

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2164771	(X3) Date Survey Completed 04/24/2025
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 6239 Sw County Line Rd, Miramar, 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	An announced CLIA recertification survey was conducted at CSL PLASMA INC from 04/16/2025 to 04/24/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6033 493.1409 Condition: Technical Consultant-Moderate Complexity.
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview, the Laboratory failed to have a Technical Consultant (TC) who meets the qualification requirements from 02/21/2025 to 04/16 /2025 for the specialty of Chemistry testing performed by the Laboratory. Refer to D6035.</p>
D6035	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory</p>

training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to provide qualifying documents for the current Technical Consultant (TC). Findings included: 1-Review of the FORM CMS-209 signed by the Laboratory Director on 04/15/2025 revealed the following: The LD was also the Clinical Consultant, there was one TC, and there was 10 Testing Personnel (TP#1, TP#2, TP#3, TP#4, TP#5, TP#6, TP#7, TP#8, TP#9 and TP#10). 2-Review of TC employment and training records revealed that the LD approved him as TC on 02/26/2025. 3-Review of TC Diploma revealed that he had a Bachelor of Science in Biomedical Engineering. 4-During an interview on 04/16/2025 at 12:00 PM the Facility Manager could not provide the transcripts, various attempts were made via email to receive transcript for TC. On 04/24/2025 there was an email confirmation that the facility could not provide the transcript for the Degree of the TC because he left the company.