

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2118829	<b>(X3) Date Survey Completed</b>  06/17/2024
<b>Name of Provider or Supplier</b>  Csl Plasma, Inc	<b>Street Address, City, State</b>  3456 Annapolis Rd, Halethorpe, MD	
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>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory failed to ensure that the individual testing or examining the PT samples (TP) signed PT attestation statements, attesting that PT specimens were run in the same way as patient samples. Findings: 1. A review of chemistry PT records from 2023 to 2024 showed that the TP did not sign the attestation statements for two out of four events. The attestation statement for the third event of 2023 (Chemistry M3 - 2023) was not available at the time of the survey. 2. During an interview on 06/17/2024 at 12:45 PM, the TC confirmed that the attestation statements were not signed by the TP.</p>
<b>D3011</b>	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and interview with the technical consultant (TC), the laboratory did not ensure that an eye wash station is located in the laboratory area where testing occurs. Findings: 1. During a tour of the laboratory on 06/17/2024 at 09:</p>

45 AM, it was observed that the eye wash station for the laboratory is located in a room which is at the opposite end of the building from the testing area. There was no eye wash station available in the laboratory where laboratory testing is performed. 2. During an interview on 06/17/2024 at 12:45 PM, the TC confirmed that the eye wash station is not located in the room where laboratory testing is performed.

**D3037**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that a copy of all PT documents is maintained by the laboratory for a minimum of two years from the date of the PT testing event. Findings: 1. A review of chemistry PT records from 2023 and 2024 showed that the attestation statement for one of four events (Chemistry M3 - 2023) was not present at the time of the survey. 2. During an interview on 06/17/2024 at 12:45 PM, the TC confirmed that the attestation statement was missing for the above listed PT event.