

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2098954	(X3) Date Survey Completed 11/12/2025
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 2430 Eastern Blvd, York, 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
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation and interview with the Assistant Manager of Quality (AMQ), the Laboratory Director (LD) failed to ensure an established Quality Assessment (QA) program was maintained to assure the quality of laboratory services provided when chemistry testing was performed for 24 of 24 months from 10/13/2023 to the date off the survey. Findings include: 1. The laboratory's Technical Consultant Qualification and Responsibilities policy stated "Below is the list of responsibilities delegated to the Technical Consultant: Ensure quality programs are established, maintained and identify failures as they occur". 2. On the day of the survey, 11/12/2025, the laboratory could not provide documentation of LD/designee review of Temperature monitoring QA activities to ensure quality programs were maintained and failures were identified as they occurred in the analytic systems specified in 493.1252 for 24 of 24 months when Total Protein testing was performed from 10/13/2023 to 11/12/2025. 3. The AMQ confirmed the findings above on 11/12/2025 at 1:30 pm.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--</p>

This STANDARD is not met as evidenced by:

Based on lack of documentation, and interview with the Assistant Manager of Quality (AMQ), the Technical Consultant (TC) failed to assess the annual competency of 2 of 14 Testing Personnel (TP) that performed Total Protein testing in 2024. Findings Include: 1. On the day of the survey, 11/12/2025 at 11:57 am, the laboratory could not provide documentation of annual competency assessment performed on TP #4 and #8 (CMS 209 form, dated 11/12/2025) for Total Protein testing performed in 2024. 2. The CMS 116 form submitted at the time of the survey revealed that 70,350 Total Protein tests were performed in 2024. 3. The AMQ confirmed the findings above on 11/12/2025 at 1:30 pm.