

**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

Tissue Bank ID No.: TS157

Director:
Mark L. Friedman, Ph.D.
VP of RA & QA

Medical Director:
Harrinarine Madhosingh, M.D.

Axogen Corporation - Distribution Facility
300 Boone Road, Suite A2 and A3
Burleson, TX 70628

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

Tissue Storage Facility

Nerve tissue

Issued: March 2, 2018

Owner: Axogen, Inc.

Expires: April 1, 2020

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

DOH-3908 (04/2011)

March 2, 2018

Mark L. Freidman, Ph.D.
VP of RA & QA
Director
Axogen Corporation - Distribution Facility
300 Boone Road, Suite A2 and A3
Burleson, TX 70628

Re: TS157

Dear Dr. Freidman:

Please find the enclosed provisional license certificate for tissue bank operation for the following location:

Axogen Corporation - Distribution Facility
300 Boone Road, Suite A2 and A3
Burleson, TX 70628

The provisional license is effective until either April 1, 2020 or the issuance of a full license following an on-site survey of your tissue bank, which will be undertaken to assess compliance with regulations 10NYCRR, Part 52. The certificate must be posted conspicuously at the approved location.

Please note that approval is limited to storage and distribution of nerve tissue that is recovered and processed by tissue banks licensed by the Department in the requisite categories. Please notify the Department at such time that you enter into tissue storage agreements with license processors so that we may verify appropriate New York State licensure.

In accordance with the provisions of 10 NYCRR 52-3.1(d), the Department will require an annual summary of the activities of your tissue bank. Information to be reported may include the numbers of tissue units stored and distributed. Note that the filing deadline (December 31, 2016) for submission of this report for calendar year 2015 has passed. In order to maintain your approval, please submit the required report within ten (10) days of receipt of this letter to Tissue Resources, NYSDOH – Wadsworth Center, Empire State Plaza, P.O. Box 509, Albany, NY 12201-0509.

Report changes in direct or indirect ownership of the facility within thirty (30) days of the change. Report changes in director within five (5) days and keep the Department informed of any relocation of facilities.

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

Sincerely,



Robert A. Jordan
Tissue Bank Consultant
Tissue Resources

Enclosures