

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2002432	(X3) Date Survey Completed 08/19/2025
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 21921 Greenfield Road, Southfield, MI	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Assistant Manager of Quality (AMQ), the Technical Consultant failed to follow its established personnel competency assessments for 8 (TP2, TP7, TP14, TP17, TP19, TP23, TP25, TP26) of 28 personnel reviewed. Findings include: 1. A review of the personnel records revealed that a six-month competency assessment was not performed after the initial competency assessment following a leave of 180 days or greater for 8 testing personnel (TP): a. TP2: A six-month competency assessment was not performed after the initial assessment on 10/31/2023; next assessment was performed on 10/15/2024. b. TP7: A six-month competency assessment was not performed after the initial assessment on 8/8/2023; next assessments were performed on 8/6/2024 and 7/29/2025. c. TP14: A six-month competency assessment was not performed after the initial assessment on 7/18/2023; next assessments were performed on 8/13/2024 and 7/29/2025. d. TP17: A six-month competency assessment was not performed after the initial assessment on 5/2/2023; next assessments were performed on 4/30/2024 and 4/15/2025. e. TP19: A six-month competency assessment was not performed after the initial assessment on 5/9/2023; next assessments were performed on 4/30/2024 and 4/15/2025. f. TP23: A six-month competency assessment was not performed after the initial assessment on 6/11/2023; next assessments were performed on 6/4/2024 and 6/3/2025. g. TP25: A six-month competency assessment was not performed after the initial assessment on 6/27/2023; next assessments were performed on 6/13/2024 and 6/8/2025. h. TP26: A six-month competency assessment was not performed after the initial assessment on 9/26/2023; next assessment was performed on 9/18/2024. 2. A review of the laboratory's</p>

policy titled "Rehired/LOA Employees Reference Guide" reveals in section titled Employee Returns to Center after 180 days reveals: a. "Any employee who returns to the business after 180 days must complete full re-training to their position including..." b. "For employes that need to retrain of CLIA, ... Six-month: ...set the required by dates....ignite Six-Month CLIA Reception activities." 3. An interview conducted on 08/19/2025 at 2:30 pm with the AMQ confirmed the missing 6-month training for personnel returning to work.

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 interview, the laboratory failed to ensure its moderate complexity testing personnel were qualified to perform Total Protein testing utilizing the Reichert Digital Refractometer. 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 (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 interview with the Assistant Manager of Quality (AMQ), the laboratory failed to ensure that testing personnel performing Total Protein testing were qualified prior to testing for 1 (TP #14) of 28 staff listed on the CMS-209. Findings include: 1. A review of testing personnel qualifications revealed that one staff (TP #14) lacked documentation demonstrating compliance with the educational requirements at 493.1423. The documentation provided was a high school transcript, which did not include a certified graduation date. 2. An interview conducted on 08/19/2025 at 2:30 p.m. with the AMQ confirmed that the required documentation was not available. 3. The laboratory was granted an additional seven (7) days following the conclusion of the survey to submit the missing documentation for the above-referenced testing personnel; however, no additional information was received.