DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	8/4/2025-8/7/2025
	FEI NUMBER 3012267107

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Steven L. Potter, Center Manager	
FIRM NAME CSL Plasma Inc.	STREET ADDRESS 2650 North Ave
CITY, STATE, ZIP CODE, COUNTRY Grand Junction, CO 81501-6405	TYPE ESTABLISHMENT INSPECTED Plasma Center

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Failure to maintain records of transfusion reaction reports and complaints, including investigation and follow up.

Specifically, your firm's field marketing team failed to address a public complaint that related to a significant infiltration that occurred due to a donation. This individual was confirmed to have donated under Donor Number (b) (4), (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C) The complaint was absent from your complaint computer system and their was no evidence of an investigation being performed or a justification as to why one was not performed. As stated in your standard operating procedure 'Donor Inquiry and Donor Complaint Policy' Version 3.0 March 2024, "Information is sent to the (b) (4) (b) (4) to investigate".

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Conor J Mccarron, Investigator	X Conor J Mccarron Investigator Signed By: 2004153102 Date Signed: 08-07-2025 08:37:59	8/7/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."