DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	4/8/2026-4/10/2026
	FEI NUMBER 3020650965

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David Harari M.D., Chief Medical Officer

FIRM NAME	STREET ADDRESS
Lucina Egg Bank	3661 Valley Centre Dr Ste 160
CITY, STATE, ZIP CODE, COUNTRY San Diego, CA 92130-3321	TYPE ESTABLISHMENT INSPECTED Human Reproductive Tissue 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

The summary of records for HCT/Ps did not contain a statement that the communicable disease testing was performed by a laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Act of 1988 or has met equivalent requirements determined by the Centers for Medicare and Medicaid Services.

Specifically,

(b) (4) of the (b) (4) donor records reviewed that were distributed from (b) (4) to (b) (4) revealed that your firm's Summary of Records sent to the recipient's clinic does not contain a statement that the communicable disease testing was performed by a laboratory that is certified to perform testing under the CLIA of 1988 or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services.

OBSERVATION 2

The summary of records for HCT/Ps did not contain the address of the establishment that made the donor-eligibility determination.

Specifically,

(b) (4) of the (b) (4) Donor Records reviewed that were distributed from (b) (4) to (b) (4) revealed that your firm's Summary of Records sent to the recipient's clinic does not contain the address of the establishment that

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Melsomar R Ramos, Investigator	X Melsomar R Ramos Investigator Signed By: MELSOMAR R. RAMOS -S Date Signed: 04-10-2026 10:05:09	4/10/2026

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made the donor eligibility determination.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Melsomar R Ramos, Investigator	X Melsomar R Ramos Investigator Signed By: MELSOMAR R. RAMOS -S Date Signed: 04-10-2026 10:05:09	DATE ISSUED 4/10/2026

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."