DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	3/10/2026-3/17/2026*
	FEI NUMBER 3013157033

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Bradley B. Tennant, CEO

FIRM NAME	STREET ADDRESS
KLEB Inc	10160 Linn Station Rd
CITY, STATE, ZIP CODE, COUNTRY Louisville, KY 40223-3813	TYPE ESTABLISHMENT INSPECTED Human Tissue

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

Documentation of equipment maintenance, cleaning, sanitization, and calibration was not maintained.

Specifically,

Your firm has not calibrated the temperature probes for the clean room and supply room since they were put in use in August 27, 2021. The firm has processed approximately (b) (4) tissues per year in this clean room.

OBSERVATION 2

Donors were not determined to be ineligible that had risk factors or clinical evidence of communicable disease agents.

Specifically,

The hospital medical records available at your firm for donor (b) (6), (b) (7)(C) showed the donor was diagnosed with (b) (6), (b) (7)(C) as a discharge diagnosis. Your firm recovered tissues from this donor on (b) (6), (b) (7)(C), determined this donor eligible on 09/24/2025, and distributed these tissues for transplantation on (b) (6), (b) (7)(C).

*DATES OF INSPECTION

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer L Sheehan, Investigator	X Jennifer L Sheehan Investigator Signed By: Jennifer L. Sheehan - S Date Signed: 03-17-2026 08:40:11	3/17/2026

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3/10/2026(Tue), 3/12/2026(Thu), 3/17/2026(Tue)

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	Jennifer L Sheehan, Investigator X Jennifer L Sheehan Investigator Signed By: Jennifer L. Sheehan - S Date Signed: 03-17-2026 08:40:11	3/17/2026

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."