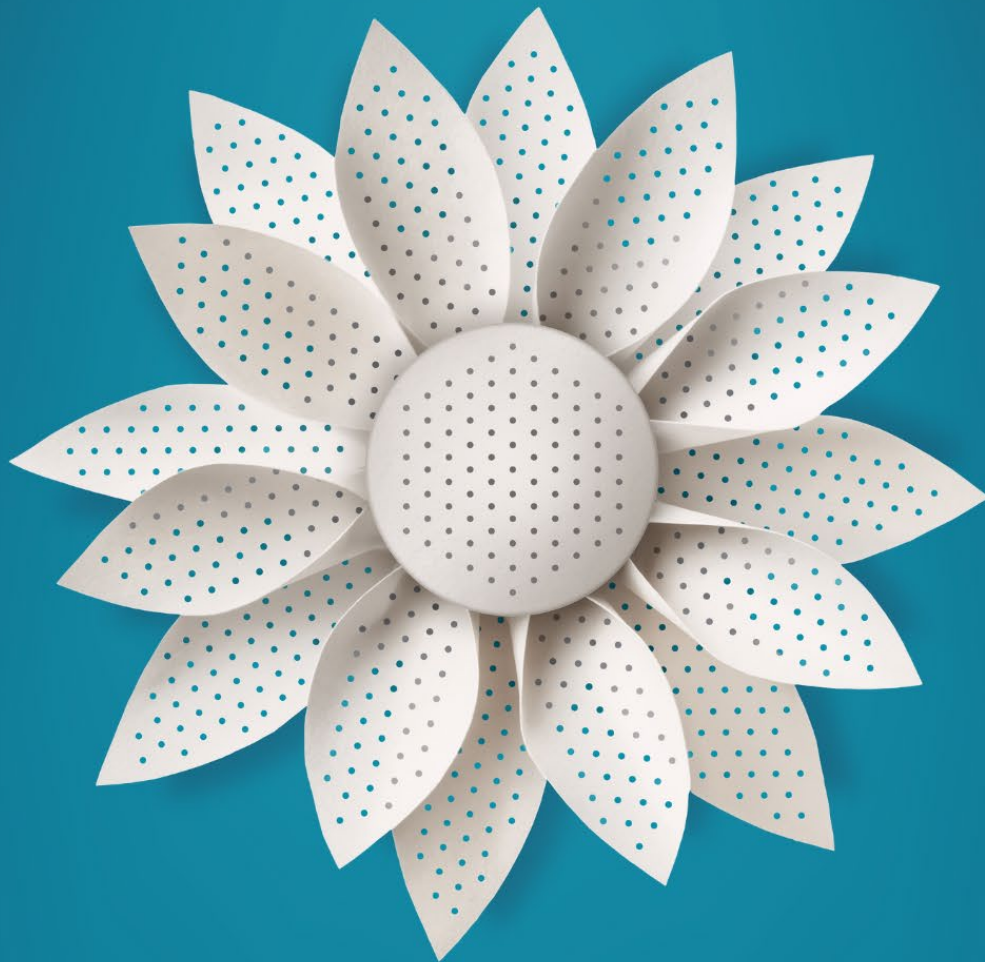


— PUREGRAFT —

ESSENCE

ACELLULAR DERMAL MATRIX | By BIMINI

TISSUE LICENSE PACKET



Certificate Table

Jurisdiction	Expiration Date
Bimini Health Tech	
Food and Drug Administraion	August 31, 2026
California	August 23, 2025
Delaware	April 30, 2026
Florida	January 24, 2026
Illinois	May 1, 2026
Maryland	Indefinite
New York	January 1, 2027
Oregon	August 3, 2026
J4 Biologics	
Food and Drug Administraion	August 31, 2026
AATB	October 17, 2027
California	See Bimini Health Tech
Delaware	Not registered
Florida	February 6, 2026
Illinois	May 1, 2026
Maryland	Indefinate
New York	December 1, 2026
Oregon	February 13, 2027
Qualtex Laboratories	
Food and Drug Administraion	August 31, 2026
CLIA Certificate of Accreditaion	July 26, 2025
Allosource	
Food and Drug Administraion	August 31, 2026
AATB	February 22, 2027
California	April 28, 2026
Delaware	April 30, 2026
Florida	November 17, 2026
Illinois	May 1, 2026
Maryland	Indefinate
New York	October 1, 2025
Oregon	September 26, 2026

Tissue Licenses and registration
for:

Bimini Health Tech
(Distributor)

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10	FEI: 3022978896	Other FDA Registrations: Blood: Devices: FEI: 3022978896 Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/16/2023 Summary Report Print Date: 12/01/2023
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Legal Name and Location: Bimini Health Tech 8400 Belleview Drive, Suite 125 Plano, Texas 75024 USA Phone: 858-386-4140 Ext.:	Reporting Official: Trevor J Denbo, VP, QA/RA 8400 Belleview Drive Suite 125 Plano, Texas 75024 USA Phone: 858-386-4140 Ext. tdenbo@BiminiHealthTech.com	Satellite Recovery Establishment: No 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)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
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												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin							X		X			Puregraft Essence
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)

BIMINI HEALTH TECH
ATTN: TREVOR DENBO
8400 BELLEVIEW DR STE 125
PLANO, TX 75024

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.

BIMINI HEALTH TECH
8400 BELLEVIEW DR STE 125
PLANO, TX 75024

OWNER(S):

JAMES F. CONLAN TRUST
OLD WILLOW PARTNERS, LLC
NYHAN FAMILY LLC

DIRECTOR:

BRADFORD CONLAN

TISSUE BANK ID Number: CTB 00082381

Issuance Date: August 24, 2024

Expiration Date: August 23, 2025

Charlet Archuleta, Acting Branch Chief
Laboratory Field Services



**DELAWARE HEALTH
AND SOCIAL SERVICES**

DIVISION OF PUBLIC HEALTH

June 10, 2025

Frankie Ng
Bimini Health Tech
8400 Belleview Drive, Suite 125, Plano, TX 75024, U.S.A.

Dear Frankie Ng,

This letter confirms that **Bimini Health Tech** is registered with the Delaware Tissue Bank until April 30, 2026.

Thank you for notifying the Bureau of Communicable Diseases office in a timely manner of any changes to the information contained in the registration form. Please continue to keep contact information current to ensure timely delivery of updates and notifications.

If you have any questions, please contact me at the number below or via my e-mail.

Best regards,

Susanna Murray

Investigator I

Delaware Department of Health and Social Services

Division of Public Health

Thomas Collins Building | 540 S. DuPont Highway, Dover, DE 19901

Office: 302-744-1024 | Cell: 302-270-0875

Susanna.Murray@delaware.gov

View current license information at: [Floridahealthfinder.gov](https://floridahealthfinder.gov)

LICENSE #: 403
CERTIFICATE #: 2115

State of Florida
AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH CARE POLICY AND OVERSIGHT

Tissue Bank
Licensed

This is to confirm that BIMNI TECHNOLOGIES LLC dba BIMINI HEALTH TECH has complied with the rules and regulations adopted by the State of Florida, Agency for Health Care Administration, and authorized in Chapter 765, Florida Statutes, and is authorized to operate the following:

BIMINI HEALTH TECH
8400 Belleview Drive
Plano, TX 75024

Authorized Services: distribute tissues

EFFECTIVE DATE: 01/25/2024

EXPIRATION DATE: 01/24/2026



A handwritten signature in black ink, appearing to be "JW", written over a horizontal line.

Jason Weida, Secretary



525-535 West Jefferson Street • Springfield, Illinois 62761-0001 • www.dph.illinois.gov

Effective Date: **May 1, 2025**

Expires: **May 01, 2026**

Bradford Conlan, Facility Director
Bimini Health Tech
8400 Belleview Dr
Plano, TX 75024

Registration Number 2023

State of Illinois
2024
Sperm/Tissue Bank Registration
Bimini Health Tech

Dear Director:

We are in receipt of your **Registration** with the State of Illinois. We welcome your cooperation to observe our State laws and you may use this document as proof of registration as required by *Title 77 Public Health Chapter I: Department of Public Health Subchapter D: Laboratories and Blood Bank Part 470 Sperm Bank and Tissue Bank Code Section 470.30 Registration Requirements.*

Sincerely,



Brandon Rakowski
*Tissue & Sperm Bank
Program Administrator
Illinois Department of Public Health
Health Care Facilities and Programs
Laboratory Regulations*

Annual registration deadline is May 1, and renewal reminders are e-mailed on February of each year.

PROTECTING HEALTH, IMPROVING LIVES



MARYLAND
DEPARTMENT OF HEALTH
OFFICE OF HEALTH CARE QUALITY

LABORATORIES AND TISSUE BANKS
7120 SAMUEL MORSE DRIVE FL 2
COLUMBIA, MARYLAND 21046-3422

TISSUE BANK PERMIT
NON - EXPIRING

NUMBER: TB3684 EFFECTIVE DATE: 06/21/2023

*Pursuant to the provisions of TITLE 17, subtitle 3, Health-General Article § 17-301 et seq.,
Annotated Code of Maryland, this permit is issued to:*

BIMINI HEALTH TECH
8400 BELLEVIEW DRIVE
PLANO, TX 75024

Director: Dr MICHAEL BAUER
Owner: OLD WILLOW PARTNERS, LLC

For operating, representing or servicing the following Tissue Bank Classes:

Skin Bank:
Skin

CONTROL: 83755

Patricia Tomasko May MD
Director

Falsification of a license shall subject the perpetrator to criminal prosecution and the imposition of civil fines.

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: 2997

Director:

**Bradford Conlan
CEO**

Medical Director:

Michael J. Bauer, MD, FACP, CTBS

Bimini Health Tech

8400 Belleview Drive, Suite 125

Plano, TX 75024

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

Tissue Storage Facility

Skin tissue

Issued: December 5, 2024

Owner: Bimini Technologies, LLC

Expires: January 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)



Health Care Regulation and Quality Improvement

800 NE Oregon Street, Suite 465

Portland, Oregon 97232

971-673-0540

971-673-0556 (Fax)

mailbox.inhomecare@odhsoha.oregon.gov

August 8, 2023

Bradford Conlan
Bimini Health Tech
8400 Belleview Drive, Suite 125
Plano, TX 75024

Dear Mr. Conlan:

This letter is to notify you that Bimini Health Tech has been placed on the Oregon Procurement Organizations/Tissue Bank Registry. This registration is in effect for three years ending on August 3, 2026.

Thank you for your cooperation. Should you have any questions, please contact our office at the above phone number or email address.

Sincerely,

A handwritten signature in cursive script, appearing to read "Maria Greene".

Oregon Procurement Organizations/Tissue Bank Registry Staff
Oregon Health Authority
Public Health Division
Health Care Regulation and Quality Improvement

If you need this information in an alternate format, please call our office at (971) 673-0540 or TTY 711

Tissue Licenses and registration
for:

J4 Biologics
(Tissue Processor)

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10	FEI: 3025971176	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/31/2023 Summary Report Print Date: 01/05/2024
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Legal Name and Location: J4 Biologics, LLC 4848 Research Drive San Antonio, Texas 78240 USA Phone: 210-701-7802 Ext.:	Reporting Official: Irma Valdez, Quality Assurance Manager 4848 Research Drive San Antonio, Texas 78240 USA Phone: 210-701-7802 Ext. valdezi@j4biologics.com	Satellite Recovery Establishment: No 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)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane			X		X	X	X	X	X			EvoPatch
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin			X		X	X	X	X	X			***See full text on next page.
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s):	Skin	Puregraft Essence Acellular Dermal Matrix
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FEl:3025971176

Legal Name:J4 Biologics, LLC

American Association of Tissue Banks

Herewith certifies
that the Institution named here

J4 Biologics, LLC

San Antonio, Texas

has met the Association's accreditation requirements
and is hereby accredited for

Deceased Donor	Authorization	Donor Screening	Recovery	Processing or Preparation	Donor Eligibility Determination	Storage	Distribution
Cardiac Tissue							
Cellular Tissue							
Musculoskeletal Tissue							
Skin				✓	✓	✓	✓
Vascular Tissue							
Non-Transplant Anatomical (NAM or NTAD)							
Living Donor	Informed Consent	Donor Screening	Recovery or Acquisition	Processing	Donor Eligibility Determination	Storage	Distribution
Autologous Tissue							
Birth Tissue				✓	✓	✓	✓
Reproductive Tissue							
Surgical bone							

In witness whereof the undersigned officers, being duly authorized, have caused this Certificate to be issued and the Corporate Seal of this Association to be affixed hereon this the 17th day of October 2024



Chair, Board of Governors

Expiration Date: October 17, 2027

Accreditation #: 00366





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)

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.

J4 BIOLOGICS,LLC

4848 RESEARCH DRIVE
SAN ANTONIO, TX 78240

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 PROVISIONAL 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.

**J4 BIOLOGICS,LLC
4848 RESEARCH DRIVE
SAN ANTONIO, TX 78240**

OWNER(S):

JAMES R GLICK, JR & JAMES W POSER
KERRY M MORRISON & MICHAEL J CRESCENZO

DIRECTOR:

JAMES R. GLICK, JR.

TISSUE BANK ID Number: CTP 00082471

Issuance Date: March 21, 2025

Expiration Date: March 20, 2026

Charlet Archuleta, Acting Branch Chief
Laboratory Field Services

View current license information at: [Floridahealthfinder.gov](https://floridahealthfinder.gov)

LICENSE #: 405
CERTIFICATE #: 2119

State of Florida
AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH CARE POLICY AND OVERSIGHT

Tissue Bank
Licensed

This is to confirm that J4 Biologics, LLC has complied with the rules and regulations adopted by the State of Florida, Agency for Health Care Administration, and authorized in Chapter 765, Florida Statutes, and is authorized to operate the following:

J4 BIOLOGICS LLC
4848 Research Dr
San Antonio, TX 78240

Authorized Services: Distribution of tissues

EFFECTIVE DATE: 01/31/2024

EXPIRATION DATE: 02/06/2026



A stylized, handwritten signature of Jason Weida.

Jason Weida, Secretary



525-535 West Jefferson Street • Springfield, Illinois 62761-0001 • www.dph.illinois.gov

Effective Date: **May 1, 2025**

Expires: **May 01, 2026**

James Glick Jr, Facility Director
J4 Biologics, LLC
4848 Research Dr
San Antonio, TX 78240

Registration Number 2623

State of Illinois
2024
Sperm/Tissue Bank Registration
J4 Biologics, LLC

Dear Director:

We are in receipt of your **Registration** with the State of Illinois. We welcome your cooperation to observe our State laws and you may use this document as proof of registration as required by *Title 77 Public Health Chapter I: Department of Public Health Subchapter D: Laboratories and Blood Bank Part 470 Sperm Bank and Tissue Bank Code Section 470.30 Registration Requirements.*

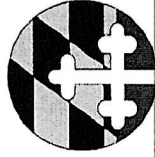
Sincerely,



Brandon Rakowski
Tissue & Sperm Bank
Program Administrator
Illinois Department of Public Health
Health Care Facilities and Programs
Laboratory Regulations

Annual registration deadline is May 1, and renewal reminders are e-mailed on February of each year.

PROTECTING HEALTH, IMPROVING LIVES



MARYLAND DEPARTMENT OF HEALTH
Office of Health Care Quality

7120 Samuel Morse Drive, Second Floor, Columbia, MD 21046

NON-EXPIRING TISSUE BANK PERMIT

Type of Provider: Clinical Laboratory

License Number: TB4026

Effective Date: 05/16/2025

**Issued to: J4 BIOLOGICS LLC
4848 RESEARCH DRIVE
SAN ANTONIO, TX 78240**

Laboratory Director: Dr MATTHEW WINDROW

Owner of Laboratory: J. POSER, J. GLICK, JR, K. MORRISON

For operating, representing or servicing the following Tissue Bank Classes:

Reproductive Tissue Bank:

Reproductive Tissue

Skin Bank:

Skin

This license is issued by the Maryland Department of Health in accordance with the applicable provisions of Maryland Code Ann., Health General Article and its rules and regulations. This license is not transferable.

Tia Witherspoon-Udocox, MBA
Executive Director
Office of Health Care Quality
Maryland Department of Health

Falsification of a license shall subject the perpetrator to criminal prosecution and the imposition of civil fines.

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: 3129

Tissue Bank Director:
James W. Poser, PhD

Medical Director:
Matthew John Windrow, MD

J4 Biologics, LLC
4848 Research Drive
San Antonio, TX 78240

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

Comprehensive Tissue Procurement Service

Skin tissue
Amniotic membrane

Tissue Processing Facility

Skin tissue
Amniotic membrane

Issued: November 22, 2024

Owner: J4 Biologics, LLC

Expires: December 1, 2026

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

DOH-3908 (04/2001)



Health Care Regulation and Quality Improvement
800 NE Oregon Street, Suite 465
Portland, Oregon 97232
971-673-0540
971-673-0556 (Fax)
mailbox.inhomecare@odhsoha.oregon.gov

February 14, 2024

Irma Valdez
J4 Biologics
4848 Research Drive
San Antonio, TX 78240

Dear Irma Valdez:

This letter is to notify you that J4 Biologics has been placed on the Oregon Procurement Organizations/Tissue Bank Registry. This registration is in effect for three years ending on February 13, 2027.

Thank you for your cooperation. Should you have any questions, please contact our office at the above phone number or email address.

Sincerely,

Oregon Procurement Organizations/Tissue Bank Registry Staff
Oregon Health Authority
Public Health Division
Health Care Regulation and Quality Improvement

If you need this information in an alternate format, please call our office at (971) 673-0540 or TTY 711

Tissue registration and CLIA
Certificate of Accreditation for:

Qualtex Laboratories
(Test Lab)

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10	FEI: 3006339676	Other FDA Registrations: Blood: FEI: 3006339676 Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2025 Last Registration Receipt Date: 12/12/2024 Summary Report Print Date: 12/20/2024
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Legal Name and Location: QualTex Laboratories 6211 IH 10 West San Antonio, Texas 78201 USA Phone: 210-731-5555 Ext.:	Reporting Official: Mark Fite, Chief Operating Officer 6211 IH 10 West San Antonio, Texas 78201 USA Phone: 210-731-5555 Ext. 2051 Mark.Fite@biobridgeglobal.org	Satellite Recovery Establishment: No Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only: Yes 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)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane				X								
Blood Vessel				X								
Bone				X		X						
Cardiac Tissue - non-valved				X								
Cartilage				X		X						
Cornea				X								
Dura Mater												
Embryo												
Fascia				X		X						
Heart Valve				X		X						
HPC Apheresis	Autologous, Family Related			X		X						
HPC Cord Blood	Autologous, Family Related			X		X						
Ligament				X		X						
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium				X								
Peripheral Blood Mononuclear Cells	Autologous, Family Related			X								
Peritoneal Membrane												
Sclera				X								
Semen												
Skin				X		X						
Tendon				X		X						
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue				X		X						

CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS
QUALTEX LABORATORIES
6211 IH 10 WEST
SAN ANTONIO, TX 78201

CLIA ID NUMBER
45D0500519

EFFECTIVE DATE
07/27/2023

LABORATORY DIRECTOR
RACHEL L BEDDARD M.D.

EXPIRATION DATE
07/26/2025

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
Monique Spruill, Director
Division of Clinical Laboratory Improvement & Quality
Quality & Safety Oversight Group
Center for Clinical Standards and Quality

405 certs2_062723

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:

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
BACTERIOLOGY (110)	03/24/2023
PARASITOLOGY (130)	08/25/2021
VIROLOGY (140)	10/29/2010
SYPHILIS SEROLOGY (210)	07/27/1995
GENERAL IMMUNOLOGY (220)	11/07/2008
ROUTINE CHEMISTRY (310)	07/27/1995
ABO & RH GROUP (510)	07/27/1995
ANTIBODY TRANSFUSION (520)	11/07/2008
ANTIBODY NON-TRANSFUSION (530)	07/27/1995

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
---------------------------------	-----------------------



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.

Tissue Licenses and registration
for:

Allosource
(Tissue Processor)

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10	FEI: 3000215346	Other FDA Registrations: Blood: Devices: FEI: 3000215346 Drugs:	Reason For Last Submission: Change in Information Last Annual Registration Year: 2024 Last Registration Receipt Date: 07/16/2024 Summary Report Print Date: 08/07/2024
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Legal Name and Location: AlloSource 6278 South Troy Circle Centennial, Colorado 80111 USA Phone: 720-873-0213 Ext.:	Reporting Official: Trevor Wright, Director of Regulatory Affairs 6278 South Troy Circle Centennial, Colorado 80111 USA Phone: 720-873-0213 Ext. twright@allosource.org	Satellite Recovery Establishment: No 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)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane		X	X		X	X	X	X	X			AlloWrap DS, AlloWrap Dry
Blood Vessel												
Bone			X		X	X	X	X	X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage			X		X	X	X	X	X			***See full text on next page.
Cornea												
Dura Mater												
Embryo												
Fascia			X		X	X	X	X	X			AlloConnex
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament			X		X	X	X	X	X			AlloConnex
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin			X		X	X	X	X	X			***See full text on next page.
Tendon			X		X	X	X	X	X			AlloConnex
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: The version of eHCTERS released on November 9, 2018 required establishments to only include 361 HCT/Ps (HCT/Ps described in §1271.10). eHCTERS is no longer used for HCT/Ps regulated as drugs, devices, and/or biological products under 21 CFR Parts 207 or 807.

Previously listed HCT/Ps regulated as Medical Devices are now listed exclusively with CDRH under AlloSource's medical device listing.

Proprietary Name(s):	Bone	AlloFuse Fibers, AlloFuse Fiber Boat, AlloFuse Micro Fibers, AlloFuse Select CM, AlloFuse Cervical Spacer, AlloFlex, AlloGro, AlloPac, CanPac, AcuPac
	Cartilage	DeNovo NT, Osteochondral Allograft Kit, ProChondrix CR
	Skin	PureSkin, AlloSkin, AlloSkin RT, AlloSkin AC, AlloMend, AlloMend UT (Ultra Thick), AlloMend Duo, ProLayer, Puregraft Essence

FEI:3000215346

Legal Name:AlloSource

American Association of Tissue Banks

Herewith certifies
that the Institution named here

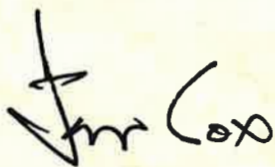
AlloSource

Centennial, Colorado

has met the Association's accreditation requirements
and is hereby accredited for

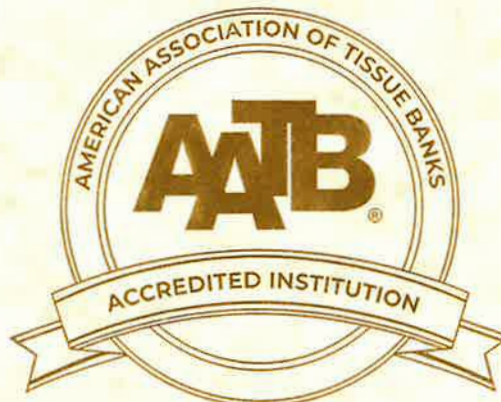
Deceased Donor	Authorization	Donor Screening	Recovery or Acquisition	Processing or Preparation	Donor Eligibility Determination	Storage	Distribution
Cardiac Tissue							
Cellular Tissue							
Musculoskeletal Tissue		✓		✓	✓	✓	✓
Skin		✓		✓	✓	✓	✓
Vascular Tissue							
Non-Transplant Anatomical (NAM or NTAD)							
Living Donor	Informed Consent	Donor Screening	Recovery	Processing	Donor Eligibility Determination	Storage	Distribution
Autologous Tissue							
Birth Tissue	✓	✓	✓	✓	✓	✓	✓
Reproductive Tissue							
Surgical bone							

In witness whereof the undersigned officers, being duly authorized, have caused this Certificate to be issued and the Corporate Seal of this Association to be affixed hereon this the 25th day of April 2024



Chair, Board of Governors

Expiration Date: February 22, 2027
Accreditation #: 00086





American Association of Tissue Banks®

Date: April 25, 2024

Via E-mail Kmeyer@allosource.org

AlloSource
6278 South Troy Circle
Centennial, Colorado 80111

This letter accompanies the accreditation certificate for AlloSource to include the accreditation of the following satellite facilities:

AlloSource - Buffalo
4444 Bryant and Stratton Way
Buffalo, NY 14221

AlloSource - Cincinnati
615 Elsinore Place
Suite 220
Cincinnati, OH 45202

AlloSource - Houston
12827 Capricorn Drive
Stafford, TX 77477

AlloSource - San Diego
7436 Mission Valley Road
San Diego, CA 92108

AlloSource - Maryland Heights
9 Worthington Access Drive
Maryland Heights, MO 63043

AlloSource - Chicago
311 W Superior
Suite 212
Chicago, IL 60654

AlloSource - Tracy
1700 N Chrisman Road
Tracy, CA 95304



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)

ALLOSOURCE - CENTENNIAL, CO
ATTN: DESIREE FRANKLIN
6278 S. TROY CIRCLE
CENTENNIAL, CO 80111

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.

ALLOSOURCE - CENTENNIAL, CO
6278 S. TROY CIRCLE
CENTENNIAL, CO 80111

OWNER(S):

DONOR ALLIANCE OF DENVER
GIFT OF HOPE ORGAN & TISSUE DONOR NETWORK
MID - AMERICA TRANSPLANT SERVICES

DIRECTOR:

DEAN ELLIOTT

TISSUE BANK ID Number: CTB 00080221

Issuance Date: April 29, 2025

Expiration Date: April 28, 2026

Charlet Archuleta, Acting Branch Chief
Laboratory Field Services



**DELAWARE HEALTH
AND SOCIAL SERVICES**

DIVISION OF PUBLIC HEALTH

March 6, 2025

Katrina Gambill
AlloSource
6278 South Troy Circle Centennial, CO 80111

Dear Katrina Gambill,

This letter confirms that **AlloSource** is registered with the Delaware Tissue Bank until April 30, 2026.

Thank you for notifying the Bureau of Communicable Diseases office in a timely manner of any changes to the information contained in the registration form. Please continue to keep contact information current to ensure timely delivery of updates and notifications.

If you have any questions, please contact me at the number below or via my e-mail.

Best regards,

Susanna Murray

Investigator I

Delaware Department of Health and Social Services

Division of Public Health

Thomas Collins Building | 540 S. DuPont Highway, Dover, DE 19901

Office: 302-744-1024 | Cell: 302-270-0875

Susanna.Murray@delaware.gov

View current license information at: Floridahealthfinder.gov

LICENSE #: 33
CERTIFICATE #: 2222

State of Florida
AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH CARE POLICY AND OVERSIGHT

Tissue Bank
Licensed

This is to confirm that ALLOSOURCE has complied with the rules and regulations adopted by the State of Florida, Agency for Health Care Administration, and authorized in Chapter 765, Florida Statutes, and is authorized to operate the following:

ALLOSOURCE INC
6278 South Troy Circle
Centennial, CO 80111

Authorized Services: distribute, storage and process tissues

EFFECTIVE DATE: 11/18/2024

EXPIRATION DATE: 11/17/2026



A handwritten signature in black ink, consisting of a stylized 'J' and 'W'.

Jason Weida, Secretary



525-535 West Jefferson Street • Springfield, Illinois 62761-0001 • www.dph.illinois.gov

Effective Date: **May 1, 2025**

Expires: **May 01, 2026**

Dean Elliott, Facility Director
AlloSource
6278 South Troy Circle
Centennial, CO 80111

Registration Number 0909

State of Illinois
2024
Sperm/Tissue Bank Registration
AlloSource

Dear Director:

We are in receipt of your **Registration** with the State of Illinois. We welcome your cooperation to observe our State laws and you may use this document as proof of registration as required by *Title 77 Public Health Chapter I: Department of Public Health Subchapter D: Laboratories and Blood Bank Part 470 Sperm Bank and Tissue Bank Code Section 470.30 Registration Requirements.*

Sincerely,



Brandon Rakowski
Tissue & Sperm Bank
Program Administrator
Illinois Department of Public Health
Health Care Facilities and Programs
Laboratory Regulations

Annual registration deadline is May 1, and renewal reminders are e-mailed on February of each year.

PROTECTING HEALTH, IMPROVING LIVES



**MARYLAND
DEPARTMENT OF HEALTH
OFFICE OF HEALTH CARE QUALITY**

LABORATORIES AND TISSUE BANKS
55 WADE AVE BLAND BRYANT BLDG
CATONSVILLE, MD 21228-4663

**TISSUE BANK PERMIT
NON - EXPIRING**

NUMBER: TB1129 EFFECTIVE DATE: 07/01/2018

*Pursuant to the provisions of TITLE 17, subtitle 3, Health-General Article § 17-301 et seq.,
Annotated Code of Maryland, this permit is issued to:*

**Allosource
6278 S TROY CIRCLE
CENTENNIAL, CO 80111**

Director: Dr ROSS WILKINS

Owner: MID-AMERICA TRANSPLANT SERVICES

For operating, representing or servicing the following Tissue Bank Classes:

Musculoskeletal Tissue Bank:

Bone, Cartilage, Demineralized Bone Matrix, Fascia Lata, Ligament, Musculoskeletal Tissue, Tendons

Skin Bank:

Skin

CONTROL: 70592

Patricia Tomsko May, MD
Director

Falsification of a license shall subject the perpetrator to criminal prosecution and the imposition of civil fines.

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: 665

Tissue Bank Director:
Dean Elliott
CEO

Medical Director:
Ross M. Wilkins, M.D.

AlloSource
6278 South Troy Circle
Centennial, CO 80111

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

Comprehensive Tissue Procurement Service

Musculoskeletal tissue

Skin tissue

Amniotic membrane

Tissue Processing Facility

Musculoskeletal tissue

Skin tissue

Amniotic membrane

Issued: September 7, 2023

Owner: AlloSource

Expires: October 1, 2025

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

DOI1-3908 (04/2001)



Health Care Regulation and Quality Improvement
800 NE Oregon Street, Suite 465
Portland, Oregon 97232
971-673-0540
971-673-0556 (Fax)

September 15th, 2023

Mr. Dean Elliott
Allosource (Centennial, CO)
6278 South Troy Circle
Centennial, CO 80111

Dear Mr. Elliott:

This letter is to notify you that Allosource (Centennial, CO) has been placed on the Oregon Procurement Organizations/Tissue Bank Registry. This registration is in effect for three years ending on September 26, 2026.

Thank you for your cooperation. Should you have any questions, please call me at the above phone number.

Sincerely,

A handwritten signature in cursive script that reads "Macie Coronel".

Macie Coronel
Administrative Specialist
Oregon Health Authority
Public Health Division
Health Care Regulation and Quality Improvement

If you need this information in an alternate format, please call our office at (971) 673-0540 or TTY 711