DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration Center for Biologics Evaluation and Research - Document Control Center 10903 New Hampshire Avenue, WO71 - G112 Silver Spring, MD 20993-0002 240-402-8360 Industry Information: www.fda.gov/oc/industry	February 02-03, 2026
	FEI NUMBER 3002721889

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Na'Kesha Green, Senior Manager, Field Quality

FIRM NAME	STREET ADDRESS
KEDPLASMA LLC	11601 E. Colonial Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Orlando, FL 32817	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 (I) (WE) OBSERVED:

Observation 1:
Failure to follow established procedures designed to ensure donor safety and program compliance.
Specifically:
a) When reviewing donor record for Donor ID (b) (6), (b) (7)(C), the donor's physical examination was not performed (b) (4) enrollment into the (b) (4), (b) (6), (b) (7)(C) immunization program. The donor's last physical examination was performed (b) (6), (b) (7)(C), during participation in the normal Source Plasma program. The donor was consented and received their first (b) (4), (b) (6), (b) (7)(C) immunization on (b) (6), (b) (7)(C) at which time the physical examination was overdue. (b) (4) immunizations followed on (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C), all without a current physical examination.

b) According to SOP 16.8, version 21, Anti-D/DeNovo Program with RBC Immunization, Table (b) (4) Step (b) (4) (Physical Exam), "The potential recipient must pass a physical exam by the Responsible Physician or Physician Substitute (b) (4) entering the program and (b) (4) while active." Despite a system prompt in (b) (4) stating "Check-In Fail; Physical is due now," the Physician Substitute bypassed this notification and failed to verify the completion of the required physical examination (b) (4) immunization.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Mona Amin Catherine J. McGraw Christi Ann Samella	Mona Amin, Consumer Safety Officer Catherine McGraw, Consumer Safety Officer Christi Ann Samella, Consumer Safety Officer	Mona Amin -S 02/03/2026

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 judgement, 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."