

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D2294204	<b>(X3) Date Survey Completed</b> 03/21/2025
<b>Name of Provider or Supplier</b> Csl Plasma, Inc	<b>Street Address, City, State</b> 2360 W Lincoln Ave Unit A, Anaheim, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of laboratory written policies and procedures for Total Protein and interviews with the laboratory staff (LS) it was determined that the laboratory failed to have available and follow by all testing personnel written procedure for the Total Protein test performed in the laboratory. The findings included: 1. On the day of the survey on March 21, 2025, at approximately 12:15 p.m. the laboratory failed to provide written policies and procedures for Total Protein test performed daily in the laboratory. 2. The LS confirmed on 03/21/2025 at approximately 2:30 p.m. that the laboratory did not have written policies and procedures available for the Total Protein test performed in the laboratory. 3. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 03/20/2025, the laboratory processes and reports 30,524 Total Protein samples annually for which the laboratory did not have a written procedure approved by the laboratory director available and followed by all testing personnel.</p>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic</p>

examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
 Based on the interviews with the laboratory director (LD) and staff, review of policies and procedures, proficiency test records, and five (5) randomly chosen patient records for Total Protein, the laboratory failed to establish required written procedures. Findings included: 1. Review of the standard operating procedures and policies revealed lack of a formal operating procedure for determination of Total Protein using the refractometer approved and signed by the laboratory director. 2. During interviews with the LD, laboratory staff, and administrative personnel at approximately 2:00 p.m. on March 21, 2025, the LD laboratory staff, and administrative personnel confirmed the lack of required written procedures for routine chemistry determination of total protein test as listed in 1 above. 3. According to the submitted laboratory declaration of test volume, the laboratory tested and reported 30,524 Total Protein samples for which there is a lack of a written procedure.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(13)

(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

This STANDARD is not met as evidenced by:  
 Based on direct observation, review of standard policies and procedures, and interview with the laboratory staff; it was determined that the laboratory director failed to ensure that a signed and dated approved written procedure for Total Protein is always available to all personnel responsible for any aspect of the testing process. See D5401 and D5403.