

### Pacific Reproductive Services

444 DeHaro Street, Suite 222  
San Francisco, CA 94107  
Tel: (415) 487-2288

65 N. Madison Ave. Suite 610  
Pasadena, CA 91101  
Tel: (626) 432-1681

Email: [info@pacrepro.com](mailto:info@pacrepro.com)

## CONTRACTED SPERM BANK FDA DOCUMENTATION

This agreement is to provide documentation for facilities which Pacific Reproductive Services contracts with in the processing, production, handling, transport, and/or storage of HCT/Ps.

Establishment Name: Pacific Reproductive Services

Address: 444 De Haro Street, Suite 222

Address: San Francisco, CA 94107

Phone: 415-487-2288 ext 231

Fax: 415-863-4358

This facility:

- Holds a current CLIA Waiver      CLIA Number 05-D0908696  
Issuing Agency CMS  
Director: Sherron Mills
- Is licensed by CA CA TB License: CNC 80069
- Is licensed by NY NY TB License: GA056

This facility is currently registered with the FDA as a HCT/P establishment

Registration Number: 3003110346

Per FDA regulations, our contract laboratories are registered with the FDA and use only FDA approved screening tests for donor testing. Tests are conducted and interpreted as per manufacture recommendations.

PRS does not perform laboratory screening or diagnostic testing on donors. All tests are sent to reference laboratories.

FDA establishment registration functions include:

Recover    Screen    Package    Label    Distribute

I agree Pacific Reproductive Services will maintain FDA registration for HCT/Ps as required and will remain compliant with all regulations governing the manufacture of HCT/P's.

I agree to notify \_\_\_\_\_ within 5 (five) business days of any change in our status. (Establishment Name)

Responsible Person: [Signature] Date: \_\_\_\_\_

1. REGISTRATION NUMBER  
*(Field Establishment Identifier)*  
 FEI: 3003110346

2. REASON FOR SUBMISSION  
 a.  INITIAL REGISTRATION / LISTING  
 b.  ANNUAL REGISTRATION / LISTING  
 c.  CHANGE IN INFORMATION  
 d.  INACTIVE

FORM APPROVED: OMB No. 0910-0643. Expiration Date: 7/31/10  
 VALIDATION-FOR FDA USE ONLY  
 VALIDATED BY FDA:02-JAN-2008  
 DISTRICT: San Francisco  
 PRINTED BY FDA:17-JAN-2008

**PART I - ESTABLISHMENT INFORMATION**

3. OTHER FDA REGISTRATIONS  
 a. BLOOD FDA 2890 NO. \_\_\_\_\_  
 b. DEVICES FDA 2891 NO. \_\_\_\_\_  
 c. DRUG FDA 2856 NO. \_\_\_\_\_

4. PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*  
 Pacific Reproductive Services, Inc.  
 444 DeLaro St.  
 Suite 222  
 San Francisco, California 94107

a. PHONE 415-487-2288 EXT \_\_\_\_\_  
 b.  SATELLITE RECOVERY ESTABLISHMENT  
 (MANUFACTURING ESTABLISHMENT FEI NO. \_\_\_\_\_)  
 c.  TESTING FOR MICRO-ORGANISMS ONLY  
 5. ENTER CORRECTIONS TO ITEM 4

6. MAILING ADDRESS OF REPORTING OFFICIAL *(Include institution name if applicable, number and street, city, state, country, and post office code)*  
 Pacific Reproductive Services  
 Attn: Sherron L. Mills, R.N., N.P.  
 444 DeLaro St.  
 Suite 222  
 San Francisco, California 94107

a. PHONE 415-487-2288 EXT 222  
 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE \_\_\_\_\_

8. U.S. AGENT

a. E-MAIL  
 9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Sherron L. Mills, R.N., N.P.  
 b. E-MAIL sherron@pactepro.com  
 c. TITLE Tissue Bank Director  
 d. DATE 18-DEC-2007

**PART II - PRODUCT INFORMATION**

Types of HCT / Ps	Establishment Functions							11. HCT/PS DESCRIBED IN 21 CFR 1271.10	12. HCT/PS REGULATED AS MEDICAL DEVICES	13. HCT/PS REGULATED AS BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process	Store	Label				
No HCT / P Specified											
a. Bone											
b. Cartilage											
c. Cornea											
d. Dura Mater											
e. Embryo											
f. Fascia											
g. Heart Valve											
h. Ligament											
i. Oocyte											
j. Pericardium											
k. Peripheral Blood Stem Cells											
l. Sclera											
m. Semen											
n. Skin											
o. Somatic Cells											
p. Tendon											
q. Umbilical Cord Blood Stem Cells											
r. Vascular Graft											
s.											
t.											
u.											
v.											

1.  SIP  
 Directed  
 Anonymous

2.  SIP  
 Directed  
 Anonymous

3.  Autologous  
 Family Related  
 Allogeneic

4.  Autologous  
 Family Related  
 Allogeneic

5.  Autologous  
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12.  Autologous  
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13.  Autologous  
 Family Related  
 Allogeneic

14.  Autologous  
 Family Related  
 Allogeneic

**DEPARTMENT OF PUBLIC HEALTH**850 Marina Bay Parkway, Bldg P, 1<sup>st</sup> Floor  
Richmond, CA 94804-6403  
(510) 620-3800

Dear Tissue Bank:

Attached below is your tissue bank license.  
Your license is void after the expiration date.NOTE: Application 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)**PACIFIC REPRODUCTIVE SERVICES, INC.**  
444 DE HARO STREET, SUITE 222  
SAN FRANCISCO, CA 94107

ATTN: SHERRON L. MILLS, NP

**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:

STATE OF CALIFORNIA  
DEPT. OF PUBLIC HEALTH  
Laboratory Field Services  
850 Marina Bay Parkway, Bldg P, 1<sup>st</sup> Floor  
Richmond, CA 94804-6403

Thank you for your cooperation.

Tear Here

Tear Here

**STATE OF CALIFORNIA DEPARTMENT OF PUBLIC HEALTH**  
**TISSUE BANK LICENSE**

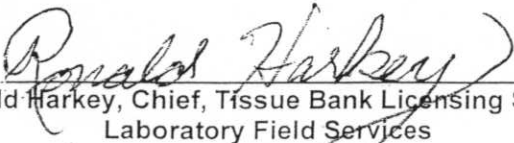
In accordance with Division 2, Chapter 4.1 of the Health and Safety Code, the entity named below is hereby licensed to engage in the operation of a tissue bank at the indicated address

**PACIFIC REPRODUCTIVE SERVICES, INC.**  
**65 N. MADISON AVENUE # 610**  
**PASADENA, CA 91101**Owner(s) Name: SHERRON L. MILLS  
Address: 660 WISCONSIN  
City, State, Zip: SAN FRANCISCO CA 94107

TISSUE BANK ID NUMBER: CNC 80421

Issuance Date: OCTOBER 27, 2009

Expiration Date: OCTOBER 26, 2010

Tissue Bank Director:  
SHERRON L. MILLS, NP  
Ronald Harkey, Chief, Tissue Bank Licensing Section  
Laboratory Field Services

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

LABORATORY NAME AND ADDRESS

PACIFIC REPRODUCTIVE SERVICES  
444 DE HARO #222  
SAN FRANCISCO, CA 94107

LABORATORY DIRECTOR

RODOLFO QUINTERO MD

CLIA ID NUMBER

05D0908696

EFFECTIVE DATE

05/29/2008

EXPIRATION DATE

05/28/2010

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.



*Judith A. Yost*

Judith A. Yost, Director  
Division of Laboratory Services  
Survey and Certification Group  
Center for Medicaid and State Operations

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- If this is a Certificate of Registration, it represents only the enrollment of the laboratory in the CLIA program and does not indicate a Federal certification of compliance with other CLIA requirements. The laboratory is permitted to begin testing upon receipt of this certificate, but is not determined to be in compliance until a survey is successfully completed.
- If this is a Certificate for Provider-Performed Microscopy Procedures, it certifies the laboratory to perform only those laboratory procedures that have been specified as provider-performed microscopy procedures and, if applicable, examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.
- If this is a Certificate of Waiver, it certifies the laboratory to perform only examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.



FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT [WWW.CMS.HHS.GOV/CLIA](http://WWW.CMS.HHS.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.

**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

*Tissue Bank ID No. : GA056*

**Tissue Bank Director:** Sherron Mills, N.P.

**Medical Director:** Madelyn Kahn, M.D.

**Pacific Reproductive Services, Inc.**  
444 DeHaro Street  
Suite 222  
San Francisco, CA 94107

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

- Comprehensive Tissue Procurement Service**
- Tissue Processing Facility**
- Semen**
- Semen**

**Issued:** April 24, 2009  
**Expired:** May 1, 2013

**Owner:** Pacific Reproductive Services, Inc.

Property of the New York State Department of Health. Valid only at the address shown. Must be conspicuously posted.  
DOH-3908 (04/2001)





**DEPARTMENT OF PUBLIC HEALTH**850 Marina Bay Parkway, Bldg P, 1<sup>st</sup> Floor.  
Richmond, CA 94804-6403  
(510) 620-3800

Dear Tissue Bank:

Attached below is your tissue bank license.  
Your license is void after the expiration date.NOTE: Application 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)**PACIFIC REPRODUCTIVE SERVICES  
444 DEHARO STREET, SUITE 222  
SAN FRANCISCO CA 94107****ATTN: SHERRON MILLS****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:

STATE OF CALIFORNIA  
DEPT. OF PUBLIC HEALTH  
Laboratory Field Services  
850 Marina Bay Parkway, Bldg P, 1<sup>st</sup> Floor  
Richmond, CA 94804-6403

Thank you for your cooperation.

Tear Here

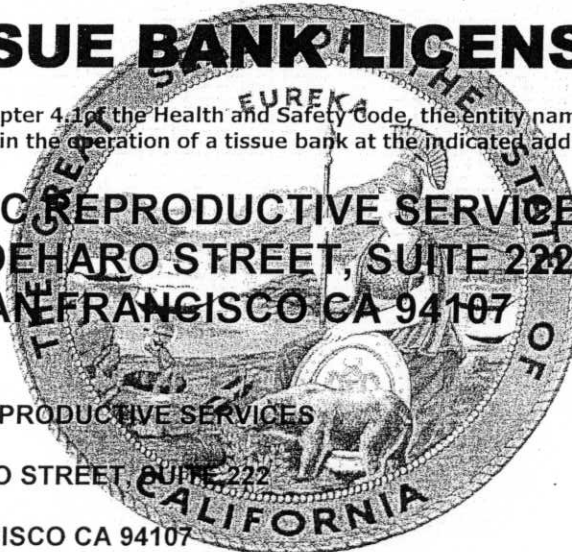
Tear Here

**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 operation of a tissue bank at the indicated address

**PACIFIC REPRODUCTIVE SERVICES  
444 DEHARO STREET, SUITE 222  
SAN FRANCISCO CA 94107**Owner(s) Name: **PACIFIC REPRODUCTIVE SERVICES**Address: **444 DEHARO STREET, SUITE 222**City, State, Zip: **SAN FRANCISCO CA 94107**TISSUE BANK ID NUMBER: **CNC 80069**Issuance Date: **NOVEMBER 18, 2009**Expiration Date: **NOVEMBER 17, 2010**

Tissue Bank Director:

**SHERRON L. MILLS**  
Ronald Harkey, Chief, Tissue Bank Licensing Section  
Laboratory Field Services

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

LABORATORY NAME AND ADDRESS

PACIFIC REPRODUCTIVE SERVICES  
65 NORTH MADISON AVENUE SUITE 610  
PASADENA, CA 91101-2038

CLIA ID NUMBER

05D0856634

EFFECTIVE DATE

02/05/2009

LABORATORY DIRECTOR

MADELYN KAHN MD

EXPIRATION DATE

02/04/2011

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.



*Judith A. Yost*

Judith A. Yost, Director  
Division of Laboratory Services  
Survey and Certification Group  
Center for Medicaid and State Operations

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- If this is a Certificate of Registration, it represents only the enrollment of the laboratory in the CLIA program and does not indicate a Federal certification of compliance with other CLIA requirements. The laboratory is permitted to begin testing upon receipt of this certificate, but is not determined to be in compliance until a survey is successfully completed.
- If this is a Certificate for Provider-Performed Microscopy Procedures, it certifies the laboratory to perform only those laboratory procedures that have been specified as provider-performed microscopy procedures and, if applicable, examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.
- If this is a Certificate of Waiver, it certifies the laboratory to perform only examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.



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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.

**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

*Tissue Bank ID No.: GA097*

**Tissue Bank Director: Sherron Mills, N.P.**

**Medical Director: Madelyn Kahn, M.D.**

**Pacific Reproductive Services  
65 North Madison Avenue, Suite 610  
Pasadena, CA 91101**

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

**Comprehensive Tissue Procurement Service  
Tissue Processing Facility**

**Reproductive tissue - semen only  
Reproductive tissue - semen only**

**Issued: January 19, 2007**

**Expired: February 1, 2011**

**DOH-5908 (04/2001)**

Property of the New York State Department of Health.

**Owner: Pacific Reproductive Services, Inc.**

Valid only at the address shown. Must be conspicuously posted.

Received Time Aug. 14. 5:21PM