

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2136878	(X3) Date Survey Completed 03/13/2025
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 2093 Elm Road Ne, Warren, OH	
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
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews with the Assistant Center Manager (ACM), the Quality Specialist (QS) and the Assistant Manager of Quality (AMQ), the Technical Consultant (TC) failed to evaluate and document the competency of one out of 12 newly listed testing personnel (TP), at least semiannually during the first year they tested donor total protein specimens in the subspecialty of Routine Chemistry. This deficient practice had the potential to affect 2,210 out of 2,210 donor total protein tests performed by TP#3 between 07/24/23 through 07/10/2024. Findings Include: 1. Review of the laboratory's "CLIA Personnel Reference Guide" policy and procedure, provided on the date of the inspection found instructions under the TC's "Description of Responsibility" to assess the competency of new testing personnel initially, at six months and 12 months within the first year of testing patient specimens. 2. Review of the laboratory's Form CMS-209, approved by the Laboratory Director via signature and date on 03/13/2025, revealed 12 out of 20 individuals newly listed, since the last CLIA inspection on 05/10/2023, and qualified by the Laboratory Director to perform moderately complex total protein testing procedures. 3. Review of the laboratory's 2023 and 2024 training and competency assessment documentation provided found the following for TP#3: 07/24/2023 - initial demonstration Not Completed - first semi-annual competency 07/10/2024 - second semi-annual competency 4. The Inspector requested the first semi-annual competency assessment for TP#3 within the first year of testing donor specimens at this center from the ACM, QS and AMQ. The AMQ confirmed the TC did not conduct the six month (first semi-annual) competency assessment for TP#3 as required by the CLIA regulations and the center's policy and</p>

procedure and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 03/13/2025 at 9:35 AM.