

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)

D4.354 Required Infectious Disease Tests

Excluding autologous tissue, oocytes and embryos, all human tissue intended for transplantation shall be from donors who are tested and found to be negative for:

- 1) antibodies to the human immunodeficiency virus, type 1 and type 2 (anti- HIV-1 and anti-HIV-2);
- 2) nucleic acid test (NAT) for HIV-1;
- 3) hepatitis B surface antigen (HBsAg);
- 4) total antibodies to hepatitis B core antigen (anti-HBc—total, meaning IgG and IgM);
- 5) antibodies to the hepatitis C virus (anti-HCV);
- 6) nucleic acid test (NAT) for HCV; and
- 7) syphilis (a non-treponemal or treponemal-specific assay may be performed).

Donors of viable leukocyte-rich tissue (e.g., semen) shall also be tested and found to be negative for antibodies to human T-lymphotropic virus type I and type II (anti-HTLV-I and anti-HTLV-II). Note: HTLV testing of donors of other tissue types may be required by law and/or regulation, including, where applicable, foreign laws and/or regulations.

All test results shall be documented in the donor's record.

(with amendments)

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- 5) antibodies to the hepatitis C virus (anti-HCV);
- 6) nucleic acid test (NAT) for HCV; and
- 7) syphilis (a non-treponemal or treponemal-specific assay may be performed).

Donors of viable leukocyte-rich tissue (e.g., semen, *certain (CT)*) shall also be tested and found to be negative for antibodies to human T-lymphotropic virus type I and type II (anti-HTLV-I and anti-HTLV-II). Note: HTLV testing of donors of other tissue types may be required by law and/or regulation, including, where applicable, foreign laws and/or regulations.

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