

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2206043	(X3) Date Survey Completed 07/29/2025
Name of Provider or Supplier Csl Plasma, Inc - Temple 521	Street Address, City, State 2603 Thornton Ln Suite 120, Temple, 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 NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, training records, competency evaluations, and interview, the technical consultant failed to evaluate and document the performance of individuals responsible for performing moderate complexity testing at least semiannually during the first year the individual tests donor specimens for one of nine employees reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled CLIA Oversight, version 22.0, under Technical Consultant Task Performance Guide on page 26 stated, "Testing personnel have completed initial training with designated trainer or are due for 6 month or annual or other approval." The directive to perform two 6-month evaluations in the first year of testing is vague. B. Review of the laboratory's plateau data showed training was performed on 03/26/2024. Review of competency evaluations showed a competency evaluation was performed on 03/28/2024. A second 6-month competency was requested on July 29, 2025 at 1025 hours but not provided. C. Interview with the Assistant Center Manager on July 29, 2025 at 1025 hours confirmed there was only one 6-month competency performed.</p>
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 review of pre-survey paperwork, educational credentials and interview, the laboratory failed to have documentation of education qualifying one out of 13 testing personnel to perform non-waived testing. 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 review of the job description, laboratory's policy and procedure, pre-survey paperwork, educational credentials and interview, the laboratory failed to ensure that one out of 13 testing personnel had documentation of qualifying education prior to performing patient testing reviewed for the moderately complex test total protein. Findings follow. A. Review of the Position Description under Job Specifications stated "Provide minimum hiring requirements, specialized knowledge, and other considerations required. Education: High school diploma or equivalent required." B. Review of the laboratory's policy and procedure titled Center Training Compliance Work Instruction, Version 2.0, on page 3 under New Hire Orientation stated, "Verify new hire's copy of High School diploma/GED". And on page 6 under New Hire Orientation stated, "If unable to provide Diploma/GED, Then Equivalent documentation of Diploma/GED confirming graduation such as transcripts or a certified letter." C. Review of the pre-survey paperwork titled Laboratory Personnel showed: 1. testing personnel #15 (as listed on the CMS Form 209) was hired 03/05 /2024. D. Review of the educational credentials showed: 1. testing personnel #15 had an Academic Excellence Certificate. There was no documentation of "diploma" or High School graduation. E. Interview with the Assistant Center Manager on July 29, 2025 at 1015 hours confirmed the findings.