  10/19/2020
<b>Name of Provider or Supplier</b>  Csl Plasma Inc	<b>Street Address, City, State</b>  1601 E Price Road, Suite C, Brownsville, TX	
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>D6018</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing (PT) records, and confirmed in interview with facility personnel, the laboratory director failed to provide documentation of his review of proficiency testing result reports for 1 of 5 events reviewed. The findings were: 1. Review of the laboratory's policy titled, "CLIA Oversight" ) CPU-WI-000171814 V2.0 stated, "Attestation statement at initial testing signed by LD/TC and results received from testing agency reviewed and signed by LD /TC." 2. Review of the laboratory's AAB proficiency testing records for Chemistry 2019 (events 1, 2, and 3) and Chemistry 2020 (events 1 and 2) found that for 2019 (event 2) the laboratory director documented his review of the score sheet on July 9, 2019. The score sheet was for the 1st event instead of the 2nd event. 3. The laboratory was asked to provide documentation of the laboratory director reviewing the scores for Chemistry 2019 (event 2) prior to the survey date. No documentation was provided. 4. An interview with the Center Manager and the Assistant Manager of Quality on October 19, 2020 at 14:30 hours in the conference room confirmed the findings.</p>