

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2028813	(X3) Date Survey Completed 04/28/2025
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 2825 N Andrews Ave, Wilton Manors, 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 on April 28, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6063 493.1421 Condition: Laboratory Testing Personnel.
D6028	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10)</p> <p>(e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to verify the education of the Technical Consultant (TC) for the period of 09/12/2024 to 04/01/2025. Findings included: 1-Review of Technical Consultant Qualification and Responsibilities policy signed by the Laboratory Director on 12/04/2024 revealed that the Academic requirement was "Bachelors in a chemical, biological, clinical laboratory science, or medical technology." 2- Review of the Diploma for the TC for the period of 09/12/2024 to 04/01/2025 revealed that he had a Bachelor of Science in Biomedical Engineering. The laboratory failed to request and review the transcripts to check if his Diploma met the requirements for TC. 3-Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director on 04/23/2025 listed 20 TP (TP#1, TP#2, TP#3, TP#4, TP#5, TP#6, TP#7, TP#8, TP#9, TP#10, TP#11, TP#12, TP#13, TP#14, TP#15, TP#16, TP#17, TP#18, TP#19 and TP#20). 4-Review of Testing Personnel (TP) Competencies for the period of reference revealed that he signed competencies from 10/09/2024 to 04/01/2025 for the following Testing Personnel (TP): TP#1 (10/09/2024), TP#2 (04/01/2025), TP#7 (11/22/2024 and 01/14/2025), TP#8 (11/13/2024), TP#9 (11/22/2024), TP#10 (01/29/2025), TP#11 (10/25</p>

/2024), TP#14 (11/13/2024), TP#15 (10/23/2024), TP#16(10/09/2024 and 03/14 /2025), TP#17 (01/22/2025), TP#18 (10/23/2024), TP#19 (02/18/2025), TP#20 (03/08 /2025) signed by the TC. 5-During an interview on 04/28/2025 with the Manager at 12:35 PM, she confirmed that the LD failed to verify that the Diploma for the TC for the period of 09/12/2024 to 04/01/2025 meet the requirements.

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 record review and staff interview, the laboratory failed to verify the education of 1 out of 20 Testing Personnel. See 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 (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to verify the education of 1 out of 20 testing personnel (TP). Findings include: 1-Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director on 04 /23/2025 listed 20 TP (TP#1, TP#2, TP#3, TP#4, TP#5, TP#6, TP#7, TP#8, TP#9. TP#10, TP#11, TP#12, TP#13, TP#14, TP#15, TP#16, TP#17, TP#18, TP#19 and TP#20). 2-Review of employee files revealed that the High School Diploma for TP#18 was a Foreign Diploma, and the laboratory could not provide the equivalence for his diploma. 3-Review of his Competency records revealed that his Initial Competency was from 10/25/2022. 4-Review of testing records revealed that his last testing day was on 04/25/2025. 5-During an interview on 04/29/2025 at 12:30 PM with the Manager, she confirmed that the laboratory failed to have documentation to proof that the TP#18 meet the minimum education requirement, she explained that they have requested the equivalence to an Accredited Organization and they were stopping him from testing from that day.