

KATHY HOCHUL

Governor

JAMES V. McDONALD, M.D., M.P.H. Commissioner JOHANNE E. MORNE, M.S.

Acting Executive Deputy Commissioner

September 5, 2023

Michael J. Bauer, M.D., Medical Director Tissue Bank Director California Cryobank, LLC 369 Lexington Avenue, Suite 401 New York, NY 10017 Facility ID: 569

Dear Dr. Bauer:

We have determined that your plan of correction satisfactorily addresses the deficiencies identified during the most recent on-site survey of your tissue bank. Please find enclosed the license certificate for operation at the following location:

California Cryobank, LLC 369 Lexington Avenue, Suite 401 New York, NY 10017

The certificate is effective until the date indicated and replaces that issued April 19, 2023. The certificate must be posted conspicuously at the approved location. Your license is specific to this location; you must notify the Department of any changes in address.

You must submit a new application if you intend to expand your services or activities beyond those listed on this certificate. All tissue for clinical use must be procured, processed, stored, and distributed by tissue banks licensed by the Department for the relevant activities.

To remain in compliance with New York State regulations, you must also:

- Report any changes in director, medical director, and compliance officer within five days;
- Report any change in ownership of five percent or more within 30 days;
- Report any accidents in retrieval, testing, processing, storage, or distribution that may affect the safety of any product within seven calendar days of discovery.

Application forms and specifics of 10 NYCRR Part 52 and Subpart 58-5 regulations are available online at https://www.wadsworth.org/regulatory/tissue-resources. If you have any questions, please call (518) 485-5341, or e-mail tissue@health.ny.gov.

Sincerely,

Alan Ravin

Alan Ranin

Tissue Bank Consultant Tissue Resources Program

Enclosure

NEW YORK STATE DEPARTMENT OF HEALTH

LICENSE FOR TISSUE BANK OPERATION

Issued in accordance with and pursuant to section 4364 Public Health Law of New York State

Facility ID: 569

Tissue Bank Director:
Michael J. Bauer, M.D., FACP, CTBS

Medical Director:
Michael J. Bauer, M.D., FACP, CTBS

Owner: CooperSurgical, Inc.

California Cryobank, LLC 369 Lexington Avenue, Suite 401 New York, NY 10017

is hereby APPROVED as a Tissue Bank for the following categories of service:

Comprehensive Tissue Procurement Service
Tissue Processing Facility
Tissue Storage Facility

Semen from donors and client-depositors Semen from donors and client-depositors

Semen, oocytes, embryos, and testicular tissue collected and processed by tissue banks licensed by the Department in the requisite categories

Issued: September 5, 2023

Expires: October 1, 2025

Property of the New York State Department of Health. Valid only at the address shown. Must be conspicuously posted.

DOH-3908 (04/2001)