DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	2/20/2025-2/26/2025* FEI NUMBER 2177738

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Holt A. Peterson, Associate Director of Operations

FIRM NAME	STREET ADDRESS
Csl Plasma, Inc.	304 E Lake St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Minneapolis, MN 55408-2453	Plasmapheresis 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

Equipment used in the collection of blood and blood components is not standardized and calibrated on a regularly scheduled basis as prescribed in the SOP Manual.

Specifically, your written screening and donor physical procedures are inadequate in that they do not follow the requirements in the user manual of (b) (4) automated vital sign machine you use to measure a donor's vital signs before donation. For example:

1. the user manual that states to place the thermometer probe tip in the posterior sublingual space, but the relevant written procedures do not state this requirement. I observed in 5 of 10 donor screening observations that the employees placed the thermometer probe under the front of a donor's tongue, rather than in the posterior sublingual pocket as required by the user manual.

2. the user manual states to place the blood pressure cuff over bare skin, but the relevant written procedures do not state this requirement. I observed in 3 of 10 donor screening observations that the employees placed the blood pressure cuff over clothing during donor screening activities.

***DATES OF INSPECTION**
2/20/2025(Thu), 2/21/2025(Fri), 2/24/2025(Mon), 2/26/2025(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kellie L Thommes, Investigator X Kellie L Thommes Investigator Signed By: Kellie L. Thommes -S Date Signed: 02-26-2025 15:06:26	2/26/2025

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."