

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D2147670	<b>(X3) Date Survey Completed</b> 05/21/2026
<b>Name of Provider or Supplier</b> Csl Plasma, Inc	<b>Street Address, City, State</b> 34500 Ford Road, Westland, 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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 site manager (SM), the laboratory failed to ensure that annual competency assessments were performed and available for review for 2 (TP5 and TP8) of 20 testing personnel (TP) reviewed. Findings include:                      1. A record review of CMS Form 209 listed TP5 and TP8 as testing personnel performing moderate complexity testing. 2. A record review of personnel competency assessment documentation revealed the following: a. A review of competency assessments for TP5 revealed the most recent competency assessment was dated 01/23 /2025 and the competency assessment for 2026 was missing. b. A review of competency assessments for TP8 revealed the most recent competency assessment was dated 08/12/2025 and the competency assessment for 2024 was missing. 3. On 05 /21/2026 at 12:25 pm, the surveyor requested competency assessment documentation for TP5 for 2026 and TP8 for 2024. The requested competency assessment documentation was not provided for review. 4. A record review of CSL Plasma "CLIA Personnel Reference Guide," Document No. DOC-000238163, page 8, states the Technical Consultant is responsible for "evaluating the competency of testing personnel initially, at 6 months, at 12 months, and annually thereafter, or when test methodology or instrumentation changes." 5. An interview with the SM on 05/21 /2026 at 12:30 pm confirmed that the competency assessment documentation for TP5 and TP8 could not be located.</p>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p>

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the site manager (SM), the laboratory failed to ensure quality assessment activities were performed and documented for 2 (2024 Q3, 2025 Q4) of 7 quarters reviewed. Findings include: 1. A record review of the laboratory's Total Protein Quarterly Monitoring Reports revealed lack of documentation for the following quarters reviewed: a. Third Quarter 2024 (07/01/2024 through 09/30/2024) b. Fourth Quarter 2025 (10/01/2025 through 12/31/2025) 2. A record review of CSL Plasma "CLIA Oversight" Policy, Document No. DOC-000270273, under the "Quarterly Review of Test System Performance and Refractometer Comparison Activity" section, pages 13-14, states the "Quarterly Total Protein Test System Monitoring Report is required to be reviewed, signed, dated, filed in the CLIA notebook, and maintained for review." 3. An interview with the SM on 05/21/2026 at 1:00 pm confirmed the Third Quarter 2024 and Fourth Quarter 2025 Total Protein Quarterly Monitoring Reports were not available for review.