Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2098954	10/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Csl Plasma Inc	2430 Eastern Blvd, York, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel #2 (TP), the laboratory failed to ensure that a qualified general supervisor was on-site during all normal scheduled working hours, in which tests were performed from 11/17/21 through the day of the survey as required by PA state regulations. Findings include: 1. The PA regulation (5.23(b)(1) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. On the day of the survey, 10/13/2023 at 01:00 pm, review of the laboratory personnel report revealed that a qualified general supervisor was not on-site during all hours of patient testing from 11/17/2021 to 10/13/2023, as required by PA state regulation. 3. The laboratory did not indicate a general supervisor on the laboratory personnel report (PA State). 4. The hours of operation for this facility are Monday to Thursday, 07:00 am to 07:00 pm, and Saturday to Sunday, 08:00 am to 04:00 pm (CMS 116). 5. TP #2 confirmed during an interview at 01:30 pm on 10/13/2023 that the laboratory director oversees another CSL Plasma laboratory, and was on site at this location at least one day a week. A qualified general supervisor was not on-site during all normal scheduled working hours of testing when the director was not physically on-site from 11/17/21 to 10/13/2023.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the

	laboratory must do the following: Perform and document calibration verification procedure - (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 review of the laboratory's Total Protein Analytic System Control Procedure, calibration verification records, and interview with testing personnel #2 (TP), the laboratory failed to include a minimal (or zero) value for semiannual calibration verifications performed on 2 of 8 Reichert T/S Refractometer's used for total protein (TP) testing in 2022. Findings include: 1. The laboratory's Total Protein Analytic System Control Procedures (page 4) 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, 10/13/2023 at 10:06 am, review of calibration records revealed the laboratory failed to include a minimal (or zero) value for semiannual calibration verifications performed on the following 2 of 8 Reichert T/S Refractometer's used for TP testing in 2022: - Reichert T/S Refractometer # 1480163: Calibrated on 07/20/2022 and reviewed by the laboratory director on 08/12/2022. - Reichert T/S Refractometer # 1480164: Calibrated on 11/02/2022 and reviewed by the laboratory director on 11/06 /2022. 3. The laboratory performed 66,064 total protein examinations in 2022 (CMS 116 annual volume). 4. TP #2 confirmed the findings above on 10/13/2020 at 01:30 pm.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interviews with testing personnel

	(TP) #2 and the assistant manager of quality (AMC), the laboratory failed to over time rotate control material testing between 10 of 19 TP who performed total protein (chemistry) testing on the Reichert T/S Refractometer from 09/01/2023 to 09/30/2023. Findings include: 1. On the date of the survey, 10/13/2023 at 12:45 pm, review of the laboratory's QC records for the Reichert T/S Refractometer's revealed that 10 of 19 TP (CMS 209 TP# 2,#4,#6,#7,#11, #14,#15, #17, #18, and #19) failed to perform QC for total protein testing from 09/01/2023 to 09/30/2023. 2. The AMC and TP #2 confirmed the findings above on 10/13/2023 at 01:30 pm.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of the annual competency assessment records and interview with testing personnel (TP) #2, the technical consultant (TC) failed to document the review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records for 1 of 19 TP that performed chemistry testing in 2022. Findings: 1. On the date of the survey, 10/13/2021 at 09:45 am, review of the annual competency assessments revealed the TC failed to document the review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records for 1 of 19 TP (CMS 209 TP #2) that performed total protein testing on the Reichert T/S Refractometer in 2022. 2. TP #2 confirmed the findings above on 10/13/2023 at 01:30 pm.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of annual competency assessment records, and interview with testing personnel (TP) #2, the technical consultant (TC) failed to evaluate and document the assessment of problem solving skills for 1 of 19 TP that performed total protein (chemistry) testing in 2022. Findings: 1. On the date of the survey, 10/13/2023 at 09: 45 am, review of the annual competency assessments revealed the TC failed to evaluate and document the assessment of problem solving skills for 1 of 19 TP (CMS 209 TP #2) that performed total protein testing using the Reichert T/S Refractometer in 2022. 2. TP #2 confirmed the findings above on 10/13/2023 at 01:30 pm.