DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160	9/8/2025-9/12/2025
	FEI NUMBER 3007941017

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Emily R. Biloski, Quality Assurance and Regulatory Compliance Manager

FIRM NAME	STREET ADDRESS
Lake Superior Centre For Regenerative Medicine	290 Munro St, Suite 2000
CITY, STATE, ZIP CODE, COUNTRY Thunder Bay, P7A7T1	TYPE ESTABLISHMENT INSPECTED Tissue Processor

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

Processes with results which could not be fully verified by inspection and tests, were not validated and approved according to established procedures.

Specifically, your firm began (b) (4) human bone on 6/3/2020 in the manufacturing of frozen (b) (4) cortical shafts. This process has not been validated. Since 1/11/2021, (b) (4) grafts have been distributed for further manufacturing.

OBSERVATION 2

Procedures were not designed to prevent circumstances that increase the risk of communicable disease introduction, transmission and spread through the use of HCT/Ps.

Specifically,

a) Your standard operating procedures (SOP), (b) (4)*-10-006* (b) (4) *Decontamination ver. #10*, (b) (4)*-10-042 Laboratory* (b) (4) *Area* (b) (4) *Cleaning ver. #9*, and (b) (4)*-10-020* (b) (4) (b) (4) *Cleaning ver. 4* indicate that (b) (4) is used to disinfect the cleanrooms and equipment, the (b) (4), and the (b) (4) used for equipment cleaning. The manufacturer's instructions indicate that a (b) (4) is required for efficacy against a fungus; however, your SOPs require a (b) (4). On 9/9/2025 following the processing of frozen (b) (4) cortical shafts, graft IDs (b) (4), from donor (b) (4), (b) (5), (b) (7)(C), I observed that (b) (4) was wiped off of (b) (4).

Environmental monitoring swabs recovered fungi or yeast in the cleanrooms on (b) (4)

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: 09-12-2025 14:21:37	9/12/2025

(b) (4) and from the (b) (4).

b) Your firm lacks an SOP describing how to pass supplies into the cleanroom in such a way that does not increase the risk of introducing contamination. The (b) (4) of sterile supplies is not wiped or disinfected between receipt from the supplier and use in the cleanroom. During processing of frozen (b) (4) (b) (4) cortical shafts, graft IDs (b) (4), from donor (b) (4), (b) (6), (b) (7)(C) on 9/9/2025, I observed the (b) (4) technician toss a (b) (4) sterile (b) (4) directly on the (b) (4) before bringing it into the cleanroom. During processing of tissue from donor (b) (4), (b) (6), (b) (7)(C) and environmental swab collection on 9/10/2025, I observed staff place (b) (4) cleanroom supplies on the (b) (4) numerous times while they donned (b) (4) to cross the (b) (4).

OBSERVATION 3

Environmental controls do not provide for adequate cleaning and disinfecting of rooms and equipment to ensure aseptic processing.

Specifically, on 9/11/2025, I observed decontaminating cleanroom (b) (4) after processing tissue from donor (b) (4), (b) (6), (b) (7)(C). A technician crawled and laid on the floor to clean (b) (4) areas (b) (4). The floor had not yet been cleaned, and apparent tissue debris was visible on portions of the floor. (b) (6), (b) (7)(C) feet rested against an (b) (4) (b) (4), after it had been cleaned. After standing up, and without changing (b) (4), (b) (6), (b) (7) C touched the (b) (4) numerous times after they had been cleaned.

OBSERVATION 4

HCT/Ps were not processed in a way that does not increase the risk of introduction, transmission, or spread of communicable disease.

Specifically, I observed the following conditions on 9/9/2025 during the processing of frozen (b) (4) cortical shafts, graft IDs (b) (4), from donor (b) (4), (b) (6), (b) (7)(C) in cleanroom (b) (4):

a) I observed the (b) (4), a nonsterile technician supporting the sterile processing technicians, drop supplies on the floor, pick them up, and return them to the (b) (4) waiting to be used. The (b) (4)

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Emily R. Biloski, Quality Assurance and Regulatory Compliance Manager

FIRM NAME	STREET ADDRESS
Lake Superior Centre For Regenerative Medicine	290 Munro St, Suite 2000
CITY, STATE, ZIP CODE, COUNTRY Thunder Bay, P7A7T1	TYPE ESTABLISHMENT INSPECTED Tissue Processor

(b) (4) did not come into direct contact with the sterile processing technicians or sterile (b) (4).

b)I saw a (b) (4), placed in front of an (b) (4), where it was (b) (4) against the (b) (4). The (b) (4) remained in place until all donor tissue had been unwrapped and placed on a sterile (b) (4).

c)I observed a (b) (4) (b) (4), was placed in front of an (b) (4) during processing. It remained in place for the majority of processing.

d)I saw the (b) (4) on table (b) (4) the sterile processing (b) (4) against the (b) (4) where they (b) (4) the edge of the (b) (4) for the duration of processing.

OBSERVATION 5

Facilities were not maintained in a clean manner to prevent the introduction, transmission, or spread of communicable disease.

Specifically,

a) Your firm stores sterilized supplies used in the processing and packaging of aseptic tissue products, including (b) (4). On 9/11/2025, I observed an apparent dead insect on the floor of the (b) (4) within approximately 12 inches from these supplies.

b) On 9/11/2025, I observed a (b) (4) with a stain approximately (b) (4) located in the (b) (4) (b) (4). The stain was located (b) (4) where I observed processing staff don sterile (b) (4) (b) (4) for processing frozen (b) (4) cortical shafts, graft IDs (b) (4), for donor (b) (4), (b) (6), (b) (7)(C) on 9/9/2025 and donor (b) (4), (b) (6), (b) (7)(C) on 9/11/2025.

c) I observed a discolored area on the (b) (4) of cleanroom (b) (4). It appeared that

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Thunder Bay, P7A7T1	Tissue Processor

the (b) (4) had been worn through. During the processing of frozen (b) (4) (b) (4) cortical shafts, graft IDs (b) (4), from donor (b) (4), (b) (5), (b) (7)(C) on 9/9/2025, the (b) (4) was positioned in (b) (4).

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EMPLOYEE(S) SIGNATURE

Emily A Walters, Investigator

X Emily A Walters
Investigator
Signed By: EMILY A. WALTERS -S
Date Signed: 09-12-2025 14:21:37

DATE ISSUED

9/12/2025

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."