



New York State Tissue Resources Program

Policy – HTLV-I testing

Effective date – 09/30/2020

Valid until – Regulatory or policy change supersedes this policy

Donors of tissues that are not leukocyte-rich need not be tested for HTLV-I for purposes of donor selection and tissue distribution.

10 NYCRR Subdivisions 52-3.4(c)(1), 52-4.7(a), 52-5.7(a), 52-6.7(a), and 52-9.5(c) require that donors of allogeneic tissue be tested for antibodies to human T-lymphotropic virus type I (HTLV-I) for purposes of donor selection. Subdivisions 52-3.4(c)(2), 52-4.9(a)(1), 52-5.9(a)(1), 52-6.9(a)(1), and 52-9.5(a) stipulate that tissue not be made available for transplantation unless the donor's blood reacts negatively in the HTLV-I test. HTLV-I is found only in lymphocytes, a subset of leukocytes. Based on this, FDA currently requires HTLV-I testing of donors of leukocyte-rich tissues only.

The Department will no longer enforce the requirement that donors of tissues that are not rich in leukocytes be tested for HTLV-I. Additionally, the Department will allow distribution for clinical use/transplantation of such tissues from donors who were not tested for HTLV-I.

The Department will continue to enforce the HTLV-I requirements as currently written in 10 NYCRR Part 52 for donors of leukocyte-rich tissues.