

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2176439	(X3) Date Survey Completed 02/06/2024
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 617 Cedar Avenue, Yeadon, PA	
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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the management trainee of quality (MTQ), assistant manager of quality (AMQ), and center manager (CM), the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met regarding having a supervisor on site during all normal scheduled working hours in which chemistry tests were performed from 06/02/2022 to the day of survey. Findings include: 1. The PA regulations (5.23(b)(1) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. On the day of the survey, 02/06/2024 at 10:30 am, review of the laboratory personnel report (PA State) and personnel credentials revealed that the laboratory failed to ensure that the PA regulations were met regarding having a qualified supervisor on site during all hours of patient testing from 06/02/2022 to 02/06/2024. 3. The laboraty's hours of operation are Monday to Friday 06:00 am to 06:00 pm and Saturday to Sunday 08:00 am to 05:00 pm. 4. The MTQ, AMQ and CM confirmed the findings above on 02/06/2024 at 1:22 pm.</p>
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>

This STANDARD is not met as evidenced by:
Based on a lack of documentation and interview with the management trainee of quality (MTQ), assistant manager of quality (AMQ), and center manager (CM), the laboratory failed to assess the competency of 1 of 1 Technical Consultant (TC) for their supervisory responsibilities performed in 2023. Findings include: 1. On the day of survey, 02/06/2024, at 11:45 am, the laboratory could not provide competency assessment records for 1 of 1 TC (CMS 209 personnel #23) for their supervisory responsibilities performed in 2023. 2. The MTQ, AMQ and CM confirmed the findings above on 02/06/2024 at 01:22 pm.

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 the CLIA 's Laboratory Personnel Report (Form CMS-209), lack of personnel qualification records, and interview with the management trainee of quality (MTQ), assistant manager of quality (AMQ), and center manager (CM), the laboratory failed to ensure that 2 of 20 testing personnel (TP) (CMS 209 personnel #15 and #20) that performed Moderate Complexity testing from 6/02/2022 to 02/06/2024 were qualified. 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 review of the CLIA 's laboratory Personnel Report (Form CMS-209), lack of personnel qualification records, and interview with the management trainee of quality (MTQ), assistant manager of quality (AMQ), and center manager (CM), the laboratory failed to ensure that 2 of 20 testing personnel (TP) who performed moderate complexity testing in 2022 and 2023 were qualified. Findings include: 1. On the day of survey, 02/06/2024 at 11:42 am, the laboratory failed to provide personnel qualification records for 2 of 20 TP (CMS 209 personnel #15 and #20) who performed moderate complexity chemistry testing from 6/02/2022 to the day of survey. 2. The laboratory performed 30,000 chemistry examinations in 2023 (CMS 116 annual

volume). 3. The MTQ, AMQ, and CM confirmed the finding above on 02/06/2024 at 1:30 pm.