

Quest Diagnostics Donor Testing Services

FDA-REGISTERED FOR HUMAN BLOOD AND TISSUE DONOR TESTING (HCT/P)

Blood donors and donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps) – such as those involved in in vitro fertilization (IVF), sperm donations, or cellular or tissue implants – must be tested for infectious diseases. The U.S. Food and Drug Administration (FDA) requires laboratories performing infectious disease testing on donors be FDA Registered. These regulations are specified in 21 CFR (Code of Federal Regulations) Part 1271 which became effective on May 25, 2005. These rules have been developed to help ensure that all blood and cell/tissue donors are properly screened and tested to prevent the transmission of infectious disease from transplanted blood, cells or tissues.

HCT/Ps include bone, ligament, skin, dura mater, heart valves, cornea, lens, stem cells (peripheral blood and cord blood), manipulated autologous chondrocytes, epithelial cells (synthetic matrix), semen, ova or other reproductive tissue.

Blood and HCT/P testing is performed using a venous blood sample from the donor. This testing is not done on the HCT/P product, e.g. cord blood, sperm, cornea etc.

REQUIRED TESTS FOR BLOOD AND HCT/P DONORS:

All Donors	HIV-1 & 2 Antibody, HBV Surface Antigen, HBV Core Antibodies, HCV Antibody, Syphilis Antibody (Optional: HIV-1/HCV NAT)
Stem Cell and Cord Blood	All donor tests, HTLV - I/II Antibody, CMV Antibody
Egg (Reproductive Cells)	All donor tests, CT/NG NAT
Semen	All donor tests, HTLV - I/II Antibody, CMV Antibody, CT/NG NAT

Donor tests use different test codes than diagnostic tests for the same diseases. The donor test codes should not be used for routine clinical and routine diagnostic evaluations. Donor testing must be performed using assay kits that are FDA-approved or FDA-cleared specifically for donor screening. Tests that are currently approved by the FDA for diagnostic screening are not necessarily FDA-approved for screening HCT/P donors. Tests are performed Monday-Friday and reports are available 48-72 hours after receipt. FDA Established Identifiers (FEI): 3005010397

Test Name	Test Code	Specimen Requirements	Transport Temperature	CPT Codes*
Donor, Chagas', RIPA	19161X	1 mL serum	Refrigerated or frozen	86753
Donor, Chagas' Screen	19677X	1 mL serum	Refrigerated or frozen	86753
Donor, <i>Chlamydia trachomatis</i> / <i>Neisseria gonorrhoeae</i> , RNA, TMA	17385X	Aptima Unisex Endocervical and Urethral swab Aptima Vaginal Swab Aptima Urine Collection Kit	Refrigerated	87491 87591
Donor, Cytomegalovirus (CMV) Total Antibodies	17388Z	1 mL serum	Refrigerated or frozen	86644
Donor, Hepatitis B Core Total Antibodies	17378X	1 mL serum	Refrigerated or frozen	86704
Donor, Hepatitis B Surface Antigen**	17375X	1 mL serum	Refrigerated or frozen	87340
Donor, Hepatitis C Antibody (Anti-HCV)**	17382Z	1 mL serum	Refrigerated or frozen	86803
Donor, HIV 1 / 2 Antibody Screen**	17380X	1 mL serum	Refrigerated or frozen	86703
Donor, HTLV-I/II Antibody Screen	17379Z	1 mL serum	Refrigerated or frozen	86790
Donor, HIV-1/HCV NAT Procleix Multiplex	17746X	3 mL EDTA plasma or 3 mL PPT plasma (2 mL minimum)	Refrigerated or frozen	87801

continued

Test Name	Test Code	Specimen Requirements	Transport Temperature	CPT Codes*
Donor, RPR**	19119X	1 mL serum	Refrigerated or frozen	86781
Donor, West Nile Virus NAT	19412X	3 mL EDTA Plasma or 3 mL PPT plasma (2 mL minimum)	Refrigerated or frozen	87798
Donor, IVF Female Panel Includes: Donor, <i>C. trachomatis</i> and <i>N. gonorrhoeae</i> ; Donor, HIV 1-/2 Ab, Screen; Donor, Hep B Surface Ag; Donor, Hep B Core Total Ab; Donor, Hepatitis C Antibody (Anti-HCV); Donor, Rapid Plasma Reagin (RPR)	19103X	3 mL serum and Aptima™ Urine Specimen Collection Kit for Male or Female Urine Specimens or Unisex Swab Specimen Collection Kit for Endocervical and Urethral Swab Specimens or Vaginal Swab Specimen Collection Kit	Refrigerated or frozen	86592 86703 86704 86803 87340 87491 87591
Donor, IVF Male Panel Includes: Donor, <i>C. trachomatis</i> and <i>N. gonorrhoeae</i> ; Donor, HIV 1-/2 Ab, Screen; Donor, Hep B Surface Ag; Donor, Hep B Core Total Ab; Donor, Hepatitis C Antibody (Anti-HCV); Donor, Rapid Plasma Reagin (RPR); Donor, HTLV I-/II Antibody Screen; Donor, Cytomegalovirus (CMV) Total Antibodies	19102X	3 mL serum and Aptima™ Urine Specimen Collection Kit for Male or Female Urine Specimens or Unisex Swab Specimen Collection Kit for Endocervical and Urethral Swab Specimens or Vaginal Swab Specimen Collection Kit	Refrigerated or frozen	86592 86703 86704 86803 87340 86644 86790 87491 87591
Donor, Stem Cells Panel Donor, HIV 1-/2 Ab, Screen; Donor, Hep B Surface Ag; Donor, Hep B Core Total Ab; Donor, Hepatitis C Antibody (Anti-HCV); Donor, Rapid Plasma Reagin (RPR); Donor, HTLV I-/II Antibody Screen; Donor, Cytomegalovirus (CMV) Total Abs	19101X	3 mL serum	Refrigerated or frozen	86592 86703 86704 86803 87340 86644 86790
Donor, Tissue Donor Panel Includes: Donor, HIV 1-/2 Ab, Screen; Donor Hep B Surface Ag; Donor, Hep B Core Total Ab; Donor, Hepatitis C Antibody (Anti-HCV); Donor, Rapid Plasma Reagin	19094X	3 mL serum	Refrigerated or frozen	86592 86703 86704 86803 87340

* The CPT code provided is based on AMA guidelines and is for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

** If reactive or equivocal, this test will reflex to additional donor testing for confirmation at an additional charge

Nichols Institute Donor Testing Laboratory:
800-336-3718 ext. 4656

14225 Newbrook Drive
PO Box 10841
Chantilly, VA 20153-0841
703-802-6900
800-336-3718

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