DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,

Ext.:

STABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10 FEI: 3020650965

Other FDA Registrations: Blood:

Devices: Drugs: Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/16/2024 Summary Report Print Date: 12/05/2024

Legal Name and Location:

Lucina Egg Bank

3661 Valley Centre Dr., Suite 160

California

San Diego, California 92130

USA

Phone: 858-436-7186

Reporting Official:

David Harari, CMO

3661 Valley Centre Dr., Suite 160 San Diego, California 92130

LISA

Phone: 858-436-7186 Ext.

dharari@fertile.com

Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

No

		Establishment Functions								1		
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte	Anonymous						Х	Х	Х			
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Dear Tissue Bank Director:

Attached below is your tissue bank license. Your license is void after the expiration date.

NOTE: applications for renewal of license must be filed with the department not less than 30 days prior to its expiration date and shall be accompanied by the annual renewal fee. (CA H&S Code §1639.2)

REPRODUCTIVE SCIENCES MEDICAL CENTER ATTN: KEVIN KIBOONG OUM, PHD 3661 VALLEY CENTRE DR. STE 100 SAN DIEGO, CA 92130



FORFEITURE OF LICENSE

A Tissue Bank license shall be forfeited by operation of law prior to its expiration date when one of the following occurs:

- (1) The tissue bank is sold or otherwise transferred.
- (2) The license is surrendered to the state department.

QUESTIONS AND INFORMATION:
If you have any questions, please write to: CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
Laboratory Field Services, Tissue Bank Section
850 Marina Bay Parkway, Building P, 1st Floor
Richmond, CA 94808-6403

Internet Address: www.cdph.ca.gov/LFS Thank you for your cooperation

STATE OF CALIFORNIA DEPARTMENT OF PUBLIC HEALTH TISSUE BANK LICENSE

In accordance with Division 2, Chapter 4.1, of the Health and Safety Code, the entity named below is hereby licensed to engage in the approved tissue bank operation(s) at the indicated facility address.

REPRODUCTIVE SCIENCES MEDICAL CENTER 3661 VALLEY CENTRE DR. STE 100 SAN DIEGO, CA 92130

ALIFORN

OWNER(S):

REPRODUCTIVE SCIENCES MEDICAL CENTER, INC DAVID HARARI MD

DIRECTOR:

KEVIN KIBOONG OUM PHD

TISSUE BANK ID Number: CTB 00080199

Issuance Date: December 19, 2024 Expiration Date: December 18, 2025

Charlet Archuleta, Acting Branch Chief Laboratory Field Services



CERTIFICATE OF ACCREDITATION

Reproductive Sciences Medical Center Laboratory San Diego, California Minh Ho, MD

CAP Number: 8470728

AU-ID: 1903827

CLIA Number: 05D0932860

The organization named above meets all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Reproductive Laboratory Accreditation Program. Reinspection should occur prior to **May 21, 2025** to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

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Kathleen G. Beavis, MD, Accreditation Committee Chair

Emily Volk, MD, FCAP, President, College of American Pathologists



CENTERS FOR MEDICARE & MEDICAID SERVICES CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS REPRODUCTIVE SCIENCES MEDICAL CENTER L 3661 VALLEY CENTRE DR STE 100 SAN DIEGO, CA 92130

CLIA ID NUMBER 05D0932860

EFFECTIVE DATE

04/04/2024

EXPIRATION DATE

04/03/2026

LABORATORY DIRECTOR

MINH HO M.D.

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



Monique Spruill, Director Division of Clinical Laboratory Improvement & Quality

Quality & Safety Oversight Group Center for Clinical Standards and Quality

certs2 030524

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)

EFFECTIVE DATE

DEPARTME

LAB CERTIFICATION (CODE) EFFECTIVE DATE

0010-028(613)

SEE VICEST 41H LIBERT BUILD BOOM LOS ANGELES. CA DODIS 2006

HEMATOLOGY (400)

03/20/2019





SHALL URATORY FIELD SERVICES

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER. PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.