



DATE EFFECTIVE: 12/31/11	Cryogenic Laboratories, Inc. Contract Establishment Agreement	FORM: QAP.70f REV: A.01
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Facility Name: _____

Facility Address: _____

City, State Zip Code: _____

This agreement is to document facilities which Facility Name: _____ contracts with in the processing, production, handling, testing, transport, or storage of HCT/Ps.

Establishment Name: Cryogenic Laboratories, Inc.

Address: 1944 Lexington Ave North

Address: Roseville, MN 55113

Phone: 800-466-2796

Fax: 651-489-8989

This facility: Is not required to hold a CLIA license
 Holds a current CLIA license (semen analysis only)
CLIA Number: 24D0399536
Issuing Agency: Minnesota Department of Health
Director: David Karabinus, Ph.D. (HCLD)

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: 3000243835

FDA establishment registration functions include:

Recover Screen Test * Package Store Label Distribute

I agree Cryogenic Laboratories will maintain FDA registration for HCT/Ps as required. In addition, Cryogenic Laboratories will remain compliant with all regulations governing the manufacture of HCT/Ps.

Facility Name: _____ agrees to notify Cryogenic Laboratories, Inc. within 48 hours of any finding from an audit or inspection which effects HCT/Ps distributed by Cryogenic Laboratories, Inc.

* While Cryogenic Laboratories does not directly perform "testing" we do contract with a FDA registered testing facility using only FDA approved screening tests for donor testing. Tests are conducted and interpreted as per manufacture recommendations.

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

Responsible Person Printed Name: _____

Responsible Person Signature: _____ **Date:** _____