

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0862932	<b>(X3) Date Survey Completed</b>  11/26/2019
<b>Name of Provider or Supplier</b>  Csl Plasma, Inc	<b>Street Address, City, State</b>  1536 S Glenstone, Springfield, MO	
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>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of procedures, instrument comparisons and interview with the center manager the laboratory failed to include a step by step procedure for instrument comparisons and define a relationship between instrument comparison test results. Findings: 1. Review of total protein procedure showed no procedure for instrument comparisons. 2. Review of total protein instrument comparisons showed no documentation to define a relationship between test results. 3. Interview with the</p>

center manager on November 26, 2019 at 10:30 AM confirmed the laboratory failed to include a step by step procedure for total protein instrument comparisons and define a relationship between instrument comparison test results.