

Establishment: _____

Address: _____

Phone: _____ Fax: _____

This agreement is to document facilities which the above named establishment contracts with (California Cryobank, Inc.) in the processing, production, handling, testing, transport, or storage of HCT/Ps.

Establishment Name: **California Cryobank, Inc.**
Address: **11915 La Grange Avenue**
Address: **Los Angeles, CA 90025-5213**
Phone: **(310) 496-5686**
Fax: **(888) 317-4729**
ATTN: Compliance Manager

This facility: Is not required to hold a CLIA license

Holds a current CLIA License

CLIA Number: 05D0542313

Issuing Agency: Centers for Medicare and Medicaid Services

Director: Charles Sims, M.D.

This facility is not registered with the FDA as a HCT/P establishment

This facility is currently registered with the FDA as a HCT/P establishment
Registration Number: 3005342355 (La Grange Headquarters)

FDA establishment registration functions include:

Recover Screen Test * Package Store Label Distribute

I agree California Cryobank will maintain FDA registration for HCT/Ps as required.

In addition, California Cryobank will remain compliant with all regulations governing the manufacture of HCT/Ps.

*If "test" is marked above as per FDA regulations, we use only FDA approved screening tests for donor testing. Tests are conducted and interpreted as per manufacture recommendations. On page 2 of this agreement I have listed the tests performed for _____ to be used for donor eligibility determination.

I agree to notify _____ within 5 business days of any change in our status.

Responsible Person Signature: _____ Date: _____

All infectious disease testing for donor eligibility is performed at ViroMed Laboratories.

All licenses and registrations can be viewed at www.cryobank.com.

Test HIV-1/HIV-2 antibody Format EIA
Tradename(s) Genetic Systems™ HIV-1/HIV-2 PLUS O EIA Sample: Serum, Plasma, Cadaveric serum
Manufacturer Bio-Rad Laboratories Use Donor Screen

Test Hepatitis B Surface Antigen Format EIA
Tradename(s) Genetic Systems™ HBsAg EIA 3.0 Sample Serum, Plasma, Cadaveric serum
Manufacturer Bio-Rad Laboratories Use Donor Screen

Test Hepatitis B core antibody Format EIA
Tradename(s) ORTHO® HBc ELISA Test System Sample Serum, Plasma
Manufacturer Ortho-Clinical Diagnostics, Inc. Use Donor Screen

Test Hepatitis C antibody Format EIA
Tradename(s) ORTHO HCV (Version 3.0 ELISA) Sample Serum, Plasma, Cadaveric serum
Manufacturer Ortho-Clinical Diagnostics, Inc. Use Donor Screen

Test HTLV I/II antibody Format ChLIA
Tradename(s) Abbott PRISM HTLV-I/HTLV-II Sample Serum, Plasma
Manufacturer Abbott Laboratories Use Donor Screen

Test RPR Format Flocculation
Tradename(s) BD Macro-Vue™ RPR Sample Serum, Plasma
Manufacturer Becton Dickinson (BD) Use Donor Screen

Test CMV Format Solid phase red cell adherence
Tradename(s) Capture-CMV® Sample Serum, Plasma
Manufacturer Immucor, Inc. Use Donor Screen

Test HIV-1/HCV NAT Format TMA
Tradename(s) Procleix® HIV-1/HCV Assay Sample Plasma, Cadaveric serum/plasma
Manufacturer Gen-Probe Use Donor Screen

Test Chlamydia trachomatis/Neisseria gonorrhoeae Format TMA
Tradename(s) APTIMA Combo 2® Sample Genital swabs, urine
Manufacturer Gen-Probe Use Diagnosis

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