

**DEPARTMENT OF PUBLIC HEALTH**

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## Advisory Note - Tissue Bank Licensure Process

Re: Policy Statements/Procedures for Sexually Transmitted Diseases testing and Interpretation of Results:

The policy statement for all tissue banks licensed in the state of California regarding the testing and evaluation of prospective donors for sexually transmitted disease (STD) markers MUST contain the following statement and reference:

“It is the policy of     (your tissue bank name)     that no tissues shall be transferred into the body of another person by means of transplantation unless the donor of the tissues has been screened and found nonreactive by laboratory tests for evidence of infection with human immunodeficiency virus (HIV), agents of viral hepatitis (HBV and HCV), and syphilis. For tissues that are rich in viable leukocytes, the tissue shall be tested for evidence of infection with human T lymphotropic virus (HTLV) and found nonreactive.” (Reference: California Health and Safety Code §1644.5(a))

**This policy statement must be on your own letterhead, signed and dated by your tissue bank director.**

Please note that such a policy is required whenever the non-autologous human tissue is to be transplanted, including reproductive tissues (ova, sperm, (or semen), embryos) and donor milk. This policy statement is required even if you purchase fully processed tissue and do not do any testing at your facility.

You may use the language as contained in quotes above inserting the name of your institution or you may paraphrase, as long as the resulting language contains the same meaning as above and includes as a minimum the five disease markers listed above. You must always include a reference to the California Health and Safety Code §1644.5(a) at the conclusion of any STD policy statement.

If your ART facility allows the legal exceptions to this law as specified in H & S Code § 1644.5 (c) & (d), you may so state. However, your policies and procedures must specify the procedures your facility will follow to comply with the mandates as specified in these statutes.

Please note: it is not considered adequate to simply state that testing for HIV Syphilis, HBV, HCV, and HTLV-1 is performed. You MUST include a statement regarding your actions (or an outcome algorithm) depending upon the outcome and evaluation of the test findings. For example, when you test for the above disease markers, you must state that for any individual who does not show a non-reactive result for any of these markers, that individual's tissue shall not be used for purposes of transplantation unless otherwise excepted in statute.