Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2051040	06/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Csl Plasma Inc	3600 Gus Thomason Rd, Suite 135, Mesquite, TX	

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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies, quality control (QC) records, CMS 116 form, and confirmed in staff interview, the laboratory failed to monitor the accuracy and precision of KOVA Refractol SP QC material over time for the total protein analyte tested on the refractometer analyzer four of four QC lots reviewed (random review November 2023 through December 2023, May 2024 through June 2024) to ensure accurate and reliable test results. Findings included: 1. Review of laboratory policies revealed the laboratory did NOT have a procedure for monitoring the accuracy and precision of test performance over time. 2. A random review of the following lots of QC tested in November 2023 through December 2023 and May 2024 through June 2024 revealed no documentation of monitoring QC over time: Low control: Lot#K306245, expiration date: 07/31/2025 High control: Lot# K305932, expiration date: 09/30/2025 Low control: Lot# K306518, expiration date: 04/30/2026 High

	control: Lot# K3056711, expiration date: 09/30/2026 On 06/27/2024 at 11:41 am, the laboratory was asked to provide documentation of monitoring QC over time for the total protein analyte tested on the refractometer analyzer using the KOVA Refractol SP QC material. None was provided. 3. Review of laboratory records revealed the laboratory had an annual volume of 108,148 total protein tests performed. 4 During an interview on 06/27/2024 at 11:41 am, the AMQ and Center Manager confirmed the laboratory failed to monitor the accuracy and precision of KOVA Refractol SP QC material over time to ensure accurate and reliable test results. Word Key: CMS: Center for Medicare & Medicaid Services
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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory instrument records, CMS 116 form, and confirmed in interview, the laboratory failed to verify at least twice annually the accuracy of 1 of 1 analytes in 2022 and 2023 for the total protein chemistry analyte tested on ten of ten refractometer analyzers. Findings include: 1. Review of laboratory policies revealed the laboratory did NOT have a policy for performing instrument comparisons for the refractometer analyzers. 2. Review of laboratory records revealed the laboratory performed testing of the total protein chemistry analyte on ten refractometer analyzers (S#s: 0850161, 0850164, 0850166, 0850168, 0850162, 0850241, 0850165, 0850163, 0850240 (used as a backup analyzer), and 0850167 (used as a backup analyzer)). 3. The laboratory was asked to provide twice annual instrument comparisons for the ten refractometers on 06/27/2024 at 10:50 am, and none were provided. The laboratory failed to perform twice annual instrument comparisons on the ten refractometers for the total protein analyte in 2022 and 2023. 4. A review of the laboratory's submitted CMS 116 application revealed an annual test volume of 108,148 total protein tests performed. 5. During an interview on 06/27 /2024 at 10:05 am, the AMQ and Center Manager confirmed the above findings. Word Key: S#s: serial numbers CMS: Center for Medicare & Medicaid Services