

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2261136	<b>(X3) Date Survey Completed</b>  04/26/2023
<b>Name of Provider or Supplier</b>  Csl Plasma, Inc	<b>Street Address, City, State</b>  2960 S Chase Ave, Milwaukee, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6017</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing records and interview with the assistant manager of quality, the laboratory director did not ensure the laboratory reported their results for protein testing for one of two proficiency events since the laboratory began donor testing on June 30, 2022. Findings include: 1. Review of proficiency testing records showed the laboratory enrolled with AAB (American Association of Bioanalysts) proficiency program for protein the third event in 2022 and event one in 2023. The records showed evaluation of the laboratory's results by AAB for event one in 2023, but no evidence AAB evaluated the protein results for the third event in 2022. The records showed testing personnel performed protein testing for the third event in 2022 on September 28, 2022. There is no evidence the laboratory submitted the results to AAB. 2. Interview with the assistant manager of quality (staff B) on April 26, 2023 at 9:45 AM confirmed the protein results from the third event in 2022 were not reported to the proficiency testing provider within the timeframes established by the proficiency testing program.</p>
<b>D6063</b>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the</p>

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 surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form CMS-209 "Laboratory Personnel Report (CLIA)" and personnel records and interview with the assistant manager of quality and center manager, the laboratory did not have documentation showing one of nine reviewed testing personnel met the qualification requirements for moderate complexity testing. Findings include: 1. The laboratory did not have documentation showing one of the nine reviewed testing personnel had graduated from high school. See D 6065.

**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 surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form CMS-209 "Laboratory Personnel Report (CLIA)" and personnel records and interview with the assistant manager of quality and center manager, the laboratory did not have documentation showing one of nine reviewed testing personnel met the qualification requirements for moderate complexity testing personnel. Findings include: 1. Review of academic credentials for nine testing personnel identified on the Form CMS-209 submitted for the survey showed the high school transcripts for one testing person (staff A) did not show the individual received a high school diploma and did not include a graduation date. Review of training and competence evaluation records showed staff A was approved to perform moderate complexity protein testing since August 2022. 2. Interview with the assistant manager of quality (staff B) and the center manager (staff C) on April 26, 2023 at approximately 9:30 AM confirmed the transcript did not show staff A had earned a high school diploma and confirmed documentation was not available to show staff A met the requirements for moderate complexity testing personnel.