Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2189480	01/02/2025
Name of Provider or Supplier	**Street Address, City, State**	
Csl Plasma, Inc	1417 Hanover Ave, Allentown, 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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review, lack of documentation and interview with the Quality Training Specialist (QTS), the laboratory failed to perform calibration verification at least once every six months for 4 out of 7 Reicher TS Meter-DSP refractometers used for total protein testing (TP) in 2023. Findings include: 1. The laboratory's Total Protein Analytic System Control Procedures policy states: "Every six months following the 6-month Activity, the Six-Month Refractometer Activity Assessment Report will be run individually for each refractometer. Values for the distilled water, mid-range and high range refractrol controls are calculated to determine R value. The Lab Director/Technical Consultant will review each report to ensure all values are

	present and linearity values are greater than or equal to an R value of 0.95." 2. On the day of the survey, 01/02/2025 at 12:00 pm, the laboratory failed to provide the Six-Month Refractometer Activity Assessment records performed in 2023 at least once every six months for the following 4 of 7 Reicher TS meters: S/N: 2940001 S/N: 2940004 S/N: 2940005 S/N: 2940006 3. The QTS confirmed the findings above on 01 /02/2025 at 12:00 pm.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on record review, lack of documentation and interview with the Quality Training Specialist (QTS), the laboratory failed to evaluate, twice a year, the relationship between test results for 7 of 7 Reicher TS Meter-DSP analyzers used for total protein (TP) from 01/18/2023 to the day of the survey. Findings include: 1. Review of the laboratory's Six-month review of NRI and equipment performance records revealed comparison of test results for TP testing using 7 of 7 Reicher TS meters was performed in 01/07/2023 and 01/02/2024. 2. On the date of the survey, 01 /02/2025 at 12:00 pm, the laboratory failed to provide documentation for the Six-month review of NRI and equipment performance performed in July 2023 and 2024. 3. The laboratory performed 35,450 chemistry tests in 2024 (CMS-116 (estimated annual volume). 4. The QTS confirmed the findings above on 01/02/2025 at 12:00 pm.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on record review and interview with the Quality Training Specialist (QTS), the laboratory failed to ensure written procedures were followed to assess calibration verifications performed for 1 of 7 Reichert TS Meter-DPS refractometers from 06/03 /2024 to the day of the survey. Findings include: 1. The laboratory's Total Protein Analytic System Control Procedures policy states: "The Lab Director (LD)/Technical Consultant (TC) will review each report to ensure all values are present and linearity of values are greater than or equal to an R value of 0.95. The LD/TC will sign and date the reports indicating their review and approval." 2. On the day of survey, 01/02 /2025, review of the laboratory's Six-Month Refractometer Activity Assessment records revealed the LD failed to review and approve the Six-Month Refractometer Activity Assessment performed for 1 of 7 Reichert TS Meter-DPS (Serial number: 2940007) on 06/03/2024 3. The QTS confirmed the above findings on 01/02/2025 at 12:15 pm.