

CHANGES TO AATB STANDARDS FOR TISSUE BANKING
14th Edition

SECTION E
PROCESSING AND STORAGE

Current (14th Edition)

E3.000 STORAGE

E3.200 Segregation of Tissue

The *SOPM* *must* address whether the segregation of *tissue* during *storage* is indicated and how it will be appropriately segregated to avoid contamination, *cross-contamination* and mix-ups.

Except for *reproductive tissue*, considerations for assessment of risk include, where applicable:

- 1) *donor* infectious disease test results are unavailable or this testing will not be performed;
- 2) the intended use of the *tissue* is primarily for *transplantation* or is restricted to research or education;
- 3) *autologous tissue* is segregated from *allogeneic tissue*;
- 4) the *donor* has been determined to be ineligible;
- 5) the ability of *packaging* and *labeling* to withstand *storage* temperatures; and/or
- 6) the ability to *decontaminate storage* equipment or the *storage* area should an *accident* occur.

Appropriate segregation *must* include considerations above and *storage* *must* be in clearly defined and labeled areas (shelves or compartments) of the *storage* equipment or *storage* area.

(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-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.

With Amendments

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As Amended

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