

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2114925	<b>(X3) Date Survey Completed</b>  05/13/2024
<b>Name of Provider or Supplier</b>  Csl Plasma, Inc	<b>Street Address, City, State</b>  4596 State St, Saginaw, MI	
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>D0000</b>	
<b>D2006</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by:  . Based on record review and interview with the Center Manager, the laboratory failed to test its proficiency testing samples in the same manner as it tests patient specimens for 5 (Q3 Chemistry 2022, Q1 Chemistry 2023, Q2 Chemistry 2023, Q3 Chemistry 2023, Q1 Chemistry 2024) of 6 proficiency testing events reviewed. Findings include:  1. A review of the laboratory's proficiency testing documentation revealed the laboratory's corrective action for its Q2 Chemistry 2022 testing event stated, "A Learning Event (LE) record will be generated by Quality Department for all Reception and Quality employees regarding cleaning of the refractometer used for Proficiency Testing. The Reception Technician that will be reading the sample will ensure that the refractometer prism is clean and dry prior to performing the first specimen vial testing. Quality employee that is observing the process will ensure that the refractometer prism is cleaned and dried prior to testing the first specimen and after each specimen is tested." 2. An interview on 5/13/24 at 11:40 am with the Center Manager revealed the quality personnel observe all testing personnel performance of proficiency testing for each event but do not observe all donor testing.</p>

**D5209**

**PERSONNEL COMPETENCY ASSESSMENT POLICIES**

CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Center Manager, the laboratory failed to perform testing personnel competency assessments in accordance with their established policies for 1 (Testing Personnel #1) of 27 testing personnel reviewed. Findings include: 1. A review of the laboratory's testing personnel competency assessments revealed a lack of competency assessments for Testing Personnel #1 for 2022 and 2023. 2. The surveyor requested competency assessment documentation for Testing Personnel #1 on 5/13/24 at 9:50 am and 10:08 am and the documentation was not made available. 3. A review of the laboratory's "CLIA Oversight" policy revealed a section titled, "Technical Consultant Task Performance Guide" stating, "Direct Observation and Assessment of Testing Personnel. Pre-requisite. Testing personnel have completed initial training with designated trainer or are due for 6 month or annual or other approval." 4. An interview on 5/13/24 at 11:34 am with the Center Manager revealed Testing Personnel #1 had been performing total protein testing for the past 6 years. 5. An interview on 5/13/24 at 12:20 pm with the Center Manager confirmed competency assessments for Testing Personnel #1 form 2022 and 2023 were not available.