

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0868530	(X3) Date Survey Completed 02/09/2024
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 3923 Park Avenue, Memphis, TN	
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
D6036	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records, record review, and staff interview, the technical consultant did not review the laboratory's proficiency testing evaluation report for 2023 event three, quarterly total protein reports, or six-month refractometer reports after duties were assigned on 09/25/23. The findings include: 1. Review of personnel records revealed delegation of technical consultant duties. The form was signed by the lab director on 09/22/23, by the technical consultant on 09/25/23, and by center quality on 09/28/23. The delegated duties included the following: Ensuring test methodologies have the capability of providing quality results. Review of test and control data and review of the center's normal reference interval. Signing of attestation statements and monitoring the completion and results of proficiency testing. Ensuring adequate analytical performance for the test system by review of the quarterly control procedures report. 2. Record review revealed the technical consultant did not review the following documents: 2023 event three proficiency testing report. "Quarterly Total Protein Test System Monitoring Report" dated 10/03/23 and 01/04/24. "Six Month Review of NRI and Equipment Performance" dated 01/04/24. "Six Month Refractometer Activity Assessment" dated 01/05/24. 3. Interview with three center management staff members on 02/16/24 at 3:15 PM confirmed the technical consultant did not review the laboratory's proficiency testing, quality assessment, quality control and refractometer assessment reports after duties were assigned on 09/25/23.</p>