

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D0670189	<b>(X3) Date Survey Completed</b>  08/08/2025
<b>Name of Provider or Supplier</b>  Csl Plasma Of Lexington	<b>Street Address, City, State</b>  1840 Oxford Circle, Lexington, KY	
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 Proficiency Testing (PT) Desk Review was conducted on August 8, 2025 by the Kentucky Office of Inspector General/Division of Healthcare. The laboratory was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 a Proficiency Testing (PT) Desk Review of the Certification and Survey</p>

	<p>Provider Enhanced Reporting (CASPER)-0155 and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) 2024 PT records (3rd event) and 2025 PT records (2nd event), the laboratory failed to successfully participate in PT program for two out of three PT testing events in the subspecialty of Routine Chemistry for Total Protein. (Refer to D2096 and D2097).</p>
<b>D2096</b>	<p><b>ROUTINE CHEMISTRY</b> 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 a Proficiency Testing (PT) Desk Review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) 2024 PT records (3rd event) and 2025 PT records (2nd event), the laboratory failed to achieve satisfactory performance (80% or greater) for two out of three testing events in the subspecialty of Routine Chemistry for Total Protein. 1. Review of the Casper -0155 report revealed the following: Routine Chemistry 2024- 3rd Event The laboratory received an unsatisfactory score of 0% for Total Protein. Routine Chemistry 2025- 2nd Event The laboratory received an unsatisfactory score of 60% for Total Protein. 2. A PT Desk Review from AAB-MLE 2024 and 2025 PT records confirmed the above findings.</p>
<b>D2097</b>	<p><b>ROUTINE CHEMISTRY</b> 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 a Proficiency Testing (PT) Desk Review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) 2024 PT records (3rd event) and 2025 PT records (2nd event), the laboratory failed to achieve an overall testing event score of satisfactory performance (80%) for two out of three testing events in the subspecialty of Routine Chemistry. 1. Review of the Casper -0155 report revealed the following: Routine Chemistry 2024 - 3rd Event The laboratory received an unsatisfactory score of 0% for Routine Chemistry. Routine Chemistry 2025- 2nd Event The laboratory received an unsatisfactory score of 60% for Routine Chemistry. 2. A PT Desk Review from AAB-MLE 2024 and 2025 PT records confirmed the above findings.</p>
<b>D6000</b>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p>

This CONDITION is not met as evidenced by:  
Based on a Proficiency Testing (PT) Desk Review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) 2024 PT records (3rd event) and 2025 PT records (2nd event), the laboratory director failed to provide overall management and direction of the laboratory services to ensure successful PT participation for two out of three testing events in the subspecialty of Routine Chemistry for Total Protein. (Refer to D6016).

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on a Proficiency Testing (PT) Desk Review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) 2024 PT records (3rd event) and 2025 PT records (2nd event), the laboratory director failed to ensure that the PT samples were tested as required under Subpart H during two out of three testing events in the subspecialty of Routine Chemistry for Total Protein. (Refer to D2096 and D2097).