

CHANGES TO AATB STANDARDS FOR TISSUE BANKING

SECTION D - ACQUISITION OF TISSUE: AUTHORIZATION, INFORMED CONSENT, DONOR SCREENING, AND TISSUE RECOVERY AND COLLECTION

D4.000 DONOR SUITABILITY

D4.300 Disease Screening

D4.350 Blood Tests

Current (13th edition)

D4.351 Specimens

Except as otherwise specified in tissue-specific standards, infectious disease testing of donor blood specimens shall be performed for each tissue donor (including maternal donors of *Fetal Tissue* or neonatal tissue), on a specimen collected at the time of donation or within seven days prior to or after donation. If the donor is one month (28 days) of age or less, a blood specimen from the birth mother must be collected within seven days prior to or after tissue donation and tested instead of a specimen from the donor. There shall be written procedures for all significant steps in the infectious disease testing process, including collection and use of appropriate blood specimen types and instructions for specimen handling. Procedures shall conform to the manufacturer's instructions for use contained in the package inserts. Specimen collection, storage, and handling procedures shall be described in the *SOPM*.

- (R) For oocytes, the donor blood specimen must be collected within 30 days prior to oocyte retrieval, or within 7 days post donation. For repeat *Semen Donor* requirements, see D4.360 Repeat Testing of *Living Donors* (R).

(with amendments, relevant part only)

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(as amended, relevant part only)

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