

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2249562	(X3) Date Survey Completed 02/20/2024
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 1410 Laurel Rd, Lindenwold, NJ	
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
D5403	<p>PROCEDURE MANUAL 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 surveyor review of the Medical Reception DOC-000936310 Written Procedure (WP) and interview with the Center Manager(CM) and Assistant Manager of Quality (AMQ), the laboratory failed to have all applicable procedures in the WP for Total Protein testing performed on the Reichert Technologies TS Meter-DSP from 1/21/22 to the date of the survey. The findings include. 1. The laboratory failed to provide instructions on how to report Total Protein patient results beyond the reportable range of 0.0 to 10.0 mg/dL either through the electronic medical record (EMR) and/or through written documentation near the Reichert Technologies TS</p>

Meter's as chosen by the laboratory in the . 2. The CM and AMQ confirmed on 2/20/24 at 12:00 pm that the laboratory did not provide instructions on how to report patient results beyond the Total Protein reportable range in the WP.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Performance Specification records (PS) for the six Reichert Technologies TS Meter-DSP's used for Total Protein testing, the Reichert Technologies TS Meter-DSP User's Guide (UG) and patient screening test result reports (TR) and interview with the Center Manager (CM) and Assistant Manager of Quality (AMQ), the laboratory failed to perform and place into use all PS requirements for Total Protein testing performed on the Reichert Technologies TS Meter-DSP's from 1/21/22 to the date of the survey. The findings include: 1. There was no evidence that the laboratory placed the established reportable range 0.0 to 10.0 mg/dL into use through either their electronic medical record (EMR) and/or written documentation near the Reichert Technologies TS-Meters to ensure that patient results beyond that range would not be reported. 2. There was no evidence that the laboratory verified the acceptable range 6.0 to 9.0 mg/dL for Total protein. 3. The CM and AMQ confirmed on 2/20/24 at 12:30 pm that the laboratory failed to perform and place into use all PS requirements for Total Protein testing.