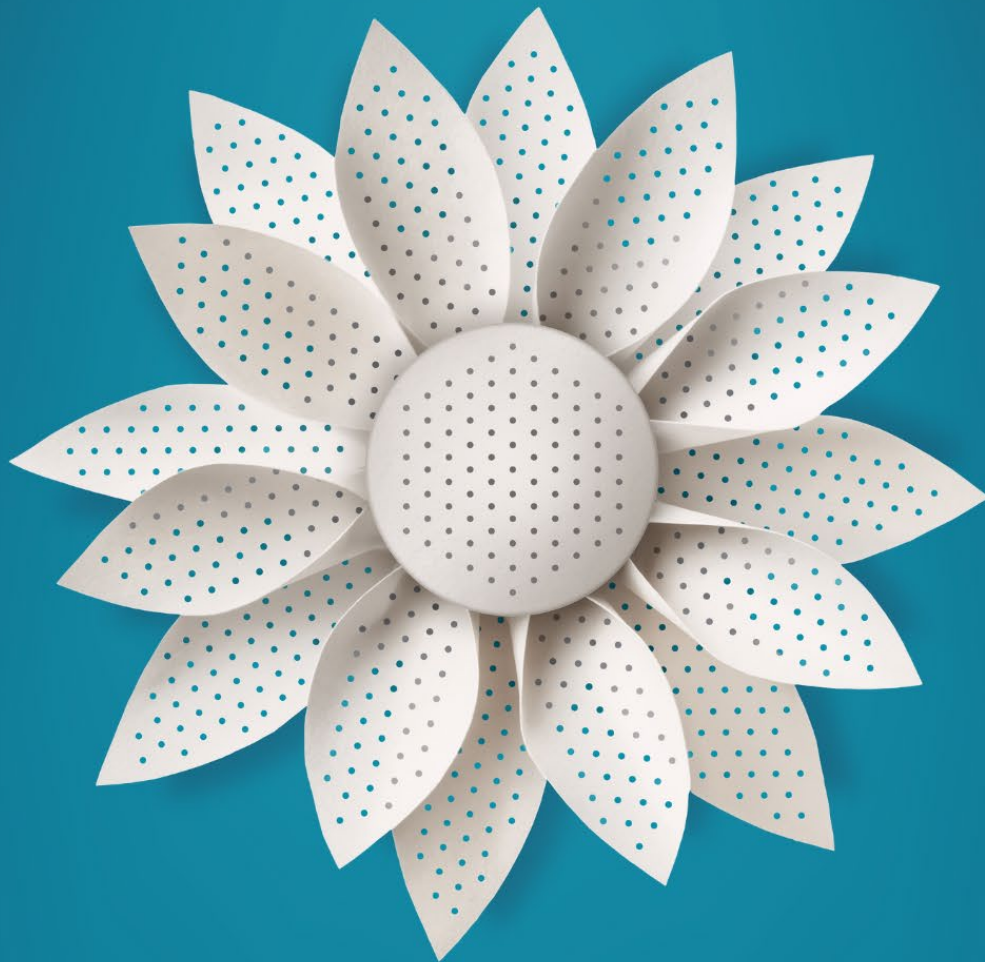


— PUREGRAFT —

# ESSENCE

ACELLULAR DERMAL MATRIX | By BIMINI

## TISSUE LICENSE PACKET



## Certificate Table

Jurisdiction	Expiration Date
<b>Bimini Health Tech</b>	
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	January 1, 2027
Oregon	August 3, 2026
<b>J4 Biologics</b>	
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	December 1, 2026
Oregon	Not registered
<b>Qualtex Laboratories</b>	
Food and Drug Administraion	December 31, 2024
CLIA Cerificate of Accreditaion	July 26, 2025
<b>Allosource</b>	
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 <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 3022978896	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> FEI: 3022978896 <b>Drugs:</b>	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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<b>Legal Name and Location:</b>  Bimini Health Tech 8400 Belleview Drive, Suite 125   Plano, Texas 75024 USA  Phone: 858-386-4140 <b>Ext.:</b>	<b>Reporting Official:</b>  Trevor J Denbo, VP, QA/RA 8400 Belleview Drive Suite 125 Plano, Texas 75024 USA Phone: 858-386-4140 Ext. tdenbo@BiminiHealthTech.com	<b>Satellite Recovery Establishment:</b> No <b>Parent Manufacturing Establishment FEI No.:</b> <b>Testing For Micro-Organisms Only:</b> 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												

**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](http://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**

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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](mailto:Harley.bucher@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](http://www.dph.illinois.gov)

Effective Date: **May 1, 2024**

Expires: May 01, 2025

**Bradford Conlan, Facility Director**  
**Bimini Health Tech**  
8400 Bellevue 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 <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 3025971176	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> <b>Drugs:</b>	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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<b>Legal Name and Location:</b>  J4 Biologics, LLC 4848 Research Drive   San Antonio, Texas 78240 USA  Phone: 210-701-7802 <b>Ext.:</b>	<b>Reporting Official:</b>  Irma Valdez, Quality Assurance Manager 4848 Research Drive San Antonio, Texas 78240 USA Phone: 210-701-7802 Ext. valdezi@j4biologics.com	<b>Satellite Recovery Establishment:</b> No <b>Parent Manufacturing Establishment FEI No.:</b> <b>Testing For Micro-Organisms Only:</b> 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.

<b>Proprietary Name(s):</b>	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

<b>Deceased Donor</b>	<b>Authorization</b>	<b>Donor Screening</b>	<b>Recovery</b>	<b>Processing or Preparation</b>	<b>Donor Eligibility Determination</b>	<b>Storage</b>	<b>Distribution</b>
Cardiac Tissue							
Cellular Tissue							
Musculoskeletal Tissue							
Skin				✓	✓	✓	✓
Vascular Tissue							
Non-Transplant Anatomical (NAM or NTAD)							
<b>Living Donor</b>	<b>Informed Consent</b>	<b>Donor Screening</b>	<b>Recovery or Acquisition</b>	<b>Processing</b>	<b>Donor Eligibility Determination</b>	<b>Storage</b>	<b>Distribution</b>
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 17<sup>th</sup> day of October 2024



Chair, Board of Governors

Expiration Date: October 17, 2027

Accreditation #: 00366





View current license information at: [Floridahealthfinder.gov](http://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 in black ink, consisting of several loops and a long horizontal stroke.

Jason Weida, Secretary



525-535 West Jefferson Street • Springfield, Illinois 62761-0001 • [www.dph.illinois.gov](http://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*  
*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.*

# 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)

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	FEI: 3006339676 DUNS: 013324464 U.S. License Number:	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  210-731-5555	REPORTING OFFICIAL: Mark Fite QualTex Laboratories 6211 IH 10 West  San Antonio, TX 78201 USA 210-731-5555 x2051 Mark.Fite@biobridgeglobal.org		U.S. AGENT:
OTHER NAMES USED IN THIS LOCATION: Qualtex Laboratories; South Texas Blood and Tissue Center	TYPE OF OWNERSHIP: CORPORATION		ESTABLISHMENT TYPE: PRODUCT TESTING LABORATORY
	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
WHOLE BLOOD								X				
RED BLOOD CELLS (RBC)								X				
RBC FROZEN								X				
RBC DEGLYCEROLIZED								X				
RBC REJUVENATED								X				
RBC REJUVENATED DEGLYCEROLIZED								X				
CRYOPRECIPITATED AHF								X				
PLATELETS								X		X		
GRANULOCYTES								X				
PLASMA								X				

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	FEI: 3006339676 DUNS: 013324464 U.S. License Number:	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  210-731-5555	REPORTING OFFICIAL: Mark Fite QualTex Laboratories 6211 IH 10 West  San Antonio, TX 78201 USA 210-731-5555 x2051 Mark.Fite@biobridgeglobal.org		U.S. AGENT:
OTHER NAMES USED IN THIS LOCATION: Qualtex Laboratories; South Texas Blood and Tissue Center	TYPE OF OWNERSHIP: CORPORATION		ESTABLISHMENT TYPE: PRODUCT TESTING LABORATORY
	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
FRESH FROZEN PLASMA								X				
PLASMA CRYOPRECIPTATED REDUCED								X				
LIQUID PLASMA								X				
THERAPEUTIC EXCHANGE PLASMA								X				
SOURCE LEUKOCYTES								X				
SOURCE PLASMA								X				
RECOVERED PLASMA								X				
BLOOD PRODUCTS FOR DIAGNOSTIC USE								X				
BLOOD BANK REAGENTS								X				
T-CELLS								X				

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	FEI: 3006339676 DUNS: 013324464 U.S. License Number:	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  210-731-5555	REPORTING OFFICIAL: Mark Fite QualTex Laboratories 6211 IH 10 West  San Antonio, TX 78201 USA 210-731-5555 x2051 Mark.Fite@biobridgeglobal.org		U.S. AGENT:
OTHER NAMES USED IN THIS LOCATION: Qualtex Laboratories; South Texas Blood and Tissue Center	TYPE OF OWNERSHIP: CORPORATION		ESTABLISHMENT TYPE: PRODUCT TESTING LABORATORY
	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
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\*\*\*\*\* 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

**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>
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FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT [WWW.CMS.GOV/CLIA](http://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 <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 3000215346	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> FEI: 3000215346 <b>Drugs:</b>	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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<b>Legal Name and Location:</b>  AlloSource 6278 South Troy Circle   Centennial, Colorado 80111 USA  Phone: 720-873-0213  <b>Ext.:</b>	<b>Reporting Official:</b>  Trevor Wright, Director of Regulatory Affairs 6278 South Troy Circle Centennial, Colorado 80111 USA Phone: 720-873-0213 Ext. twright@allosource.org	<b>Satellite Recovery Establishment:</b> No <b>Parent Manufacturing Establishment FEI No.:</b> <b>Testing For Micro-Organisms Only:</b> 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

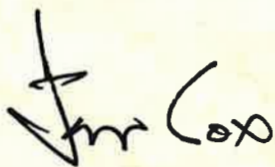
**AlloSource**

**Centennial, Colorado**

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

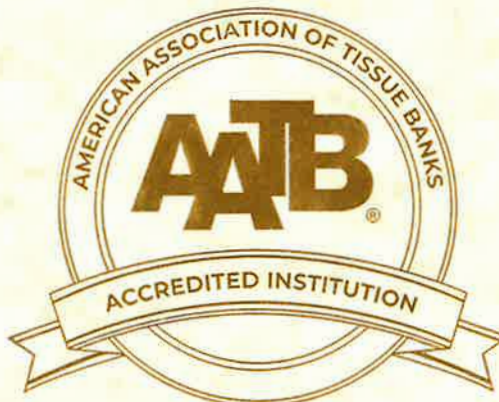
<b>Deceased Donor</b>	<b>Authorization</b>	<b>Donor Screening</b>	<b>Recovery or Acquisition</b>	<b>Processing or Preparation</b>	<b>Donor Eligibility Determination</b>	<b>Storage</b>	<b>Distribution</b>
Cardiac Tissue							
Cellular Tissue							
Musculoskeletal Tissue		✓		✓	✓	✓	✓
Skin		✓		✓	✓	✓	✓
Vascular Tissue							
Non-Transplant Anatomical (NAM or NTAD)							
<b>Living Donor</b>	<b>Informed Consent</b>	<b>Donor Screening</b>	<b>Recovery</b>	<b>Processing</b>	<b>Donor Eligibility Determination</b>	<b>Storage</b>	<b>Distribution</b>
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 25<sup>th</sup> day of April 2024



Chair, Board of Governors

Expiration Date: February 22, 2027  
Accreditation #: 00086





**American Association of Tissue Banks®**

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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, 1<sup>st</sup> Floor  
Richmond, CA 94804-6403

Internet Address: [www.cdph.ca.gov/LFS](http://www.cdph.ca.gov/LFS)

Thank you for your cooperation.

TB 100 TBLC (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



**DELAWARE HEALTH  
AND SOCIAL SERVICES**

**DIVISION OF PUBLIC HEALTH**

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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](mailto:Harley.bucher@delaware.gov)



View current license information at: [Floridahealthfinder.gov](http://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 stylized, handwritten signature in black ink, consisting of several loops and a long horizontal stroke.

Jason Weida, Secretary





525-535 West Jefferson Street • Springfield, Illinois 62761-0001 • [www.dph.illinois.gov](http://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*  
*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*