NEW YORK STATE DEPARTMENT OF HEALTH

PROVISIONAL LICENSE FOR TISSUE BANK OPERATION

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

Facility ID: 557

HPC Bank Director: Ayanna S. Bryan, PhD

Medical Director: Patricia A. Shi, MD, MS

Owner: New York Blood Center

CryoGene, Inc 12621 Silicon Drive, Suite 116 San Antonio, TX 78249

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

Tissue Storage Facility

Hematopoietic progenitor cells derived from umbilical cord blood on behalf of New York Blood Center

Issued: January 22, 2025

Expires: February 1, 2027

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

DOH-3908 (04/2001)



Governor

JAMES V. McDONALD, MD, MPH
Commissioner

JOHANNE E. MORNE, MS Executive Deputy Commissioner

January 22, 2025

Ayanna S. Bryan, PhD HPC Bank Director New York Blood Center 310 East 67th Street New York, NY 10065 Fac ID: 557

Dear Colleague,

Please find enclosed the provisional license certificate for hematopoietic progenitor cell bank operation at the following location:

CryoGene, Inc 12621 Silicon Drive, Suite 116 San Antonio, TX 78249

The certificate is effective until the date indicated, or the issuance of a full license following an onsite survey of your facility. The certificate, which has been amended to reflect the change in facility name and facility address, replaces that issued February 21, 2024. 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, specifics of 10 NYCRR Part 52 and Subpart 58-5 regulations, and updated policies are available online at wadsworth.org/regulatory/tissue-resources. If you have any questions, please call (518) 485-5341, or e-mail tissue@health.ny.gov.

Sincerely,

Diane Sullivan

Diane Sullivan, BS, MT Tissue Bank Consultant Tissue Resources Program

Enclosure