

Adopt

**Title 17. Public Health
Division 1. State Department of Health Services**

**Chapter 2. Laboratories
Subchapter 1. Service Laboratories**

Group 10. Facilities Processing Sperm from Donors with Sexually Transmitted Infections.

Adopt Section 1235 as follows:

Section 1235. Definitions.

The following definitions shall apply to this article:

(a) "Antiretroviral therapy" means the treatment of patients prophylactically or with known retroviral infections with a combination of drugs to suppress the virus and stop the progression of the disease.

(b) "Assisted reproductive technology" (ART) means conception promoted by artificial or partially-artificial means, such as *in vitro* fertilization and intrauterine insemination.

(c) "Reactive" means the diagnostic finding that antibodies to an infectious disease have been detected in an individual in response to an infectious agent, such as HIV or HTLV.

(d) "Serodiscordant" means a sperm donor and recipient who differ in their antibody screening tests for sexually transmitted diseases, in which one tests reactive and the other, nonreactive.

(e) "Sexually transmitted infections" means viral infections that can be transmitted through sexual contact, including human immunodeficiency viruses (HIV) types 1 and 2, human T-cell lymphotropic viruses (HTLV) types 1 and 2, hepatitis A virus (HAV), hepatitis B virus (HBV), hepatitis C virus (HCV), human papilloma virus (HPV), Epstein Barr virus (EBV), herpes simplex virus (HSV) type 2, and human herpes viruses (HHV) types 6 and 8.

(f) "Sperm washing" means the process of separating sperm from the seminal fluid by centrifugation and re-suspension, density gradient centrifugation, direct swim-up techniques, or other processes that render sperm free from seminal fluid.

Note: Authority cited: Sections 1639, 1644.5, and 131200, Health and Safety Code.
Reference: Sections 1644.5, 131050, and 131051, Health and Safety Code.

Adopt Section 1236 as follows:

Section 1236. Standards for Handling and Storage of Sperm from Donors Reactive for HIV or HTLV.

(a) All donors of sperm shall be screened and found nonreactive by laboratory tests for evidence of infection pursuant to section 1644.5(a) of the Health and Safety Code, prior to initiation of insemination or ART services.

(b) For a serodiscordant donor and recipient in which the recipient tests nonreactive and the donor tests reactive for HIV or HTLV, the facility providing insemination or ART services shall be responsible for the following:

(1) Maintaining a current and valid tissue bank license issued under chapter 4.1 of division 2 of the Health and Safety Code.

(2) Processing, transferring, and storing sperm, ova, and zygotes used for insemination or ART where either the donor or recipient has tested reactive for HIV or HTLV in an area of the facility separate from specimens not infected.

(3) Processing sperm from a donor who has tested reactive for HIV or HTLV using protocols to minimize the infectiousness of the sperm as specified in subdivision (c) of this section.

(c) A facility providing insemination or ART services shall only use sperm from a donor who has tested reactive for HIV or HTLV when the sperm is processed according to the standards set forth in "Recommendations for Reducing the Risk of Viral Transmission During Fertility Treatment with the Use of Autologous Gametes: A Committee Opinion," published by the American Society for Reproductive Medicine (ASRM) in 2012 and available at <https://www.asrm.org/Guidelines>.

(d) Any amendments to the 2012 publication of "Recommendations for Reducing the Risk of Viral Transmission During Fertility Treatment with the Use of Autologous Gametes: A Committee Opinion," any later editions, or any amendments thereto, published by ASRM shall become effective for all department-licensed facilities

providing insemination or ART services 90 days after publication by ASRM, unless the department provides written notice to the contrary to all such facilities.

Note: Authority cited: Sections 1639, 1644.5, and 131200, Health and Safety Code.
Reference: Sections 1644.5, 1644.6, 131050, and 131051, Health and Safety Code.

Adopt Section 1237 as follows:

Section 1237. Responsibility for Compliance.

(a) A licensed tissue bank that provides insemination or ART services, along with the owner(s) and director of the tissue bank, shall be responsible for the following when using sperm from a donor who has tested reactive for HIV or HTLV:

(1) Ensuring that the donor and recipient have each established an ongoing relationship with a qualified physician to provide for their medical care during and after completion of fertility services.

(2) Developing and implementing procedures for minimizing the infectiousness of sperm from donors who have tested reactive for HIV or HTLV, pursuant to the standards set forth in "Recommendations for Reducing the Risk of Viral Transmission During Fertility Treatment with the Use of Autologous Gametes: A Committee Opinion," published by ASRM in 2012 and available at <https://www.asrm.org/Guidelines>, and any amendments thereto or later-published editions or amendments thereto that become effective.

(3) Obtaining and documenting informed consent from the donor and recipient regarding the potential medical risks of using sperm from a reactive donor for the proposed procedure, prior to initiation of the procedure. Documentation of informed consent shall be maintained on file in the tissue bank for at least five (5) years.

(b) If a licensed tissue bank fails to comply with the requirements of this section, the department may initiate an action to suspend or revoke its license pursuant to section 1643.1 of the Health and Safety Code.

Note: Authority: Sections 1639, 1644.5, and 131200, Health and Safety Code.
Reference: Sections 1639.3, 1643, 1643.1, 1644.5, 1644.6, 131050, and 131051, Health and Safety Code.