Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2206043	02/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Csl Plasma, Inc - Temple 521	2603 Thornton Ln Suite 120, Temple, 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	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 review of the Reichert Technologies Quick reference guide, validation procedures, laboratory's verification studies performed on its six Reichert refractometers, and staff interview, it was revealed the laboratory failed to have documentation of verifying the reportable range for total protein was comparable to the ranges established by the manufacturer for five of six refractometers. The findings included: 1. Review of the Reichert Technologies quick reference guide found on page 2 under the heading Results- " The meter's range is 0.0 to 15.1 g/100 mL plasma protein." 2. Review of laboratory procedure titled Validation for the Installation or Reinstallation of the Refractometer (effective 01-Jul-20 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 precision .... 8. 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." 1. A review of the laboratory's verification studies performed on the Reichert refractometers in December 2021 revealed the facility

	failed to have documentation of verifying the reportable range for total protein met the manufacturer's specifications of 0.0 to 15.1 g/dl for five of six refractometers in use. Serial Number 14496-1020 - verified values 6.1 g/dl to 10.3 g/dl on 12/17/2020 Serial Number 14500-1020 - verified values 6.1 g/dl to 10.4 g/dl on 12/17/2020 Serial Number 14499-1020 - verified values 6.0 g/dl to 10.4 g/dl on 12/17/2020 Serial Number 14497-1020 - verified values 6.0 g/dl to 10.3 g/dl on 12/17/2020 Serial Number 14494-1020 - verified values 6.1 g/dl to 10.5 g/dl on 12/17/2020 Serial Number 14501-1020 - verified values -0.1 g/dl to 10.3 g/dl on 11/3/2021 4. 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". 5. Interview with the Assistant Manager of Quality conducted February 16, 2022 at 10:43 AM in the conference room confirmed the laboratory did not verify the manufacturer's reference ranges below 6.0 g/dl or above 10.5 g/dl on the five refractometers verified in December 2020 prior to using them for specimen testing.