

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2166715	<b>(X3) Date Survey Completed</b>  03/30/2021
<b>Name of Provider or Supplier</b>  Csl Plasma Inc	<b>Street Address, City, State</b>  5270 Babcock St Ne, Ste 14, Palm Bay, FL	
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>D0000</b>	A Recertification survey was conducted on March 30, 2021. CSL Plasma Inc. clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D2089</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to participate in proficiency testing (PT) that resulted in a score of zero percent (0%) for the third event in 2020 in the specialty of Routine Chemistry. Findings: Review of the American Association of Bioanalysts PT records for third event of 2020 showed the laboratory received a score of 0% for the analyte total protein. During an interview on 03/30/2021 at 9:45 AM, the Assistant Manager Quality stated the proficiency testing results were not submitted before the submission date.</p>