DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	2/3/2026-2/6/2026 FEI NUMBER 3022099864

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael W. Solomon, Regional Director of Operations

FIRM NAME	STREET ADDRESS
CSL Plasma Inc	3501 Cedar St Space 7
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Philadelphia, PA 19134-4609	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

The phlebotomy site is not prepared by a method that gives maximum assurance of a sterile container of blood.

a) On 2/3/2026 phlebotomist (b) (6), (b) (7)(C) palpated the scrubbed area as (b) (6), (b) (7)(C) positioned the needle to perform the venipuncture on donor (b) (4), (b) (6), (b) (7)(C). Management stopped the procedure and instructed her to rescrub the site. Unit (b) (4), (b) (6), (b) (7)(C) was collected after arm preparation was completed successfully.

b) I observed phlebotomist (b) (6), (b) (7)(C) on 2/3/2026 perform the arm scrub around, but not touching, the apparent venipuncture site from donor (b) (4), (b) (6), (b) (7)(C)(b) (6), (b) (7)(C) Management intervened and instructed her to rescrub the site. After repeating the arm scrub, she performed the venipuncture at the site of the previous mark. Unit (b) (4), (b) (6), (b) (7)(C) was collected.

OBSERVATION 2

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

Specifically, 2 out of 27 Biological Product Deviation Reports (BPDR) submitted between January 2023 and February 2026 were reported over 45 days from discovery. Both BPDRs were reported with discrepant discovery dates that fell within 45 days of reporting.

a) According to Quality Event QE-070152, your Assistant Manager of Quality discovered on 12/28/2024 that unit (b) (4), (b) (6), (b) (7)(C) had been collected from an unsuitable donor (b) (6), (b) (7)(C). Lookback report I542-18600 was generated dated 12/31/2024. BPDR 891098 was submitted on 2/12/2025, 46 days after discovery. The report showed a discovery date of 12/31/2025.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Emily A Walters, Investigator	X Emily A Walters Investigator Signed By: EMILY A. WALTERS -S Date Signed: 02-06-2026 13:35:15	2/6/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	2/3/2026-2/6/2026 FEI NUMBER 3022099864

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael W. Solomon, Regional Director of Operations

FIRM NAME	STREET ADDRESS
CSL Plasma Inc	3501 Cedar St Space 7
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Philadelphia, PA 19134-4609	Plasmapheresis Center

b) According to Quality Event QE-098773, on 8/8/2025, your Senior Reception Technician discovered a donor who had succeeded in donating under the incorrect profile on previous occasions. Lookback report I542-27689 was generated dated 8/12/2025 and showed that (b) (4) units had been collected at this site and distributed, including unit (b) (4), (b) (6), (b) (7)(C). BPDR 902951 was submitted on 9/23/2025, 46 days after discovery. The report showed a discovery date of 8/13/2025.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Emily A Walters, Investigator	X Emily A Walters Investigator Signed By: EMILY A. WALTERS -S Date Signed: 02-06-2026 13:35:15	2/6/2026

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."