

Align OPTN Policy with U.S. Public Health Service Guideline, 2020: Donor and Candidate Testing Resources

Donor testing requirements

Donor Type	Required Testing (HIV, HBV, HCV)	Timeframe	OPTN Policy
Deceased	<ul style="list-style-type: none"> • HIV antibody (anti-HIV) donor screening test or antigen/antibody (Ag-Ab) combination test • HIV RNA by donor screening or diagnostic NAT • HBV surface antigen (HBsAg) donor screening test • HBV core antibody (total anti-HBc) donor screening test • HBV DNA by donor screening or diagnostic NAT • HCV antibody donor screening test (anti-HCV) • HCV RNA by donor screening or diagnostic NAT 	Within 96 hours of procurement	<p>2.9: Required Deceased Donor Infectious Disease Testing</p> <p>3/1/21 additions: HIV and HBV NAT requirements, timeframe for donor samples, clarified HBV core antibody</p>
Living	<ul style="list-style-type: none"> • HIV antibody (anti-HIV) or HIV antigen/antibody (Ag/Ab) • HIV RNA by NAT • HBV surface antigen (HBsAg) • HBV core antibody (total anti-HBc) • HBV DNA by NAT • HCV antibody (anti-HCV) • HCV RNA by NAT 	Within 28 days of procurement	<p>14.4.A: Living Donor Medical Evaluation Requirements</p> <p>3/1/21 addition: HIV and HBV NAT requirements, clarified HBV core antibody</p>

Candidate and recipient testing requirements

	Required Testing	Timeframe	OPTN Policy
Pre-transplant*	<ul style="list-style-type: none"> • HIV using a CDC-recommended laboratory algorithm • HBV surface antigen (HBsAg) • HBV core antibody (total anti-HBc) • HBV surface antibody (HBsAb) • HCV antibody (anti-HCV) • HCV RNA by NAT 	<p>Samples must be drawn during hospital admission for transplant but prior to anastomosis of the first organ.</p> <p>Results are not required prior to transplant.</p>	<p>15.2: Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements</p> <p>3/1/21 additions: Universal candidate testing for HIV, HBV, and HCV</p>

Post-transplant*	<ul style="list-style-type: none"> • HIV RNA by NAT • HBV DNA by NAT • HCV RNA by NAT 	4-8 weeks post-transplant	15.3.C: Required Post-Transplant Infectious Disease Testing 3/1/21 additions: Universal recipient testing for HIV, HBV, and HCV
Liver Recipient Additional Post-transplant Testing*	<ul style="list-style-type: none"> • HBV by NAT 	11-13 months post-transplant	15.3.C: Required Post-Transplant Infectious Disease Testing 3/1/21 addition: Universal liver recipient testing at 11-13 months for HBV

*If a candidate is known to be infected with HIV, HBV, or HCV, then testing for the known viral infection or infections is not required. Testing is still required for all other viral infections.

FAQs:

What is NAT testing?

Nucleic Acid Testing, or NAT, looks at the expression of deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) to determine if somebody is infected with a pathogen.¹ There are many types of NAT testing, and the tests may appear labeled many different ways in a hospital’s electronic medical record (EMR) or on a laboratory’s requisition form. Some of the more common types of NAT testing include polymerase chain reaction (PCR), nucleic acid amplification tests (NAAT), strand displacement assays (SDA), and transcription-mediated assays (TMA).

Why is NAT testing preferred for donors and recipients?

NAT tests are far more sensitive than antibody tests, especially in the early stages of infection² and in immunocompromised persons.³ These tests have a much shorter “window period”- the time between infection and when the virus is detectable by testing.⁴ Universal NAT testing means fewer unintended transmissions and earlier recipient detection and treatment.

¹ <https://www.fda.gov/medical-devices/vitro-diagnostics/nucleic-acid-based-tests>

² <https://www.cdc.gov/mmwr/volumes/69/rr/rr6904a1.htm>

³ Centers for Disease Control and Prevention (CDC) (2013). Testing for HCV infection: an update of guidance for clinicians and laboratorians. *MMWR. Morbidity and mortality weekly report*, 62(18), 362–365.

⁴ Ibid.

What is the difference between a screening and a diagnostic test? Which is required for candidates and recipients?

Screening tests are intended to detect disease prior to the onset of symptoms, and tend to be more sensitive and less specific. Diagnostic tests are intended to establish a patient's diagnosis in the presence of symptoms.⁵ OPTN policy does not specify whether candidates or recipients are required to have screening or diagnostic tests for their pre- and post-transplant testing. The PHS guideline does not specify whether pre-transplant testing should be screening or diagnostic, but recommends that post-transplant testing use diagnostic tests.⁶

Where can I find more information about specific tests?

The FDA has a [website for nucleic acid based tests](#) that includes information on microbial tests. Additional tests can be found in the [Clinical Laboratory Improvement Amendments \(CLIA\) searchable database](#). In addition, the Association of Public Health Laboratories (APHL) has [a list of approved tests for HIV, HBV, and HCV](#). This contains both information on serologic tests, such as antibody testing, and molecular tests, such as NAT.

Product inserts contain information on acceptable use and necessary specimen parameters. Contact your infectious disease laboratory if you have any questions about specific tests they have available.

Where can I find testing information for donors?

The FDA provides a [list of licensed donor screening tests](#).

Where can I find pre-transplant candidate testing requirements for HIV?

OPTN Policy 15.2: Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements requires that transplant candidates be tested for HIV using a CDC-recommended laboratory HIV testing algorithm. The CDC published a full guideline on [Laboratory testing for the diagnosis of HIV infection](#) in 2014, and an [updated quick reference guide](#) in 2018. The CDC published a resource in 2018 on [FDA-approved HIV Antigen/Antibody \(Ag/Ab\) screening tests](#) and their product inserts for acceptable use. In addition, they have a resource on the [advantages and disadvantages of different FDA-Approved HIV assays](#). If a candidate tests negative by HIV Ag/Ab, they are not required to have HIV Nat testing performed.

⁵ <https://www.fda.gov/media/142767/download>

⁶ Ibid.