Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2187812	02/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Csl Plasma, Inc	5957 E Virginia Beach Blvd Suite 1, Norfolk, VA	

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 announced CLIA recertification survey was conducted at CSL Plasma, Inc. (Norfolk) on February 8, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
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 a review of procedures, calibration verification records, lack of

	documentation, and interviews, the facility failed to document a six (6) month Total Protein (TP) calibration verification protocol for one (1) of six (6) Reichert refractometer point of care analyzers in calendar year 2022. Findings include: 1. Review of the facility's laboratory procedures revealed a Digital Refractometer policy (#CPU-WI-000167212) that outlined a TP calibration verification "requirement at least once every six months to include three levels (Refract S1 Distilled Water Zero, Refract S2 Mid-Range Control, Refract S3 High Range Control)". 2. Review of the facility's 2022 TP calibration verification records revealed the following 6 Reichert refractometer analyzers' (Equipment Numbers: 5130001, 5130002, 5130003, 5130004, 5130005, 5130006) calibration verification documents on the following dates: 5130001- 1/17/22, 7/16/22; 5130002- 1/17/22, 7/16/22; 5130003- 1/17/22, 7/16 /22; 5130004- 1/17/22, 7/16/22; 5130005- 1/17/22; 5130006- 1/17/22, 7/16/22. Reichert refractometer Equipment # 5130005 lacked a 6 month calibration verification assayed with a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range on 7/16/22. The inspector requested to review documentation of TP calibration verification utilizing Refract S1-S3 for Reichert Equipment # 5130005 performed on 7/16/22 -7/17/22. The Assistant Quality Assurance (QA) Manger stated on 2/08/23 at approximately 10:30 AM, "An employee missed doing the three level calibration verification on that meter on the due date in July 2022." 3. An exit interview with the Center Manager and Assistant QA Manager on 2/08/23 at approximately 11:30 AM confirmed the above findings.