

OCHSNER CLINIC

8/29/07

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076487.htm>

FDA Warning Letter:

- Failure to test a specimen from an anonymous or directed donor of reproductive cells or tissue to adequately and appropriately reduce the risk of transmission of relevant communicable disease agents of the genitourinary tract, including *Chlamydia trachomatis* and *Neisseria gonorrhoea*
- Failure of a responsible person to determine and document the eligibility of an anonymous or directed donor of reproductive cells or tissue
- Failure to screen an anonymous or directed donor of reproductive cells or tissue by reviewing the donor's relevant medical records for risk factors for, and clinical evidence of, relevant communicable disease agents and diseases
- Failure to collect a donor specimen for testing for relevant communicable diseases within 30 days before oocyte recovery or up to seven days after recovery
- Failure to retain documentation associated with communicable disease testing, donor screening for communicable diseases, and donor eligibility determination for donors of reproductive cells or tissue
- Failure to establish and maintain procedures for all steps you perform in testing, screening, determining donor eligibility, and to comply with all other requirements of Subpart C "Donor Eligibility" in 21 CFR 1271