Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D2133040	02/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Csl Plasma, Inc	2200 N Yarbrough Dr, Suite K, El Paso, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview, the laboratory failed to retain QC package inserts for the Kova Refractol-SP Serum Protein Reference Control (used to verify the accuracy of results on the Reichert refractometers) for a minimum of two years. Findings follow. Review of quality control records found the lab failed to retain Kova Refractol-SP Serum Protein Reference Control assay sheets for all lots used for a minimum of 2 years. No assay sheets for lots used prior to 06/10 /2019 were available for review . QC package inserts for lot numbers in use prior to 6 /10/2019 on 02/23/2021 were requested at 0940 hours but were not provided. Interview with the technical consultant on February 23, 2021 at 0940 hours in the conference room acknowledged they hold records for 2 years, but did not have QC package inserts prior to 06/10/2019, that the QC package inserts in the binder were all they had.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by:

	Review of personnel delegation of duties, personnel files and interview of facility personnel found that the laboratory did not have a procedure for assessing the competency of the technical consultant. The findings included: 1. Review of the Technical Consultant Qualification and Responsibilities Signed by the laboratory director 05/18/2020, and the Technical consultant on 05/21/2020) found the laboratory director had delegated the following duties to the Technical Consultant: Ensure test methodology have the capability of providing quality results. Review test and control data to ensure verification procedures are adequate to determine accuracy, precision and performance including the establishment and review of the center's normal reference interval. Observe laboratory personnel to ensure test methods are performed as required for accurate and reliable results. Sign the attestation statement on the Proficiency Testing reporting form; monitor the completion and results of proficiency testing. Ensure quality control programs are established, maintained and identify failures as they occur. Ensure adequate analytical performance for the test system by reviewing the Quarterly Control Procedures Report. Ensure all necessary corrective actions are taken and documented when significant deviations occur. Ensure an approved procedure is available for any aspects of the testing process. Resolve technical problems and ensure corrective action is taken for deviations and the test system is functioning properly prior to reporting test results. Ensure, prior to testing, all personnel have the appropriate education, experience and training and have demonstrated they can perform testing operations reliably. Identify training needs and assure training is appropriate for the testing performed. Evaluate the competency of testing personnel initially at 6 months, 12 months and annually thereafter or when the test methodology or instrumentation changes. Approve testing personnel to perform regulated tests independently. 2. Review of personnel files found no assessment of competency for the technical consultant in her current role. The laboratory provided a competency assessment (testing personnel) dated February 4, 2019, with no additional records for review. 3. Interview of the Quality training specialist conducted February 23, 2021 at 10:48 AM confirmed there was no competency assessment performed for the Technical consultant after assuming this role in May 2020.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on review of calibration verification records and interview, the laboratory failed to perform an evaluation of the calibration verification results to determine whether the Reichert refractometers were linear and met acceptable criteria. Findings follow.
1. Review of 48 of 48 calibration verifications of the refractometers, as listed by date and refractometer equipment number did not show whether the refractometers were linear throughout the reportable range: a. 09/29/2020: 1970001, 1970002, 1970003, 1970004, 1970005, 1970006, 1970008, 1970009, 1970088; b. 08/30/2020: 1970007; c. 08/17/2020: 1970009; d. 06/29/2020: 1970002; e. 04/02/2020: 1970001, 1970003, 1970004, 1970005, 1970006, 1970007, 1970008, 1970088; f. 03/22/2020: 1970007; g. 03/16/2020: 1970088; h. 12/04/2019: 1970009; i. 10/30/2019: 1970001, 1970002, 1970003, 1970004, 1970005, 1970006, 1970008, 1970009; j. 09/24/2019: 1970007; k. 09/18/2019: 1970088; l. 06/25/2019: 1970088; m. 06/02/2019: 1970088; n. 05/03 /2019: 1970001, 1970002, 1970003, 1970004, 1970005, 1970006, 1970007, 1970008, 1970009; o. 04/16/2019: 1970004, 1970005, 1970006; p. 04/06/2019: 1970007. 2. Review of calibration verification activities performed 09/29/2020 showed the laboratory used distilled water and Kova Refractol-SP Serum Protein Reference Controls: Distilled water (0/0 +/- 0.1), Normal Control, acceptable range 7.2 - 8.0 g /dL, and High Control, acceptable range 10.1 - 10.9. The following refractometers were tested by equipment number with the results of the Distilled water (0.0 +/- 0.1) Normal (N) and High (H) Controls in g/dL testing each control once and verifying they were within the reference control range: a. 1970001: DI H2O 0, N 7.6, H 10.4 b. 1970002: DI H2O -0.1, N 7.5, H 10.2 c.1970003: DI H2O -0.1, N 7.6, H 10.4 d. 1970004: DI H2O -0.1, N 7.7, H 10.2 e. 1970005: DI H2O 0, N 7.6, H 10.3 f. 1970006: DI H2O -0.1, N 7.5, H 10.2 g. 1970008: DI H2O 0, N 7.6, H 10.5 h. 1970009: DI H2O -0.1, N 7.8, H 10.6 i. 1970088: DI H2O 0, N 7.6, H 10.3 3. Surveyor observed on 02/23/2021 at 1100 hours for 48 of 48 calibration verification records, there was no evaluation of the calibration verification data to ensure the refractometers were linear throughout the reportable range of the test system. 4. Evaluation of the data was requested on 02/23/2021 at 1100 hours in the conference room. Other reports were provided, but none showed an evaluation of the calibration verification data. 5. Interview with the technical consultant on February 23, 2021 at 1200 hours in the conference room confirmed there was no evaluation of the data and that report had been discontinued in July of 2019 and replaced with the Refractometer CLIA TP Test System Performance report.