DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	4/6/2026-4/9/2026
	FEI NUMBER 3014026593

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Chad M Simeur, Plasma Logistics Center Director

FIRM NAME	STREET ADDRESS
CSL Plasma Inc.	3750 Perry Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Whitestown, IN 46075-8814	Source Plasma Storage and Distribution

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 submit a biological product deviation report within 45 days from the date you acquired information suggesting that a reportable event occurred.

Specifically,

You failed to submit a biological product deviation report (BPDR) for deviation QE-042876 when you discovered on (b) (4) that you inappropriately distributed (b) (4) units of (b) (4) source plasma that were (b) (4) for (b) (4) under shipment number (b) (4) on (b) (4) and shipment number (b) (4) on (b) (4)

OBSERVATION 2

Human blood or blood components which had a reactive screening test for a relevant transfusion-transmitted infection were, but the product labeling did not include the appropriate elements.

Specifically,

You failed to label (b) (4) units of (b) (4) source plasma as (b) (4) for (b) (4) and with the "BIOHAZARD" legend under shipment number (b) (4) distributed on (b) (4) and shipment number (b) (4) distributed on (b) (4)

See **OBSERVATION 1**.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lesley Mae P Lutao, Investigator	X Lesley Mae P Lutao Investigator Signed By: Lesley Mae P. Lutao - S Date Signed: 04-09-2026 09:20:21	4/9/2026

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OBSERVATION 3

Due to inadvertent temperature exposure Source Plasma was required to be relabeled as "Source Plasma Salvaged," however, the original label was not covered with a complete new label containing the appropriate information

Specifically,

You failed to label (b) (4) units of (b) (4) source plasma products as "Source Plasma Salvaged" when the products were inadvertently exposed to a storage temperature warmer than -20 °C and colder than +10 °C during deviation QE-035190 discovered on 03/14/2024.

These products were shipped for further manufacturing into (b) (4) products under shipment (b) (4) on (b) (4)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Lesley Mae P Lutao, Investigator

X Lesley Mae P Lutao
Investigator
Signed By: Lesley Mae P. Lutao - S
Date Signed: 04-09-2026 09:20:21

DATE ISSUED
4/9/2026

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."