

CHANGES TO AATB STANDARDS FOR TISSUE BANKING

SECTION E - PROCESSING, PRESERVATION, QUARANTINE, AND STORAGE

E3.000 QUARANTINING

Current (13th edition)

E3.200 Situations Requiring Quarantine

Human tissue shall be *Quarantined* until the tissue is either determined to be suitable for transplantation or appropriate *Disposition* is accomplished. All tissue shall be *Quarantined* until the following criteria for donor suitability are satisfied:

- 1) All required infectious disease testing has been completed, reviewed by the *Responsible Person*, and found to be negative or non-reactive; and
 - 2) Donor screening has been completed, reviewed by the *Responsible Person*, and determined to indicate freedom from risk factors for and clinical evidence of HIV, hepatitis B, and/or hepatitis C infection.
- (R) Tissues from *Client Depositors* known to be reactive on tests for anti-HIV-1, anti-HIV-2, anti-HTLV-I, anti-HTLV-II, anti-HCV, or HBsAg shall be stored in a physically separated area clearly identified from tissue of seronegative *Client Depositors*. Release of such tissues shall require the *Informed Consent* of the *Recipient* and her physician. *Cryopreserved Reproductive Tissues* from untested *Client Depositors* shall be stored in a physically separate area clearly defined from those of tested *Client Depositors*.

Tissue shall be *Quarantined* at any phase of the operation when its release could affect the *Safety*, effectiveness, or quality of the tissue, and subsequently, the health of the *Recipient*. The following tissue shall be *Quarantined*:

- 1) Tissue that is pending completion of *Processing*, packaging, *Preservation*, or labeling and final-release-approval signature;
- 2) Tissue collected from donors not meeting established donor suitability criteria, including unacceptable test results;
- 3) Tissue involved in a *Recall* pending investigation, documentation, and *Resolution*;
- 4) Tissue failing to meet technical or *Quality Assurance* specifications;
- 5) Tissue pending discard as medical waste; and
- 6) Tissue returned by a *Consignee*, pending evaluation.

(with amendments)

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- (R) *Cryopreserved Reproductive Tissues from untested Client Depositors shall be stored in a physically separate area clearly defined from those of tested Client Depositors.* Tissues from *Client Depositors* known to be reactive on tests for anti-HIV-1, anti-HIV-2, ~~anti-HTLV-I, anti-HTLV-II,~~ anti-HCV, or HBsAg *or any other test excluding CMV without subsequent negative confirmatory testing as approved by the Reproductive Tissue Bank's Medical Director* shall be stored in a physically separated area clearly identified from tissue of seronegative *Client Depositors*. *See F2.200 for documentation required for release.* ~~Release of such tissues shall require the *Informed Consent* of the *Recipient* and her physician. *Cryopreserved Reproductive Tissues* from untested *Client Depositors* shall be stored in a physically separate area clearly defined from those of tested *Client Depositors*.~~

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(as amended)

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