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	12/16/2024-12/20/2024
	FEI NUMBER 3007198422

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Chantelle R. Barker , Center Director

FIRM NAME	STREET ADDRESS
Octapharma Plasma, Inc.	115 Walnut St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Terre Haute, IN 47807-3441	Source 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 WE OBSERVED:

OBSERVATION 1

Failure to collect blood by aseptic methods in a sterile system.

Specifically,

On 12/17/2024, I observed a phlebotomist fail to prevent contamination during arm preparation on source plasma donor [redacted] with collection number [redacted]. After scrubbing the venipuncture site with [redacted] seconds and allowing the site to air dry for [redacted] seconds, I observed the phlebotomist touch the sterilized venipuncture site with [redacted] gloved hand to palpate the targeted vein. Unaware the venipuncture site was contaminated, the phlebotomist proceeded to take the phlebotomy set needle, and prepare to perform venipuncture. I immediately informed the Center Director of the imminent hazard prompting intervention.

X David A Moore
Investigator
Signed By: 2002807636
Date Signed: 12-20-2024 09:14:30

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	David A Moore, Investigator Lesley Mae P Lutao, Investigator X Lesley Mae P Lutao Investigator Signed By: Lesley Mae P. Lutao - S Date Signed: 12-20-2024 08:13:59	12/20/2024

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."