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<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm161286.htm>

FDA Warning Letter:

- Failure to test a specimen from a 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 to test a specimen from the donor of viable, leukocyte-rich cells or tissue to adequately and appropriately reduce the risk of transmission of relevant communicable diseases
- Failure to collect a donor specimen for testing for relevant communicable diseases within 30 days prior to oocyte recovery or up to seven days after oocyte recovery or up to seven days before or after recovery of semen
- 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