ESSENCE

ACELLULAR DERMAL MATRIX | By BIMINI

TISSUE LICENSE PACKET



Certificate Table

Jurisdiction	Expiration Date								
Bimini He	ealth Tech								
Food and Drug Administraion	December 31, 2024								
California	August 23, 2025								
Delaware	April 30, 2025								
Florida	January 24, 2026								
Illinois	May 1, 2025								
Maryland	Indefinite								
New York	In review, pending supplier registraion								
Oregon	August 3, 2026								
J4 Biologics									
Food and Drug Administraion	December 31, 2024								
AATB	October 17, 2027								
California	See Bimini Health Tech								
Delaware	Not registered								
Florida	February 6, 2026								
Illinois	May 1, 2025								
Maryland	Not registered								
New York	Not registered								
Oregon	Not registered								
Qualtex La	aboratories								
Food and Drug Administraion	December 31, 2024								
CLIA Cerificate of Accreditaion	July 26, 2025								
Allos	ource								
Food and Drug Administraion	August 31, 2026								
AATB	February 22, 2025								
California	April 28, 2025								
Delaware	April 30, 2025								
Florida	November 17, 2026								
Illinois	May 1, 2025								
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

Ext.:

FEI: 3022978896

Other FDA Registrations: Blood:

Devices:FEI: 3022978896

Drugs:

Fatablish mant Frontier

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

Legal Name and Location:

Bimini Health Tech

8400 Belleview Drive, Suite 125

Plano, Texas 75024

USA

Phone: 858-386-4140

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:

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)).

No

		Establishment Functions										
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
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							Х		Х			Puregraft Essence
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information provided.

Proprietary Name(s):

FEI: 3022978896 Legal Name: Bimini Health Tech

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



February 12, 2024

Trevor J. Denbo Bimini Health Tech 8400 Belleview Drive, Suite 125, Plano, TX 75024

Dear Trevor J. Denbo,

This letter confirms that **Bimini Health Tech** is registered with the Delaware Tissue Bank until April 30, 2025.

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,

Harley Bucher

Investigator I

Delaware Department of Health and Social Services

Division of Public Health

Stockley Campus | 102 Lloyd Lane, Georgetown, DE 19947

Office: 302-744-1033 | Cell: 302-270-0526

Harley.bucher@delaware.gov

State of Florida

AGENCY FOR HEALTH CARE ADMINISTRATION DIVISION OF HEALTH CARE POLICY AND OVERSIGHT

Tissue Bank

Licensed

This is to confirm that <u>BIMNI TECHNOLOGIES LLC</u> dba <u>BIMINI HEALTH TECH</u> 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



2

Jason Weida, Secretary





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

Effective Date: May 1, 2024 Expires: May 01, 2025

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

Registration Number 2023

State of Illinois <u>2024</u> 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.



MARYLAND DEPARTMENT OF HEALTH OFFICE OF HEALTH CARE OUALITY

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

Patrisia Tomsko May Mot Director

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



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,

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

Ext.:

FEI: 3025971176

Reporting Official:

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

Legal Name and Location:

San Antonio, Texas 78240

Phone: 210-701-7802

J4 Biologics, LLC 4848 Research Drive

USA

4848 Research Drive San Antonio, Texas 78240

Irma Valdez, Quality Assurance Manager

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)).

					Establishr	nent Function	ons					
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane			Х		Х	Х	Х	Х	Х			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			Х		Х	Х	Х	Х	Х			***See full text on next page.
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

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

FEI: 3025971176 Legal Name: J4 Biologics, LLC

Additional Information:

No additional information provided.

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



State of Florida

AGENCY FOR HEALTH CARE ADMINISTRATION DIVISION OF HEALTH CARE POLICY AND OVERSIGHT

Tissue Bank

Licensed

This is to confirm that <u>J4 Biologics</u>, <u>LLC</u> 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

EXPIRATION DATE: 02/06/2026

EFFECTIVE DATE: 01/31/2024



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Jason Weida, Secretary





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

Effective Date: May 1, 2024 Expires: May 01, 2025

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

Registration Number 2623

State of Illinois <u>2024</u> 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.

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 BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES	1 21. 0000000000	REASON FOR SUBMISSION Annual Registration	DISTRICT OFFICE:Dallas VALIDATED BY FDA: 12/21/2023
LEGAL NAME AND LOCATION: QualTex Laboratories 6211 IH 10 West at First Park Ten Blvd San Antonio, TX 78201 USA	REPORTING OFFICIAL: Mark Fite QualTex Laboratories 6211 IH 10 West		U.S. AGENT:
210-731-5555	San Antonio, TX 78201 USA 210-731-5555 x2051 Mark.Fite@biobridgeglobal.org		
OTHER NAMES USED IN THIS LOCATION: Qualtex Laboratories; South Texas Blood and Tissue Center	TYPE OF OWNERSHIP: CORPORATION DONOR/RECIPIENT RELATION	NSHIP:	ESTABLISHMENT TYPE: PRODUCT TESTING LABORATORY

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS		PATHOGEN REDUCED	POOLED
WHOLE BLOOD								Х		,		
RED BLOOD CELLS (RBC)								Х				
RBC FROZEN								Х				
RBC DEGLYCEROLIZED								Х				
RBC REJUVENATED								Х				
RBC REJUVENATED DEGLYCEROLIZED								Х				
CRYOPRECIPITATED AHF								Х				
PLATELETS								Х		х		
GRANULOCYTES								Х				
PLASMA								Х				

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES	PEI: 3006339676 REASON FOR SUBMISSI DUNS: 013324464 Annual Registration U.S. License Number:	ON DISTRICT OFFICE:Dallas VALIDATED BY FDA: 12/21/2023
LEGAL NAME AND LOCATION: QualTex Laboratories 6211 IH 10 West at First Park Ten Blvd San Antonio, TX 78201 USA	REPORTING OFFICIAL: Mark Fite QualTex Laboratories 6211 IH 10 West	U.S. AGENT:
210-731-5555	San Antonio, TX 78201 USA 210-731-5555 x2051 Mark.Fite@biobridgeglobal.org	
OTHER NAMES USED IN THIS LOCATION: Qualtex Laboratories; South Texas Blood and Tissue Center	TYPE OF OWNERSHIP: CORPORATION DONOR/RECIPIENT RELATIONSHIP:	ESTABLISHMENT TYPE: PRODUCT TESTING LABORATORY

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
FRESH FROZEN PLASMA								Х				
PLASMA CRYOPRECIPITATED REDUCED								Х				
LIQUID PLASMA								Х				
THERAPEUTIC EXCHANGE PLASMA								Х				
SOURCE LEUKOCYTES								Х				
SOURCE PLASMA								Х				
RECOVERED PLASMA								Х				
BLOOD PRODUCTS FOR DIAGNOSTIC USE								Х				
BLOOD BANK REAGENTS								Х				
T-CELLS								Х				·

DEPARTMENT OF HEALTH AND HUMAN SERVICE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND INTERPRETATION AND	PRODUCT LIST		FEI: 3006 DUNS: 0133 U.S. License			SON FOR SUB al Registration	BMISSION		T OFFICE:Dall			
LEGAL NAME AND LOCATION: QualTex Laboratories 6211 IH 10 West at First Park Ten Blvd San Antonio, TX 78201 USA			REPORTING Mark Fite QualTex Lab 6211 IH 10 V	ooratories	:			U.S. AGE	ENT:			
210-731-5555			San Antonio 210-731-555 Mark.Fite@t	55 x2051								
OTHER NAMES USED IN THIS LOCATION	l:		TYPE OF C	WNERSHIP	:			ESTABLISH	MENT TYPE:			
Qualtex Laboratories; South Texas Blood an	nd Tissue Cent	er	CORPORA	TION				PRODUC	T TESTING L	ABORATORY	•	
			DONOR/RECIPIENT RELATIONSHIP:									
PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED

***** End Of Report *****

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

EXPIRATION DATE

07/26/2025

LABORATORY DIRECTOR

RACHEL L BEDDARD M.D.

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, Director

Division of Clinical Laboratory Improvement & Quality

Quality & Safety Oversight Group Center for Clinical Standards and Quality

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:

LAB CERTIFICATION (CODE) EFFECTIVE DATE

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

LAB CERTIFICATION (CODE)



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**

Ext.:

FEI: 3000215346

Other FDA Registrations: Blood:

Drugs:

Reason For Last Submission: Change in Information Last Annual Registration Year: 2024 Last Registration Receipt Date: 07/16/2024

Devices:FEI: 3000215346 Summary Report Print Date: 08/07/2024

Legal Name and Location:

AlloSource

6278 South Troy Circle

Centennial, Colorado 80111

USA

Phone: 720-873-0213

Reporting Official:

Trevor Wright, Director of Regulatory Affairs

6278 South Troy Circle Centennial, Colorado 80111

Phone: 720-873-0213 Ext. twright@allosource.org

Satellite Recovery Establishment:

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)).

No

	Donor Type(s)	Establishment Functions										
HCT/P(s)		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane		Х	Х		Х	Х	х	Х	Х			AlloWrap DS, AlloWrap Dry
Blood Vessel												
Bone			Х		Х	х	Х	Х	Х			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage			Х		Х	Х	Х	Х	Х			***See full text on next page.
Cornea												
Dura Mater												
Embryo												
Fascia			Х		Х	х	Х	Х	Х			AlloConnex
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament			Х		Х	X	Х	Х	Х			AlloConnex
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin			Х		х	х	Х	Х	х			***See full text on next page.
Tendon			Х		Х	Х	Х	Х	Х			AlloConnex
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

44:4:4-4	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.

y Name(s)	

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

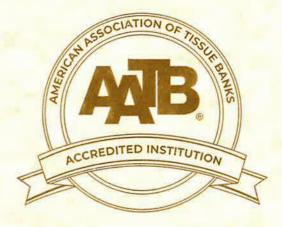
Deceased Donor	Authorization	Donor Screening	Recovery or Acquisition	Processing or Preparation	Donor Eligibility Determination	Storage	Distribution
Cardiac Tissue							
Cellular Tiss <mark>ue</mark>							
Musculoskeletal Tissue		✓		✓	✓	√	✓
Skin		√		✓	✓	✓	1
Vascular Tissue						1	
Non-Transplant Anatomical (NAM or NTAD)							
Living Donor	Informed Consent	Donor Screening	Recovery	Processing	Donor Eligibility Determination	Storage	Distribution
Autologous Tissue		1 2					
Birth Tissue	✓	√	V	V	✓	1	✓
Reproductive Tissue				4			
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



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 6278 S TROY CIR ATTN: KATRINA GAMBILL CENTENNIAL CO 80111-6422

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 94804-6403

Internet Address: www.cdph.ca.gov/LFS Thank you for your cooperation.

TB 100 TBLIC (8-23)

Tear Here Tear Here

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 listed 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, 2024 Expiration Date: April 28, 2025

Robert J. Thomas, Branch Chief Laboratory Field Services

Robert J. Thomas



January 26, 2024

Katrina Lambert AlloSource 6278 South Troy Circle, Centennial, CO 80111

Dear Katrina Lambert,

This letter confirms that **AlloSource** is registered with the Delaware Tissue Bank until April 30, 2025.

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,

Harley Bucher

Investigator I

Delaware Department of Health and Social Services

Division of Public Health

Stockley Campus | 102 Lloyd Lane, Georgetown, DE 19947

Office: 302-744-1033 | Cell: 302-270-0526

Harley.bucher@delaware.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 <u>ALLOSOURCE</u> 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



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Jason Weida, Secretary





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

Effective Date: May 1, 2024 Expires: May 01, 2025

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

Registration Number 0909

State of Illinois <u>2024</u> 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.



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 Tomoko May Mit

Falsification of a license shall subject the perpetrator to criminal prosecution and the impostition 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

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

Centennial, CO 80111

Comprehensive Tissue Procurement Service

Musculoskeletal tissue

Skin tissue

Amniotic membrane

Tissue Processing Facility

Musculoskeletal tissue

Skin tissue

Amniotic membrane

Issued: September 7, 2023

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)

Owner: AlloSource



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,

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