

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2238325	(X3) Date Survey Completed 08/13/2025
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 4441 Pennell Road Suite B, Unit 152a, Aston, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A desk review for proficiency testing results was conducted by the Pennsylvania State Agency for CSL Plasma, Inc on 08/13/2025. The laboratory was found out of compliance with the following conditions: 493.803 Condition: Successful participation.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CASPER 0155 report and graded results from the proficiency testing (PT) organization, American Association of Bioanalysts-Medical Laboratory</p>

	<p>Evaluation (AAB-MLE), the laboratory failed to successfully participate in PT for Total Protein (TP) and the sub-specialty of Routine Chemistry. The laboratory had unsatisfactory scores for the 1st and 2nd Events of 2025. Refer to D2096 and D2097.</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CASPER 0155D Report and graded results from the proficiency testing organization, American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE), the laboratory failed to achieve an overall testing score of satisfactory performance for the routine chemistry analyte: Total Protein (TP) . The laboratory had unsatisfactory scores for the 1st and 2nd events of 2025. Findings include: 1. Review of the CASPER 0155D report revealed the following unsatisfactory scores: - 2025 Event 1 TP: 40% - 2025 Event 2 TP: 0% 2. Further review of the laboratory's 2025 AAB-MLE PT agency's graded results confirmed the above findings resulting in unsatisfactory performance for the routine chemistry analyte: TP.</p>
<p>D2097</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(g)</p> <p>(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CASPER 0155D Report and graded results from the proficiency testing organization, American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE), the laboratory failed to achieve an overall testing score of satisfactory performance for the sub-specialty: routine chemistry. The laboratory had unsatisfactory scores for the 1st and 2nd events of 2025. Findings include: 1. Review of the CASPER 0155D report revealed the following unsatisfactory scores: - 2025 Event 1 TP: 40% - 2025 Event 2 TP: 0% 2. Further review of the laboratory's 2025 AAB-MLE PT agency's graded results confirmed the above findings resulting in unsatisfactory performance for the sub-specialty: routine chemistry. .</p>