

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

### Donor testing, collection, and storage requirements

Donor Type	Required Testing (HIV, HBV, HCV)	Testing Timeframe	Required Stored Samples		OPTN Policy	Reporting
			Collection Timeframe	Storage Timeframe		
<b>Deceased</b>	<ul style="list-style-type: none"> <li>• HIV antibody (anti-HIV) donor screening test or antigen/antibody (Ag-Ab) combination test</li> <li>• HIV RNA by donor screening or diagnostic NAT</li> <li>• HBV surface antigen (HBsAg) donor screening test</li> <li>• HBV core antibody (total anti-HBc) donor screening test</li> <li>• HBV DNA by donor screening or diagnostic NAT</li> <li>• HCV antibody donor screening test (anti-HCV)</li> <li>• HCV RNA by donor screening or diagnostic NAT</li> </ul>	Within 96 hours of procurement	Samples must be collected within 24 hours prior to organ procurement.	Samples must be stored for at least 10 years after the date of organ transplant.	2.9: Required Deceased Donor Infectious Disease Testing  2.2: OPO responsibilities	OPTN Donor Data and Matching System (DonorNet) and DRR
<b>Living</b>	<ul style="list-style-type: none"> <li>• HIV antibody (anti-HIV) or HIV antigen/antibody (Ag/Ab)</li> <li>• HIV RNA by NAT</li> <li>• HBV surface antigen (HBsAg)</li> </ul>	Within 28 days of procurement	Samples must be collected within 24 hours prior to organ recovery.	Samples must be stored for at least 10 years after the date of	14.4.A: Living Donor Medical Evaluation Requirements  14.8.B: Living Donor	Living Donor Registry

	<ul style="list-style-type: none"><li>• HBV core antibody (total anti-HBc)</li><li>• HBV DNA by NAT</li><li>• HCV antibody (anti-HCV)</li><li>• HCV RNA by NAT</li></ul>			organ transplant.	Specimen Collection and Storage	
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## Candidate and recipient testing requirements

	Required Testing	Timeframe	OPTN Policy	Reporting
<b>Pre-transplant*</b>	<ul style="list-style-type: none"> <li>• HIV using a CDC-recommended laboratory algorithm</li> <li>• HBV surface antigen (HBsAg)</li> <li>• HBV core antibody (total anti-HBc)</li> <li>• HBV surface antibody (HBsAb)</li> <li>• HCV antibody (anti-HCV)</li> <li>• HCV RNA by NAT</li> </ul>	<p>For all candidates 12 years or older, 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> <p>7/1/22 additions: Pediatric Candidate Pre-Transplant HIV, HBV, and HCV Testing</p>	TRR
<b>Post-transplant*</b>	<ul style="list-style-type: none"> <li>• HIV RNA by NAT</li> <li>• HBV DNA by NAT</li> <li>• HCV RNA by NAT</li> </ul>	28-56 days (4-8 weeks) post-transplant	<p>15.3.C: Required Post-Transplant Infectious Disease Testing</p> <p>3/1/21 additions: Universal recipient testing for HIV, HBV, and HCV</p>	TRF
<b>Liver Recipient Additional Post-transplant Testing*</b>	<ul style="list-style-type: none"> <li>• HBV by NAT</li> </ul>	335-395 days (11-13 months) post-transplant	<p>15.3.C: Required Post-Transplant Infectious Disease Testing</p> <p>3/1/21 addition: Universal liver recipient testing at 11-13 months for HBV</p>	TRF

\*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:

### Recipient Testing

#### Clarification of HIV testing requirements:

[https://www.cdc.gov/hiv/pdf/guidelines\\_testing\\_recommendedlabtestingalgorithm.pdf](https://www.cdc.gov/hiv/pdf/guidelines_testing_recommendedlabtestingalgorithm.pdf)

#### What is HepB surface antibody testing?:

The presence of anti-HBs is generally interpreted as indicating recovery and immunity from hepatitis B virus infection. Anti-HBs also develops in a person who has been successfully vaccinated against hepatitis B.

<https://www.cdc.gov/hepatitis/hbv/pdfs/serologicchartv8.pdf>

#### Is testing required for all recipients or just those with risk criteria identified?

Per OPTN Policy 15.3.C:

1. Transplant programs must test all recipients post-transplant for:
  - a. HIV ribonucleic acid (RNA) by nucleic acid test (NAT)
  - b. HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT)
  - c. HCV ribonucleic acid (RNA) by nucleic acid test (NAT)
2. Testing must be performed on the recipient at least 28 days but no later than 56 days posttransplant.
3. If the candidate is known to be infected with HIV, HBV, or HCV, then testing for the known viral infection or infections is not required, however the other tests required according to this policy must still be performed.
4. The transplant program must offer recipients treatment of or prophylaxis for HIV, HBV, or HCV, when medically appropriate.
5. Transplant programs must conduct HBV NAT testing on liver recipients at least 335 days but no later than 395 days post-transplant.

#### For living donors, the transmissible disease screening:

can be *either* donor screening *or* diagnostic testing. Living donor medical evaluation testing is not required to be donor screening testing by OPTN policy.