

DATE EFFECTIVE: 12/31/11	<b>Fairfax Cryobank Contract Establishment Agreement</b>	<b>FORM: QAP.70e REV: B.01</b>
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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: Fairfax Cryobank**  
**Address: 3015 Williams Drive, Suite 110**  
**Address: Fairfax, VA 22031**  
**Phone: 703-698-3976**  
**Fax: 703-698-3933**

This facility:  Is not required to hold a CLIA license  
 Holds a current CLIA license (semen analysis only)  
**CLIA Number: 49D1102767**  
**Issuing Agency: Virginia Department of Health**  
**Director: William Roudebush, 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: 3004731690

FDA establishment registration functions include:

Recover    Screen    Test \*    Package    Store    Label    Distribute

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

Facility Name: \_\_\_\_\_ agrees to notify Fairfax Cryobank, Inc. within 48 hours of any finding from an audit or inspection which effects HCT/Ps distributed by Fairfax Cryobank, Inc.

\* While Fairfax Cryobank does not directly perform "testing" we do contract with a FDA registered, CLIA licensed 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: \_\_\_\_\_