

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2175677	(X3) Date Survey Completed 09/21/2021
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 3440 Bell St Ste 206, Amarillo, 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
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 review of the laboratory's validation records, CMS 116 application form, and confirmed in an interview the laboratory failed to verify the lowest value of the laboratory reportable range for total protein on 6 of 6 Reichert TS Meter-DSP refractometers. The findings were: 1. Review of the the procedure titled "Validation for the Installation or Reinstallation of the Refractometer (CPU-FORM-000167252)" revealed under Reportable Range, "The reportable range for Total Protein is 0.0 g /100ml to 10.0 g/100 ml (0.0g/dL to 10.0g/dL)." 2. Review of the validation records revealed three KOVA Refractrol materials were used for reportable range validation study. Custom 6.0 Lot# K303956 Exp: 2/28/22 Refractrol Normal Lot# K303960 Exp: 4/30/22 Refractrol High Lot# K303251 Exp: 8/31/21 3. Review of the validation records revealed the three Refractrol materials ranges provided by the manufacturer were: Custom 6.0 Lot# K303956 Range: 6.0 +/- 0.4 g/dL (5.6 g/dL-6.4 g/dL). Refractrol Normal Lot# K303960 Range: 7.6 +/- 0.4 g/dL (7.2 g/dL-8.0 g/dL). Refractrol High Lot# K303251 Range: 10.4 +/- 0.4 g/dL (10.0 g/dL-10.8 g/dL). 3. Review of the validation records revealed the lowest value the laboratory verified for six of six Reichert TS Meter-DSP refractometers were: SN#: 13042-0819 The lowest value verified was: 6.0 g/dL SN#: 13317-0919 The lowest value verified was: 5.9 g /dL SN#: 13313-0919 The lowest value verified was: 6.1 g/dL SN#: 13315-0919 The</p>

lowest value verified was: 6.0 g/dL SN#: 13314-0919 The lowest value verified was: 6.1 g/dL SN#: 13306-0919 The lowest value verified was: 6.0 g/dL 4. Review the CMS 116 application form signed by the LD on 09/17/2021 revealed the annual volume was 30,000 for total protein testing. 5. An interview with the center manager on 9/21/21 at 3:45 pm in the conference room confirmed the laboratory failed to verify the TS meters could accurately detect values less than the 6.0 g/dL value used for defERENCE of donors. Key: CMS=Center of Medicare and Medicaid Service LD=Laboratory Director