

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0672155	(X3) Date Survey Completed 05/25/2021
Name of Provider or Supplier Csl Plasma Of Pleasant Grove	Street Address, City, State 10121 Lake June Road Suite 503, Dallas, TX	
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
D0000	An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory procedures, review of laboratory records for the Reichert Protein Refractometers, and staff interview, it was revealed that the laboratory failed to ensure instrument verification studies for reportable range</p>

were performed for 7 of 7 Reichert Protein Refractometers currently in use. Findings included: 1. During a tour of the testing areas on 05/25/2021 at 10:10 AM, the following 7 Reichert Protein Refractometers were observed to be in use: Serial Number 07132-0514 Serial Number 07133-0514 Serial Number 10842-0617 Serial Number 07129-0514 Serial Number 07134-0514 Serial Number 07135-0514 Serial Number 07128-0514 2. Review of laboratory procedure titled, "Validation for the Installation or Reinstallation of the Refractometer" (Approved on 6/30/2020) revealed the following steps in the validation process: " ...6. Receive BioRad Trilevel Minipak Liquid Unassayed MultiQual 1,2,3 ...7. The level 3 BioRad MultiQual will be used to verify manufacturer's accuracy and establish precision8. Prepare to Test: Select 3 different employees trained to operate the refractometer ... 9. Each employee will run 5 replicates of each level of control and record results on the attached Data Sheets ... 12. Enter the values for each employee on the spreadsheet. There should be fifteen (15) values for each control level. Excel will perform the calculation for Center Accuracy and Center Precision." The laboratory procedure failed to define steps for verification of the reportable range of each Reichert Protein Refractometer. 3. Review of the Reichert Protein Refractometer verification studies revealed the Level 1, 2 and 3 quality control values from each of the 5 replicates performed by the 3 different employees. A "center accuracy" was determined for each refractometer. "Center Accuracy" was defined as "equal to the calculated mean". The following data for each in use refractometer was obtained: a. Serial Number 07132-0514 Center Accuracy: Level 1= 6.6g/100mL; Level 2=8.6 g/100mL; Level 3=10.8 g/100mL b. Serial Number 07133-0514 Center Accuracy: Level 1 =6.0 g/100mL; Level 2 =7.6 g/100mL; Level 3= 8.9 g/100mL c. Serial Number 10842-0617 Center Accuracy: Level 1= 6.4 g/100mL; Level 2= 8.5 g/100mL; Level 3 =10.5 g/100mL d. Serial Number 07129-0514 Center Accuracy Level 1= 6.4 g/100mL; Level 2= 8.4 g/100mL; Level 3= 10.6 g/100mL e. Serial Number 07134-0514 Center Accuracy: Level 1= 6.2 g/100mL; Level 2= 8.4 g/100mL; Level 3= 10.7 g/100mL f. Serial Number 07135-0514 Center Accuracy: Level 1= 4.5 g/100mL; Level 2= 7.7 g/100mL; Level 3= 9.1 g/100mL g. Serial Number 07128-0514 Center Accuracy: Level 1= 6.4 g/100mL; Level 2= 8.4 g/100mL; Level 3= 10.6 g/100mL The laboratory failed to access the data collected in order to define and verify an acceptable reportable range for each refractometer in use. 4. During an interview with the assistant quality manager at 11:00 AM on 5/25/2021, in the conference room, the assistant manager was asked to provide documentation of the verified reportable range for the Reichert Protein Refractometers. No documentation was provided. The laboratory failed to ensure instrument verification studies for reportable range were performed for 7 of 7 Reichert Protein Refractometers 5. In an email sent 05/27/2021 at 10:49am, the assistant quality manager provided the following information: "As listed in CPU-SOP-000170311, Medical Reception, the Reichert Refractometer range is 0.0 to 15.1 g/100ml. CSL uses the highest level of control available on the market to test the device and due to it being at the 10.0 g/100 ml our reportable range is set at 0.0 to 10.0 g/100ml. If results are greater than 10.0, the donor is advised that the result is greater than 10.0 and they are deferred for the day as the acceptable range for plasma donation is 6.0 to 9.0g/100ml Therefore the control values used are testing across our reportable range of the device. I hope this better explains and shows the reportable range question." Further review of the Reichert Protein Refractometer verification studies revealed the laboratory failed to provide data to support a low value of "0 g/100mL" for 7 of the 7 refractometers (Serial Numbers 07132-0514; 07133-0514; 10842-0617; 07129-0514; 07134-0514; 07135-0514; and 07128-0514) and the laboratory failed to provide data to support a high value of "10 g/100mL" for 2 of 7 refractometers (Serial Numbers 07133-0514 and 07135-0514). This confirmed the above findings.