Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2232537	(X3) Date Survey Completed 07/29/2024
Name of Provider or Supplier Csl Plasma, Inc	**Street Address, City, State** 6515 Abrams Rd, Dallas, 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 out of compliance with the CLIA regulations. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on the review of the laboratory's submitted CMS 209, testing personnel records, and confirmed in an interview, the laboratory failed to have high school educational documentation or equivalency to qualify 1 of 26 testing personnel (TP) who performed moderate complexity testing on moderate complexity of Reichert digital refractometers. (Refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a

	chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on the review of the laboratory's submitted CMS 209, testing personnel credential records, and confirmed in an interview, the laboratory failed to have high school educational documentation or equivalency to qualify 1 of 26 TP who performed moderate complexity testing on Reichert digital refractometers. The findings were: 1. Review of the laboratory's submitted CMS 209, Laboratory Personnel Report, signed by the LD on 07/02/2024 revealed the laboratory identified 26 TP who performed moderate complexity testing on Reichert digital refractometers. 2. Review of the laboratory's TP educational credential records revealed the laboratory failed to have high school educational documentation or equivalency to qualify 1 of 26 TP who performed moderate complexity testing on Reichert digital refractometers. TP#2 Hired Date: 01/09/2023 3. An interview with the Assistant Manager of Quality on 07/24/2024 at 1:00 pm in a conference room confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services TP=Testing personnel LD=Laboratory Director