

ANDREW M. CUOMO Governor **HOWARD A. ZUCKER, M.D., J.D.**Commissioner

SALLY DRESLIN, M.S., R.N.Executive Deputy Commissioner

February 7, 2020

Michelle Ottey, Ph.D., HCLD Tissue Bank Director Fairfax Cryobank, Inc. – Fairfax 3015 Williams Drive, Suite 200 Fairfax, VA 22031

Re: Fac ID 16

Dear Dr. Ottey:

On January 28-29, 2020, Diane Sullivan of the Tissue Resources Program staff conducted an on-site survey of the tissue banking activities at the following location:

Fairfax Cryobank, Inc. – Fairfax 3015 Williams Drive, Suite 200 Fairfax, VA 22031

During this time, the physical facilities and records of procurement, processing and distribution of semen from anonymous donors and client-depositors were reviewed along with storage records of reproductive tissue. No deficiencies were identified, no plan of correction required. Fairfax Cryobank, Inc. – Fairfax is in full compliance with Department regulations.

The license is effective until March 1, 2022. The certificate replaces that issued December 6, 2019. The certificate must be posted conspicuously at the approved location.

In accordance with the provisions of Section 52-3.7(d), the Department may request a summary of the activities of your tissue bank. Please report, in writing, any changes in tissue bank director and/or medical director within five (5) days of the change. Also, report changes in direct or indirect ownership within thirty (30) days and keep the Department informed of any relocation of the facility.

Regulations applicable to tissue banks, including reproductive tissue banks, are available from this office and online at https://www.wadsworth.org/regulatory/tissue-resources. If you have any questions, please call (518) 485-5341, or e-mail to btraxess@health.ny.gov.

Sincerely,

Diane Sullivan

Tissue Bank Consultant Tissue Resources Program

me Sullivan

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

Tissue Bank ID No.: 16

Tissue Bank Director:

Michelle Ottey, Ph.D., HCLD

Laboratory Director

Medical Director:

Harvey J. Stern, M.D., Ph.D.

Fairfax Cryobank, Inc. - Fairfax

3015 Williams Drive, Suite 200

Fairfax, VA 22031

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, ovarian tissue, and testicular tissue from donors and client-depositors

Issued: February 7, 2020

Expires: March 1, 2022

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

Owner: Genetics & IVF Institute, Inc.

DOH-3908 (04/2001)