DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	2/24/2026-2/26/2026
	FEI NUMBER 3001238010

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark A. Thomas, Owner/Executive Director

FIRM NAME	STREET ADDRESS
Biograft Transplant Services Inc	11205 South Main Street Ste. 114
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77025-5602	TYPE ESTABLISHMENT INSPECTED Tissue Recovery Establishment

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

Environmental conditions were not monitored for microorganisms.

Specifically, your firm has not established or performed an environmental monitoring program for microorganisms in the dedicated recovery suite where HCT/Ps are recovered. You have not conducted viable air monitoring, non-viable particulate monitoring, surface monitoring of work areas, or personnel monitoring (e.g. contact plates or swabs). Additionally, your firm has not established written procedures defining monitoring locations, frequency, alert and action levels, or required corrective actions for out-of-limit results.

From 2022 to the present, you have recovered HCT/Ps from over (b) (4) donors in this recovery suite without performing environmental monitoring to evaluate the microbiological quality of the environment.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Mizanne E Lewis, Investigator

X Mizanne E Lewis
Investigator
Signed By: MIZANNE E. LEWIS - S
Date Signed: 02-26-2026
15:06:11

DATE ISSUED
2/26/2026

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."