

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE**1. REGISTRATION NUMBER**
(FDA Establishment Identifier)**2. REASON FOR SUBMISSION**

VALIDATION--FOR FDA USE ONLY

**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)**

FEI: 3005108367

- a. ☐ INITIAL REGISTRATION / LISTING
 b. ☒ ANNUAL REGISTRATION / LISTING
 c. ☐ CHANGE IN INFORMATION
 d. ☐ INACTIVE

VALIDATED BY FDA:24-DEC-2015
 DISTRICT: Los Angeles
 PRINTED BY FDA:22-JAN-2016

PART I - ESTABLISHMENT INFORMATION**3. OTHER FDA REGISTRATIONS**

a. BLOOD FDA 2830 NO. _____
 b. DEVICES FDA 2891 NO. _____
 c. DRUG FDA 2656 NO. _____

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)

Pacific Reproductive Services, Inc

65 North Madison Avenue
 Suite 610
 Pasadena, California 91101

a. PHONE 626-432-1681 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 M. Mills
 444 DeHaro 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 M. Mills

b. E-MAIL smills@pacrepro.com

c. TITLE Owner

d. DATE 23-DEC-2015

PART II - PRODUCT INFORMATION**10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps**

Types of HCT / Ps

Establishment Functions

	Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/PS DESCRIBED IN 21 CFR 1271.10	12. HCT/PS REGULATED AS MEDICAL DEVICES	13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
a. Bone												
b. Cartilage												
c. Cornea												
d. Dura Mater												
e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
f. Fascia												
g. Heart Valve												
h. Ligament												
i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
j. Pericardium												
k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
l. Sclera												
m. Semen <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous	X	X		X	X	X	X	X	X			
n. Skin												
o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
p. Tendon												
q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
r. Vascular Graft												
s.												
t.												
u.												
v.												

DEPARTMENT OF PUBLIC HEALTH

850 Marina Bay Parkway, Bldg P, 1st 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
3015 WILLIAMS DR STE 110
FAIRFAX, VA 22031

ATTN: STEPHEN POOL, PHD

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, 1st 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, 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
65 N. MADISON AVENUE, STE 610
PASADENA, CA 91101

Owner(s) Name: GENETICS & IVF INSTITUTE, INC.

Address: 3015 WILLIAMS DRIVE

City, State, Zip: FAIRFAX, VA 22031

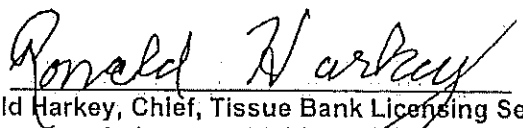
TISSUE BANK ID NUMBER: CNC 80421

Issuance Date: AUGUST 24, 2016

Expiration Date: AUGUST 23, 2017

Tissue Bank Director:

STEPHEN POOL, PHD


Ronald Harkey, Chief, Tissue Bank Licensing Section
Laboratory Field Services

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

Tissue Bank ID No.: GA097

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

Medical Director:
Rudolfo Quintero, 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

Semen from donors and client-depositors
Semen from donors and client-depositors

Issued: March 25, 2016

Owner: Pacific Reproductive Services, Inc.

Expires: April 1, 2018

Property of the New York State Department of Health. Valid only at the address shown. Must be conspicuously posted.

DOH-3908 (04/2001)



**MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF HEALTH CARE QUALITY**

**SPRING GROVE CENTER
BLAND BRYANT BUILDING
55 WADE AVENUE
CATONSVILLE, MD 21228-4663**

TISSUE BANK PERMIT

NUMBER: TB1639 EFFECTIVE PERIOD: 07/01/2014 - 06/30/2015

*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:*

**Pacific Reproductive Services
65 N MADISON AVE, STE 610
PASADENA, CA 91101**

Director: Dr RODOLFO QUINTERO

Owner: SHERRON MILLS

For operating, representing or servicing the following Tissue Bank Classes:

Reproductive Tissue Bank:

Sperm

CONTROL: 56212

Patricia Tomasko May, MD
Director

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

CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF WAIVER

LABORATORY NAME AND ADDRESS

PACIFIC REPRODUCTIVE SERVICES
65 NORTH MADISON AVE STE 610
PASADENA, CA 91101-2038

CLIA ID NUMBER

05D0856634

EFFECTIVE DATE

02/05/2015

LABORATORY DIRECTOR

RODOLFO QUINTERO M.D.

EXPIRATION DATE

02/04/2017

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.



Karen W. Dyer
Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality