

National Physicians Cooperative of the Oncofertility Consortium[®]

Section 10. Sample Labeling

Date Adopted	Supersedes Procedure #
3/18/2009	2/3/2009

Review Date	Print Name	Signature

Background

1. FDA regulations define that patient samples must be labeled and segregated according to infectious disease status. If the infectious disease status is not known, that still must be noted.
2. All cryopreserved patient and research materials will be stored at Reprotech, Ltd.
3. The results of the infectious disease testing must be available before shipping the tissue to Reprotech and the samples and canes must be labeled appropriately.
4. All patient samples will be labeled and identified for patient's own future use.
5. **Technical Note:** We recommend the use of a Brady Labeler with Label Number PTL-21-427 ONLY (these are LN2 Safe). If a labeler is not available, these same labels may be hand written.

Sample Labeling:

Center Specific Labeling for Patient and Plasma Samples:

1. Each center will create a 2-5 letter designation code that is unique to their center to be used in patient and plasma sample labeling (e.g. PENN or UCSD). Please use the designation as a prefix for sample labeling of all patient and plasma samples. Please ONLY use the CODE that you create (this is the same CODE as is listed in your Reprotech agreement).
2. Develop an accession log in which patient and plasma samples are assigned a unique identifying number that is a consecutive number starting with 001.
3. Assign each patient and plasma sample a unique identifier that consists of your center prefix and the unique number assigned in step 2 above (e.g. PENN 001). Use this unique identifier on all patient and plasma vials. For example, the first patient at UCSD is UCSD-001.
4. Do not use the patient's hospital number, medical record number, or social security number on any of the samples.

Vials

Patient samples; ovarian tissue

- Label 1.8ml Nunc CryoTube vials with:
 1. Patient's last name
 2. Patient's first name
 3. Unique identification number with center specific prefix
 4. Date of freezing
 5. Date of birth
 6. OVARY
 7. Number of the vial: "# of #" (e.g. 1 of 20, 2 of 20, etc. – a single ovary is generally frozen in 20 vials)
 8. Number of pieces of tissue/vial (assume three, if not noted otherwise)
 9. NOTE: If Brady Labeler (or other label machine) is used, write patient's last name and ID number on the vial before affixing the printed label

Patient samples; plasma (these samples are banked with patient tissue samples)

- Label 1.8ml Nunc CryoTube vials with:
 1. Patient's last name
 2. Patient's first name
 3. Unique identification number with center specific prefix
 4. Date of freezing
 5. Date of birth
 6. PLASMA
 7. Number of the vial: "# of #" (e.g. 1 of 4, 2 of 4, etc. – plasma is generally frozen in 4 vials)
 8. NOTE: If Brady Labeler (or other label machine) is used, write patient's last name and ID number on the vial before affixing the printed label

Cane Labeling:

General Comments

- All samples should be placed on standard "silver" colored canes
- Please mark canes with **black** Cryomarker (no blue, red, etc.)
- Cane tag color indicates infectious disease status of the sample
- ALL tissue should be considered infectious disease status unknown and stored as such until proven otherwise
- Cane and cane tag should have patient's last name, date of freeze, and cane number for that patient
- As infectious disease results become available, a cane tag should be added to the cane. Infectious disease testing must be complete before shipping the patient samples to Reprotech.
- All samples of LIKE cane tag color should be stored in the same canister under liquid nitrogen
- Samples on canes should **not** be lifted beyond the neck of the liquid nitrogen storage tank to add the cane tag

Cane Labeling Color Scheme

1. **NO CANE TAG**--Infectious Disease Testing Unknown. When tissue is frozen, cane will be labeled *without* a cane tag on the stainless steel top.
2. **WHITE Cane Tag**-- **Research** Tissue: Infectious Disease Status Known: all results negative/non-reactive. *SEE NOTE
3. **GREEN Cane Tag**-- **Patient** Tissue: Infectious Disease Status Known: all results negative/non-reactive.
4. **RED Cane Tag**-- **Patient** Tissue: Infectious Disease Status Known: one or more results positive/ reactive.
5. **YELLOW Cane Tag**-- **Research** Tissue: Infectious Disease Status Known: one or more results positive/ reactive. *SEE NOTE
6. **BLUE Cane Tag**-- Patient **Plasma** Sample. Store with patient tissue samples.

Technical Notes

1. *NOTE: A positive CMV result does not make a tissue donor ineligible. Therefore, if patient tests positive for CMV, their samples should be labeled as if they are "Infectious Disease Status Known: all results negative/non-reactive."
2. All frozen samples, including patient tissue, research tissue, and plasma samples should be shipped together to long term storage at Reprotect. In some cases, research tissue may be shipped to an alternate location at the direction of the NPC Administrative Unit.
3. Legibility of cane labels and vial labels is essential.
4. In placing sample labels on the vial, be certain that the top of the fluid meniscus is visible for seeding.
5. When ordering cane tags, be sure that the blue and green tags are light in color so that labeling is visible.
6. **SAMPLE LABELS: See separate page.**