Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2093240	02/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Csl Plasma, Inc - Northglenn	11874 Washington St, Northglenn, CO	

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
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of the procedure manual, test records, and staff interview, the laboratory failed in 2017 and 2018 to twice a year evaluate and define the relationship among all digital refractometers which are used to test total protein levels in plasma specimens. Findings include: a. The laboratory currently has eight digital refractometers in use to perform plasma total protein determinations before clients donate plasma. b. The procedure titled, "Six Month Refractometer Comparison" states, "The 6-month linearity should be completed on the same day the Lab Director /Technical Consultant will perform the 6-month comparison." c. The same procedure states, "Compare the mid-range control results from the six-month linearity completed that day. The results across all refractometers are to be within +/- 0.4g/100mL from the control reference value." d. Log sheets titled, "Performed Calibrations" completed on 4-3-17, 9-30-17, 3-27-18, and 9-23-18, listed the results of testing the mid-range control on each of the eight refractometers but the control reference value was not indicated on the log sheet nor defined in the test procedure. e. The same procedure states, "Select PASS if all mid-range refractometer controls that were reviewed are within the defined range. If any refractometers were out of tolerance, select PASS if they have been removed from service. If one or more results are not within acceptable limits, record PASS for Six Month Comparison as complete." f. The log sheet titled, "Performed Calibrations" completed on 4-3-17, 9-30-17, 3-27-18, and 9-23-18, indicated "PASS" for the test results obtained from the QC material on each of the

	refractometers, and indicated "PASS" for each of the 6-month refractometer comparisons performed by the laboratory director. g. Staff stated that "PASS" meant that the result of testing the mid-range control was within the defined range of the control material. h. Staff stated that "PASS" meant that the comparison of the refractometers performed by the laboratory director had been completed and was determined to be acceptable. i. No evidence existed to show the mid-range control material tested on 4-3-17, 9-30-17, 3-27-18, and 9-23-18 had been evaluated to define the relationship between the test results obtained on all the refractometers as required by federal CLIA regulation.