

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2130555	(X3) Date Survey Completed 05/05/2025
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 321 Mall Drive, Portage, MI	
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
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> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Center Manager, the laboratory failed to follow its written competency assessment policy for 2 of 2 personnel (TP K, TP Q). Findings include: 1. A review of the laboratory competency assessments records revealed the following required evaluations were not present: a. TP K: Six-month competency assessment due March 2025 was not completed. b. TP Q: Six-month competency assessment due February 2025 was not completed. 2. A review of the laboratory competency assessment policy revealed that competency assessments for new personnel should be conducted initially, 6-months and annually thereafter. 3. Interview with the Center Manager on 05/05/2025 at 11:00 am confirmed that the 6-month competency assessments had not been performed.</p>