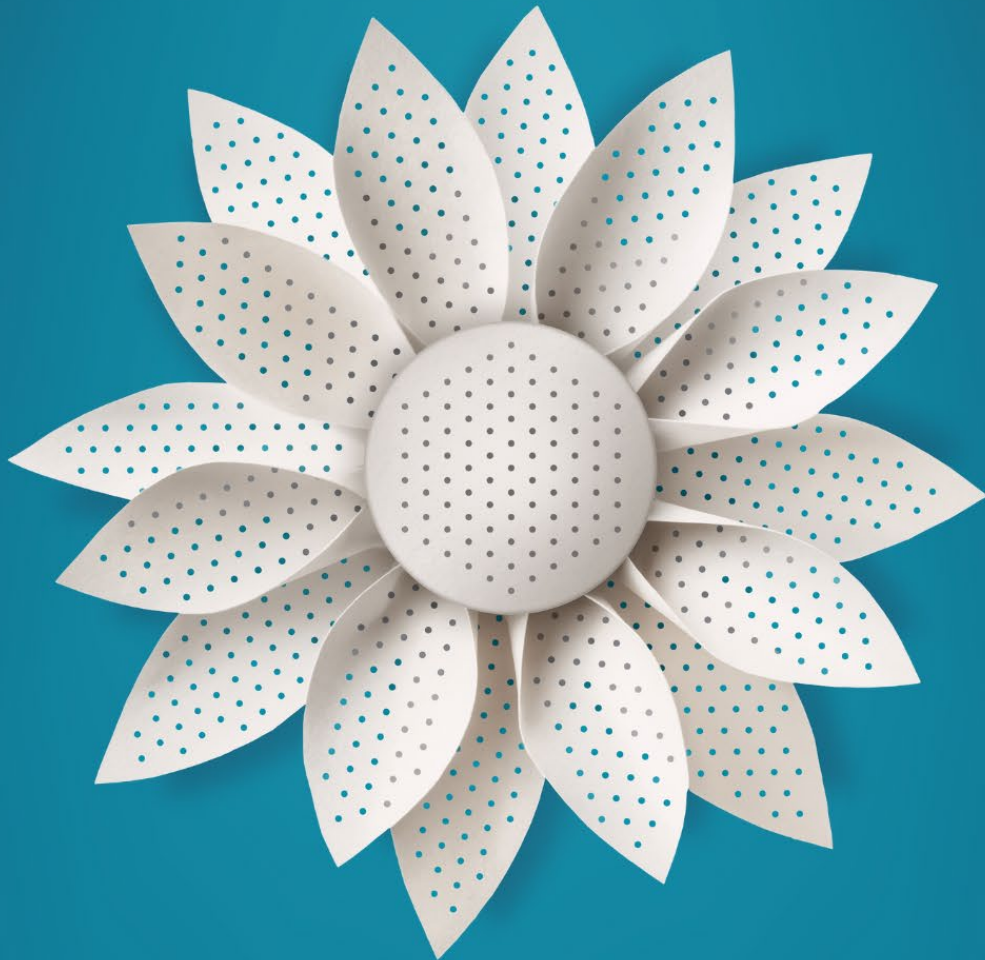


— PUREGRAFT —

ESSENCE

ACELLULAR DERMAL MATRIX | By BIMINI

TISSUE LICENSE PACKET



First certificate within expires: May 1, 2024

Certificate Table

Jurisdiction	Expiration Date
Bimini Health Tech	
Food and Drug Administration	December 31, 2024
California	August 23, 2024
Delaware	April 30, 2025
Florida	January 24, 2026
Illinois	May 1, 2025
Maryland	Indefinite
New York	In review, pending supplier registration
Oregon	August 3, 2026
J4 Biologics	
Food and Drug Administration	December 31, 2024
California	Not registered
Delaware	Not registered
Florida	February 6, 2026
Illinois	May 1, 2024
Maryland	Not registered
New York	Not registered
Oregon	February 13, 2027
Qualtex Laboratories	
Food and Drug Administration	December 31, 2024
CLIA Certificate of Accreditation	July 26, 2025

Tissue Licenses and registration
for:

Bimini Health Tech
(Distributor)

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10	FEI: 3022978896	Other FDA Registrations: Blood: Devices: FEI: 3022978896 Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/16/2023 Summary Report Print Date: 12/01/2023
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Legal Name and Location: Bimini Health Tech 8400 Belleview Drive, Suite 125 Plano, Texas 75024 USA Phone: 858-386-4140 Ext.:	Reporting Official: Trevor J Denbo, VP, QA/RA 8400 Belleview Drive Suite 125 Plano, Texas 75024 USA Phone: 858-386-4140 Ext. tdenbo@BiminiHealthTech.com	Satellite Recovery Establishment: No Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only: No Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin								X		X		Puregraft Essence
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

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
8400 BELLEVIEW DR STE 125
ATTN: TREVOR DENBO
PLANO TX 75024-0431**

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 TB LIC (8-23)

Tear Here

Tear Here

STATE OF CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

PROVISIONAL TISSUE BANK LICENSE

In accordance with Division 2, Chapter 4.1, of the Health and Safety Code, the entity named below is hereby licensed to engage in the listed 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: CTP 00082381

Issuance Date: August 24, 2023

Expiration Date: August 23, 2024

Robert J. Thomas

Robert J. Thomas, Branch Chief
Laboratory Field Services



**DELAWARE HEALTH
AND SOCIAL SERVICES**

DIVISION OF PUBLIC HEALTH

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

View current license information at: 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, consisting of a stylized, cursive "JW" followed by a period.

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
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 imposition 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,

A handwritten signature in cursive script that reads "Marcie Greene".

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

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

Tissue Licenses and registration
for:

J4 Biologics
(Tissue Processor)

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10	FEI: 3025971176	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/31/2023 Summary Report Print Date: 01/05/2024
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Legal Name and Location: J4 Biologics, LLC 4848 Research Drive San Antonio, Texas 78240 USA Phone: 210-701-7802 Ext.:	Reporting Official: Irma Valdez, Quality Assurance Manager 4848 Research Drive San Antonio, Texas 78240 USA Phone: 210-701-7802 Ext. valdezi@j4biologics.com	Satellite Recovery Establishment: No Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only: No Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane			X		X	X	X	X	X			EvoPatch
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin			X		X	X	X	X	X			***See full text on next page.
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

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

Legal Name: J4 Biologics, LLC

View current license information at: 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 handwritten signature in black ink, appearing to be "JW", positioned above a horizontal line.

Jason Weida, Secretary



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

Effective Date: **October 18, 2023**

Expires: **May 01, 2024**

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

Registration Number 2623



State of Illinois
2023
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.



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 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 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
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 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								X				
PLASMA CRYOPRECIPIATED 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 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
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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

LAB CERTIFICATION (CODE) EFFECTIVE DATE



**FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
 OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
 YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
 PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.**