Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2118112	06/02/2026
Name of Provider or Supplier	**Street Address, City, State**	
Csl Plasma, Inc - Mechanicsburg	4880 Carlisle Pike, Mechanicsburg, PA	

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	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 review of policies, competency assessment (CA) records and interview with the Assistant Manager of Quality (AMQ), the laboratory failed to follow the established procedure used to assess the competency of 1 of 1 Technical Consultant (TC) for their delegated supervisory responsibilities performed from 07/16/2025 to 06/02/2026. Findings include: 1. Review of the laboratory's CLIA Personnel Reference Guide revealed the following, "For individuals, other than the Laboratory Director, functioning in the role of Technical Consultant competency evaluations are required. The evaluations are performed by the Laboratory Director and captured in the training file. Competency is evaluated during initial training and annually thereafter. *It should be noted that each Laboratory Director performs competency assessments initially and annually for Technical Consultants whom they have delegated responsibilites to." 2. On the day of survey, 6/02/2026 at 9:15 am, review of CA records revealed the laboratory failed to follow the established procedure used to assess the initial and annual competency of 1 of 1 Technical Consultant for their delegated duties performed from 07/16/2025 to 06/02/2026. 3. The laboratory performed 62,492 Chemistry tests in 2025 (CMS-116, estimated annual volume dated 05/06/2026). 4. The AQM confirmed the findings above on 06/02/2026 at 11:00 am.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness

	of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of policies, record review, and interview with the Assistant Manager of Quality (AMQ), the laboratory failed to review the effectiveness of corrective actions taken to resolve and prevent the recurrence of problems for 3 of 4 six month refractometer activity assessments (RAA) performed from 09/26/2024 to 06/02/2026. Findings include: 1. On the day of survey, 6/02/2026 at 10:00 am, review of the laboratory's CLIA Oversight policy revealed the following, "Review each refractometer report, each report reviewed within 7 days of completing the 6 Month Activity." 2. Review of the RAA revealed the laboratory failed to follow the established procedure for 3 of 4 RAA performed from 09/26/2024 to 06/02/2026. 3. Further review of the laboratory's Error Management Form (EMF) records revealed the corrective actions taken to ensure timely review of the RAA reports were ineffective and failed to prevent recurrence: - RAA performed 11/30/2024: reviewed on 03/12/2025 (102 days from completion) - RAA performed 11/24/2025: reviewed on 12/04/2025 (10 days from completion) - RAA performed 05/22/2026: not reviewed as of date of survey, 06/02/2026 (11 days from completion) 4. The laboratory performed 62,492 Chemistry tests in 2025 (CMS-116, estimated annual volume dated 05/06/2026). 5. The AQM confirmed the findings above on 06/02/2026 at 11:00 am.