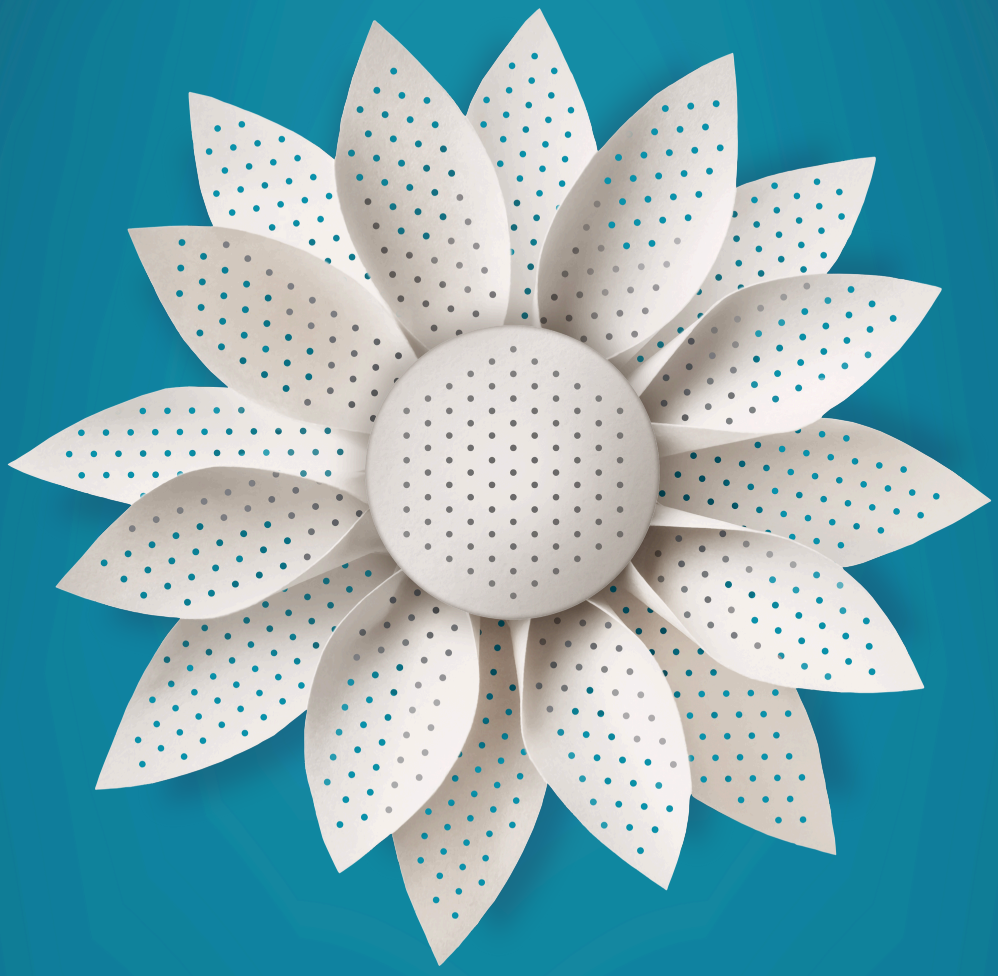
ESSENCE™

ACELLULAR DERMAL MATRIX | By BIMINI

TISSUE LICENSE PACKET



Bimini Health Tech +1-858-348-8050 | info@biminihealthtech.com | www.biminihealthtech.com

Certificate Table

Jurisdiction	Expiration Date
Bimini Health Tech	
Food and Drug Administraion	December 31, 2026
California	August 23, 2026
Delaware	April 30, 2027
Florida	January 24, 2028
Illinois	May 1, 2026
Maryland	Indefinite
New York	January 1, 2027
Oregon	August 3, 2026
J4 Biologics	
Food and Drug Administraion	December 31, 2026
AATB	October 17, 2027
California	March 20, 2027
Delaware	April 30, 2027
Florida	February 6, 2028
Illinois	May 1, 2027
Maryland	Indefinite
New York	December 1, 2026
Oregon	February 13, 2027
Qualtex Laboratories	
Food and Drug Administraion	Decemeber 31, 2026
CLIA Cerificate of Accreditaion	July 26, 2027
Allosource	
Food and Drug Administraion	December 31, 2026
AATB	February 22, 2027
CLIA Cerificate of Accreditaion	March 03, 2026 (Ext 07/31/26)
California	April 28, 2027
Delaware	April 30, 2027
Florida	November 17, 2026
Illinois	May 1, 2027
Maryland	Indefinate
New York	October 1, 2027
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: 2026
Last Registration Receipt Date: 12/12/2025
Summary Report Print Date: 12/15/2025

Legal Name and Location:

Bimini Health Tech
8400 Belleview Drive, Suite 125

Plano, Texas 75024
USA

Phone: 858-348-8050 **Ext.:**

Reporting Official:

Frankie Ng, VP, Operations
8400 Belleview Drive
Suite 125
Plano, Texas 75024
USA
Phone: 909-576-1023 Ext.
FNg@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)).

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												

FDA information collection OMB Control number: 0910-0543, expiration date: 08/31/2026

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)

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.

BIMINI HEALTH TECH

8400 BELLEVIEW DR STE 125
PLANO, TX 75024

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, 2025
Expiration Date: August 23, 2026

Charlet Archuleta, Acting Branch Chief
Laboratory Field Services

DELAWARE HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

March 3, 2026

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

Dear Gladys Fonseca,

This letter confirms that **Bimini Health Tech** is registered with the Delaware Tissue Bank until April 30, 2027.

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,

Malia Wise

Malia Wise
Delaware Division of Public Health
Bureau of Infectious Disease Prevention & Control
Ph. 302-744-1015 Fax 302-739-2550
DHSS_DPH_tissuebank@delaware.gov

View current license information at: Floridahealthfinder.gov

LICENSE #: 403
CERTIFICATE #: 2442

State of Florida

AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH QUALITY ASSURANCE

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: 01/25/2026

EXPIRATION DATE: 01/24/2028

Shevaun L. Harris, Secretary

IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH

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.

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 Tomsko May, MD
Director

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

Oregon Health Authority

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

FEI: 3025971176

Other FDA Registrations:
Blood:
Devices:
Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2026
Last Registration Receipt Date: 11/20/2025
Summary Report Print Date: 12/01/2025

Legal Name and Location:

J4 Biologics, LLC
4848 Research Drive

San Antonio, Texas 78240
USA

Phone: 210-701-7802 **Ext.:**

Reporting Official:

Kristi Krumbholz, Director of Quality Assurance
4848 Research Drive
San Antonio, Texas 78240
USA
Phone: 726-248-8036 Ext.
kristi@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)).

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												

FDA information collection OMB Control number: 0910-0543, expiration date: 08/31/2026

Additional Information: No additional information provided.

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

FEI: 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

Jim Cox

Chair, Board of Governors

Expiration Date: October 17, 2027
Accreditation #: 00366

AMERICAN ASSOCIATION OF TISSUE BANKS
AATB®
ACCREDITED INSTITUTION

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

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: CTB 00082471
Issuance Date: March 21, 2026
Expiration Date: March 20, 2027

Charlet Archuleta, Acting Branch Chief
Laboratory Field Services

DELAWARE HEALTH AND SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH

February 20, 2026

J4 Biologics
4848 Research Drive, San Antonio, TX 78240

Dear Kristi Krumbholz,

This letter confirms that **J4 Biologics** is registered with the Delaware Tissue Bank until April 30, 2027.

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,

Malia Wise

Malia Wise
Delaware Division of Public Health
Bureau of Infectious Disease Prevention & Control
Ph. 302-744-1015 Fax 302-739-2550
DHSS_DPH_tissuebank@delaware.gov

View current license information at: Floridahealthfinder.gov

LICENSE #: 405
CERTIFICATE #: 2409

State of Florida

AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH QUALITY ASSURANCE

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: Distribute Tissues

EFFECTIVE DATE: 02/07/2026

EXPIRATION DATE: 02/06/2028

Shevaun L. Harris, Secretary

IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH

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

Effective Date: **May 1, 202**

Expires: May 01, **2027**

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

Registration Number 2623

State of Illinois
2026
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.

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

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)

Oregon Health Authority

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: 2026
Last Registration Receipt Date: 11/25/2025
Summary Report Print Date: 12/01/2025

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)).

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						

FDA information collection OMB Control number: 0910-0543, expiration date: 08/31/2026

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

07/27/2025

LABORATORY DIRECTOR

RACHEL L. BEDDARD

EXPIRATION DATE

07/26/2027

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.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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

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

PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.
FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA.

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: Annual Registration/Listing
Last Annual Registration Year: 2026
Last Registration Receipt Date: 12/12/2025
Summary Report Print Date: 12/15/2025

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)).

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												

FDA information collection OMB Control number: 0910-0543, expiration date: 08/31/2026

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 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

Jim Cox

Chair, Board of Governors

Expiration Date: February 22, 2027
Accreditation #: 00086

AMERICAN ASSOCIATION OF TISSUE BANKS
AATB
ACCREDITED INSTITUTION

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

CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS

ALLOSOURCE
6278 S TROY CIR
CENTENNIAL, CO 80111

CLIA ID NUMBER

06D0865727

EFFECTIVE DATE

03/04/2024

LABORATORY DIRECTOR

DR. HANNIS W. THOMPSON

EXPIRATION DATE

03/03/2026

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.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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

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	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
MICROBIOLOGY - BACTERIOLOGY (110)	03/04/1994		
MICROBIOLOGY - MYCOLOGY (120)	06/27/2011		

PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.
FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA.

CLIA Laboratory Details

Please note that all of the laboratories found using the CMS CLIA Laboratory Demographic Information Tool on the CMS website are certified by the United States Government Department of Health and Human Services under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform laboratory testing as of the Data Source Date listed. Please note the most up to date information may not appear on the linked certificate.

CLIA Identification Number:	06D0865727
Facility Name:	ALLOSOURCE
Lab Director:	DR. HANNIS W. THOMPSON
Address:	6278 S TROY CIR CENTENNIAL, CO 80111
Phone Number:	720 873-0213
Certificate Type:	Compliance
Certificate Effective Date:	03/04/2024
Certificate Expiration Date:	03/31/2026
Facility Type:	Tissue Bank/Repositories
Certificate URL:	https://iqies.cms.gov/api/clia/v1/public/assets/CLIA-Certificate-06D0865727-2024-03-04.pdf

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.

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

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, 2026
Expiration Date: April 28, 2027

Charlet Archuleta, Acting Branch Chief
Laboratory Field Services

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

Jason Weida, Secretary

IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH

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

Effective Date: **May 1, 2026**

Expires: May 01, **2027**

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

Registration Number 0909

State of Illinois
2026
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.

DELAWARE HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

April 2, 2026

Allosource
6278 South Troy Circle, Centennial, CO 80111

Dear Desiree Franklin,

This letter confirms that **Allosource** is registered with the Delaware Tissue Bank until April 30, 2027.

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,

Malia Wise

Malia Wise
Delaware Division of Public Health
Bureau of Infectious Disease Prevention & Control
Ph. 302-744-1015 Fax 302-739-2550
DHSS_DPH_tissuebank@delaware.gov

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 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
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 18, 2025**

Owner: AlloSource

Expires: **October 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)

Oregon Health Authority

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