

CENTER FOR FERTILITY AND GYNECOLOGY

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<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048105.htm>

FDA Warning Letter:

- Failure to test specimens from anonymous or directed reproductive donors using appropriate FDA-licensed, approved, or cleared donor screening tests
- Failure to test for Human T-lymphotropic virus, types I and II (HTLV-IM) and/or cytomegalovirus (CMV)
- Failure to test a specimen from donors **[redacted]**, **[redacted]** and **[redacted]** for *Chlamydia trachomatis* and *Neisseria gonorrhoea*
- Failure to collect a donor specimen for testing for relevant communicable diseases at the time of recovery of cells or tissue from the donor; or up to seven days before or after recovery
- 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 of a responsible person to determine and document the eligibility of an anonymous or directed donor of reproductive cells or tissue
- Failure to establish and maintain a standard operating procedure governing the release of an HCT/P from a donor whose specimen tests reactive for CMV