DONOR ELIGIBILITY SYSTEM
BY EVERSANA

# Reproductive Cells and Tissues Labeling Matrix

The labeling recommendations summarized in the matrix below are intended solely as an aid to the client in determining appropriate labeling for reproductive HCT/Ps. It should be used as augmentation to the actual FDA regulations and guidance documents.

| Eligibility Status | Storage Labeling* | HCT/P Container Labeling (in addition to Yws storage labeling) | Distribution Labeling (in addition to storage labeling) |
|---|---|---|---|
| Donor Eligibility Not Required | Autologous Use:<br>1. "FOR AUTOLOGOUS USE ONLY"; and<br>2. "NOT EVALUATED FOR INFECTIOUS SUBSTANCES" (Unless you have performed all screening/testing).<br>Sexually Intimate Partner (SIP):<br>1. "NOT EVALUATED FOR INFECTIOUS SUBSTANCES" (Unless you have performed all screening/testing); and<br>2. "WARNING: Advise patient of communicable disease risks" (If screening/testing has not been performed, or if results of screening/testing indicate presence of risk factor for communicable disease); and<br>If screening and testing was performed, additional warning labeling if applicable:<br>1. "WARNING: Reactive test results for (name of disease)"<br>2. Biohazard Legend (if results of testing or screening indicate presence of risk factor for communicable disease). | 1. A distinct identifier (i.e., number, name, medical record number, etc.) that relates the HCT/P to all applicable records. | |

*Where physically impossible to include warnings on container labels, warning may be placed on labeling that accompanies the HCT/P. FDA has acknowledged this necessity because the containers for some HCT/Ps, such as those used for semen cryopreservation, are so small that they do not accommodate the warning language. In addition, the use of a tie-tag with warning language may not be feasible because it is difficult to securely attach to a container stored in liquid nitrogen. In such cases, the warning language may accompany the HCT/P.

ADDITIONAL LABELING:

If reproductive tissue will be donated to a directed recipient under 1271.90(a)(3) or a directed or anonymous donation Should be under 1271.90(a)(4) or 1271.90(b), and the screening and testing is performed before transfer to the recipient rather than at the time of recovery, then under 1271.90(c)(6) you must label the HCT/P: "Advise recipient that screening and testing of the donors were not performed at the time of cryopreservation of the reproductive cells or tissue, but have been performed subsequently."

| | | | |
|---|---|---|---|
| Donor Eligibility Pending | 1. Quarantine: Donor Eligibility Determination Not Complete | 1. For Autologous, SIP, Directed Donation: A distinct identifier (i.e., number, name, medical record number, etc.) that relates the HCT/P to all applicable records.<br>2. For Anonymous Donation: A distinct identification code (i.e., does not reveal information that could be used to identify the donor) affixed to the container that relates the HCT/P to all applicable records. | 1. HCT/P must not be implanted, transplanted, infused or transferred until the donor eligibility determination is complete. |
| Donor Eligible | 1. Eligible HCT/Ps<br>2. Records referenced in 1271.55 must accompany an HCT/P at all times. | 1. For Autologous, SIP, Directed Donation: A distinct identifier (i.e., number, name, medical record number, etc.) that relates the HCT/P to all applicable records.<br>2. For Anonymous Donation: A distinct identification code (i.e., does not reveal information that could be used to identify the donor) affixed to the container that relates the HCT/P to all applicable records. | 1. Records referenced in 1271.55 must accompany an HCT/P when placed into distribution. |
| Donor Ineligible | 1. "Quarantine: Ineligible HCT/Ps<br>2. "WARNING: Advise patient of communicable disease risks"; and<br>3. Biohazard Legend.<br>4. Records referenced in 1271.55 must accompany an HCT/P at all times.<br>If testing was reactive:<br>1. "WARNING: Reactive test results for (name of disease agent or disease)". | 1. For Autologous, SIP, Directed Donation: A distinct identifier (i.e., number, name, medical record number, etc.) that relates the HCT/P to all applicable records.<br>2. For Anonymous Donation: A distinct identification code (i.e., does not reveal information that could be used to identify the donor) affixed to the container that relates the HCT/P to all applicable records | 1. Records referenced in 1271.55 must accompany an HCT/P when placed into distribution. |
| Non-Clinical Use | 1. "For Non-Clinical Use Only"; and<br>2. Biohazard Legend. | 1. A distinct identifier that relates the HCT/P to all applicable records. | |

*Where physically impossible to include warnings on container labels, warning may be placed on labeling that accompanies the HCT/P. FDA has acknowledged this necessity because the containers for some HCT/Ps, such as those used for semen cryopreservation, are so small that they do not accommodate the warning language. In addition, the use of a tie-tag with warning language may not be feasible because it is difficult to securely attach to a container stored in liquid nitrogen. In such cases, the warning language may accompany the HCT/P.

ADDITIONAL LABELING:

If reproductive tissue will be donated to a directed recipient under 1271.90(a)(3) or a directed or anonymous donation Should be under 1271.90(a)(4) or 1271.90(b), and the screening and testing is performed before transfer to the recipient rather than at the time of recovery, then under 1271.90(c)(6) you must label the HCT/P: "Advise recipient that screening and testing of the donors were not performed at the time of cryopreservation of the reproductive cells or tissue, but have been performed subsequently."