Donor Transplant Eligibility: Laboratory Testing

Laboratory testing can help avoid transmission of infectious disease through transplanted human cells, tissues, and cellular and tissue-based products (HCT/Ps). Examples of HCT/Ps include hematopoietic stem cells derived from peripheral and cord blood, and reproductive HCT/Ps such as oocytes and semen. Testing helps avoid disease transmission by identifying diseases or disease agents in potential donors. Testing may also help avoid disease transmission through transplanted tissues with latent infections; immunosuppressive drugs used to prevent transplant rejection can reactivate such infections.[1,2]

The US Food and Drug Administration (FDA) and Organ Procurement Transplantation Network require testing of all donors of HCT/Ps for infections including HIV-1, HIV-2, hepatitis B virus (HBV), hepatitis C virus (HCV), and *Treponema pallidum* (syphilis); testing for West Nile virus (WNV) is required for living donors.[1] Depending on HCT/P type, requirements may also include testing for human T-lymphotropic virus (HTLV), cytomegalovirus, *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trypanosoma cruzi*, the parasite that causes Chagas disease (**Table 1**).[3,4]

Quest Diagnostics offers a menu of pretransplant tests that includes donor screening panels for infectious diseases (**Table 1**). These panels, based on FDA guidelines for approved testing,[3,5] include tests for HIV-1/2, HBV, HCV, CMV, *T pallidum*, and others. Quest also offers HLA compatibility testing and other transplant-related testing that support the laboratory phases in the continuum of transplant care.

The information in this Test Guide is provided for informational purposes only and is not intended as medical advice. Test selection and interpretation, diagnosis, and patient management decisions should be based on the physician's education, clinical expertise, and assessment of the patient.

Table 1. Infectious Disease Panels for Donor Transplant Eligibility Testing

Test code	Test name	Primary clinical use	Donor type
39949	Specialized Transplant Services, Donor[a]	Priority handling of donor specimens	Donors of HCT/Ps and reproductive HCT/Ps; viable, leukocyte-rich cells or tissues; stem cells
17385	Donor, *Chlamydia trachomatis/ Neisseria gonorrhoeae,* RNA, TMA	Screen for *C trachomatis* and *N gonorrhoeae* RNA in potential donors of reproductive HCT/Ps	Donors of reproductive HCT/Ps
91986	Donor, Chagas Screen	Screen for *Trypanosoma cruzi* infection in potential donors of HCT/Ps	Donors of HCT/Ps
17388	Donor, Cytomegalovirus Antibody, Total	Screen for CMV infection in potential donors of viable, leukocyte-rich cells or tissues	Donors of HCT/Ps
90557	Donor, Cytomegalovirus Antibody, Total with Reflex to IgG, IgM[b]	Screen with reflex to diagnostic testing for CMV infection in potential donors of viable, leukocyte-rich cells or tissues	Viable, leukocyte-rich cells or tissues
19618	Donor, Cytomegalovirus Antibody, Total with Reflex to IgM[b]		
17378	Donor, Hepatitis B Core Total Antibody	Screen for history of HBV infection in potential donors of HCT/Ps	HCT/Ps
17375	Donor, Hepatitis B Surface Antigen with Reflex to Confirm[b]	Screen and confirmation for acute or chronic HBV infection in potential donors of HCT/Ps	HCT/Ps
93305	Donor, Hepatitis C Antibody (Anti-HCV)	Screen for acute or chronic HCV infection in potential donors of HCT/Ps	HCT/Ps
17380	Donor, HIV-1/2 plus O Antibody Screen	Screen for HIV-1 and HIV-2 infection in potential donors of HCT/Ps	HCT/Ps

(Continued)

Table 1. Infectious Disease Panels for Donor Transplant Eligibility Testing *(cont'd)*

Test code	Test name	Primary clinical use	Donor type
94973	Donor, HIV-1/2 plus O Antibody Screen with Reflex to Differentiation[b]	Screen for HIV-1 and HIV-2 infection with reflex to confirmation/differentiation	HCT/Ps
19854	Donor, HIV-1/HCV/HBV NAT Procleix® with Reflex[b]	Screen for HIV-1, HCV, and HBV RNA in potential donors of HCT/Ps	HCT/Ps
17379	Donor, HTLV-I/II Antibody Screen	Screen for human T-cell lymphotrophic virus I and II infection in potential donors of viable, leukocyte-rich cells and tissues	Viable, leukocyte-rich cells and tissues
93309	Donor, Stem Cells Donor Panel	Screen for CMV, HBV, HCV, HIV, HTLV-I/II, syphilis, and WNV in potential stem cell donors	Stem cells
17389	Donor, Syphilis IgG Antibody	Screen for acute or chronic *Treponema pallidum* infection in potential donors of HCT/Ps	HCT/Ps
93308	Donor, Tissue Donor Panel Includes hepatitis B core total antibody (17378); hepatitis B surface antigen reflex to confirmation (17375); hepatitis C antibody (93305); HIV-1/HBV/HCV NAT Procleix® with reflex (19854); HIV-1/2 plus O antibody screen (17380); syphilis IgG antibody (17389); West Nile virus NAT (19412).	Screen blood donors and donors of HCT/Ps for infectious diseases	HCT/Ps
19412	Donor, West Nile Virus, NAT	Screen for WNV RNA in potential donors of HCT/Ps	HCT/Ps

CMV, cytomegalovirus; HCT/Ps, human cells, tissues, and cellular and tissue-based products; HTLV, human T-cell lymphotropic virus; TMA, transcription-mediated amplification; WNV, West Nile virus.

[a] Specialized transplant services include collection and shipping kits provided to the customer, direct shipping via FedEx, donor-specific requisitions, and rapid turnaround (24 hours from receipt of sample). Test code 39949 designates special handling for these services; it is a single-use test code that may be applied to 1 or more tests listed in this guide.

[b] Reflex tests are performed at an additional charge and are associated with an additional CPT code(s).

References

1. Donor screening and testing. Centers for Disease Control and Prevention. Updated January 30, 2019. Accessed March 15, 2021. https://www.cdc.gov/transplantsafety/protecting-patient/screening-testing.html
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5. Complete list of donor screening assays for infectious agents and HIV diagnostic assays. US Food and Drug Administration Updated October 23, 2020. Accessed March 15, 2021. https://www.fda.gov/vaccines-blood-biologics/complete-list-donor-screening-assays-infectious-agents-and-hiv-diagnostic-assays/