

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D2115866	<b>(X3) Date Survey Completed</b>  11/01/2022
<b>Name of Provider or Supplier</b>  Csl Plasma, Inc	<b>Street Address, City, State</b>  4401 N Winnetka Ave, New Hope, MN	
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>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by:                      . Based on document review and interview with laboratory personnel, the laboratory failed to review proficiency testing (PT) results and take corrective actions for unsuccessful results for one of three PT events completed in 2022. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Assistant Manager of Quality (AMQ) during a tour of the laboratory at 1:05 p.m. on 11/01/22. 2. The laboratory performed PT using the American Association of Bioanalysts (AAB) provider. 3. Review of PT results and investigation of unacceptable PT results was required as established in the laboratory's Proficiency Testing Performance Guide located in the CLIA Oversight policy. 4. The PT results from the AAB 2022 Q1 event were found in the 2022 Q2 event records. The laboratory failed to obtain and review the PT results for the AAB 2022 Q2 event prior to date of survey. 5. AAB 2022 Q2 event results obtained on date of survey, 11/01/22, indicated the laboratory received unsuccessful scores for five of five testing challenges for the 2022 Q2 event. Investigation and corrective action documentation for the unsuccessful scores was not found in laboratory records. The laboratory was unable to provide investigation and corrective action records upon request. 6. In an interview at 3:15 p.m. on 11/01/22, the AMQ confirmed the above finding. .</p>