Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2107932	06/01/2026
Name of Provider or Supplier	**Street Address, City, State**	
Csl Plasma Inc	2041 George Jenkins Blvd Ste 7, Lakeland, FL	

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 survey of the laboratory's proficiency test results was performed on 06 /01/2026 for CSL Plasma INC. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2016 493. 803(a)(b)(c) Condition: Successful Participation D6000 493.1403 Condition: Moderate Complexity Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on surveyor proficiency testing (PT) desk review, review of the laboratory's AAB-Medical Laboratory Evaluation (AAB-MLE) PT records and the review of the Centers for Medicare & Medicaid Services (CMS) Casper reports 153 and 155, and

	email communication with the AAB-MLE PT program, the laboratory failed to successfully participate in the Subspecialty of Routine Chemistry for the analytes of Routine Chemistry and Total Protein for 2 out of 3 testing events in 2025 and 2026. Findings included: Review of the AAB-Medical Laboratory Evaluation proficiency testing records and the review of the CMS 153 and 155 reports, on 04/02/2026 at 11: 21 AM, the laboratory had unsatisfactory testing scores for the analytes of Routine Chemistry and Total Protein for 2 out of 3 testing events in 2025 and 2026 (See D2096).
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (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. This STANDARD is not met as evidenced by: Based on surveyor proficiency testing (PT) desk review, review of the laboratory's AAB-Medical Laboratory Evaluation (AAB-MLE) PT records and the review of the Centers for Medicare & Medicaid Services (CMS) Casper reports 153 and 155, and email communication with the AAB-MLE PT program, the laboratory failed to successfully participate in the Subspecialty of Routine Chemistry for the analytes of Routine Chemistry and Total Protein for 2 out of 3 testing events in 2025 and 2026. Findings included: Review of the laboratory's AAB-MLE PT records review of the CMS CASPER 153 and 155 reports, and email communication with the AAB-MLE PT program, the laboratory failed to successfully participate in the Subspecialty of Routine Chemistry for the analytes of Routine Chemistry and Total Protein for 2 out of 3 testing events in 2025 and 2026. 1. Event #2 2025 Routine Chemistry- 0% Total Protein- 0% 2. Event #1 2026 Routine Chemistry- 60% Total Protein- 60%
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 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. This CONDITION is not met as evidenced by: Based on surveyor proficiency testing (PT) desk review, review of the laboratory's AAB-Medical Laboratory Evaluation (AAB-MLE) PT records and the review of the Centers for Medicare & Medicaid Services (CMS) Casper reports 153 and 155, and email communication with the AAB-MLE PT program, the Laboratory Director failed to ensure the laboratory performed PT in such a manner as to achieve and maintain satisfactory performance with successful PT in the Subspecialty of Routine Chemistry for the analytes of Routine Chemistry and Total Protein for 2 out of 3 testing events in 2025 and 2026, resulting in initial unsuccessful PT participation (See 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 surveyor proficiency testing (PT) desk review, review of the laboratory's AAB-Medical Laboratory Evaluation (AAB-MLE) PT records and the review of the Centers for Medicare & Medicaid Services (CMS) Casper reports 153 and 155, and email communication with the AAB-MLE PT program, the Laboratory Director failed to ensure the laboratory performed PT in such a manner as to achieve and maintain satisfactory performance with successful PT in the Subspecialty of Routine Chemistry for the analytes of Routine Chemistry and Total Protein for 2 out of 3 testing events in 2025 and 2026, resulting in initial unsuccessful PT participation (See D2096).