OPTN
Organ Procurement & Transplantation Network

Seasonal West Nile Virus Testing Required for All Donors

Sponsoring Committee:	OPTN Ad Hoc Disease Transmission Advisory Committee
Public Comment:	August 27 – October 1, 2025
Board Approved:	December 12, 2025
Effective Date:	June 24, 2026

Purpose of Policy Changes

The purpose of these policy changes is to improve patient safety by reducing the morbidity and mortality associated with West Nile Virus (WNV) transmission via solid organ transplantation by requiring seasonal WNV testing for all potential living and deceased donors.[1] Persons with WNV infection are typically asymptomatic, and there is no treatment or vaccine for the virus. Screening of potential donors can detect WNV infection even in persons who do not have symptoms. OPOs and living donor hospitals are not required to test donors for WNV. Some OPOs and living donor hospitals screen donors for WNV, but screening practices are not standardized. Unintended transmission of WNV to recipients can lead to severe illness or death.[2]

These policy changes establish a standardized, mandatory approach to WNV testing during the months of highest WNV risk, replacing inconsistent voluntary practices among OPOs and living donor hospitals and improving overall transplant recipient safety and outcomes.

Policies Affected

Policy Number	*Policy Name*
2.9	Required Deceased Donor Infectious Disease Testing
14.4	Medical Evaluation Requirements for Living Donors

Proposal History

This proposal was developed in response to a recommendation from the Centers for Disease Control and Prevention (CDC). WNV is spread through the bite of an infected mosquito and is the leading cause of arboviral disease in the United States. During 1999-2023, there have been over 59,000 cases and 2,900 deaths in the United States. [3] WNV can also be transmitted person-to-person through organ transplantation and blood transfusion.

[1] West Nile and Organ Transplantation, Centers for Disease Control and Prevention, https://www.cdc.gov/west-nile-virus/causes/organ-transplantation.html (Accessed May 21, 2025).

[2] West Nile: Symptoms, Diagnosis, and Treatment, Centers for Disease Control and Prevention, https://www.cdc.gov/west-nile-virus/symptoms-diagnosis-treatment/index.html (Accessed May 21, 2025).

[3] "Historic Data (1999–2024)," Centers for Disease Control and Prevention, https://www.cdc.gov/west-nile-virus/data-maps/historic-data.html (Accessed June 20, 2025).

In October 2024, the CDC presented findings from an investigation of 11 WNV transmission clusters among solid organ transplant recipients in the U.S. from 2002 to 2023. Among 30 affected organ recipients, 26 (87%) showed evidence of WNV infection, among whom 20 (77%) developed encephalitis and 8 (40% of those with encephalitis) died.[4]

- The CDC recommended the Committee implement seasonal WNV testing requirements for all potential deceased and living donors, in alignment with CDC and FDA guidelines.
- The Committee established the *Require West Nile Virus Seasonal Workgroup*, including representatives from the OPTN OPO and Living Donor Committees, the CDC, and the FDA, to explore key considerations: whether testing should be mandatory; defining a seasonal timeframe; determining the appropriate test; and establishing result timing during the transplant process.
- The proposal was released for public comment from **August 27 – October 1, 2025** and approved by the OPTN Board of Directors in **December 2025**.

Summary of Changes

- OPOs and living donor hospitals will be required to test all potential donors for WNV between **July 1 and October 31** using an FDA-licensed, approved, or cleared nucleic acid test (NAT).
- For **deceased donors**, NAT results must be available prior to organ implantation.
- For **living donors**, NAT must be performed within **14 days** of the planned organ recovery date — or as close to that date as possible — and results must be available prior to organ recovery.

Please note: On June 18, the OPTN Board of Directors approved an emergency action to change the living donor testing window for WNV from 14 days prior to organ recovery to 7 days prior to organ recovery. Members will be notified when this change will go into effect.

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[4] Sutter RA, Lyons S, Gould CV, Staples JE, Lindsey NP. West Nile Virus and Other Nationally Notifiable Arboviral Diseases — United States, 2022. MMWR Morb Mortal Wkly Rep 2024;73:484–488. DOI: http://dx.doi.org/10.15585/mmwr.mm7321a2.

Implementation

Transplant hospitals, OPOs, and living donor recovery hospitals will need to be aware of the new requirements and update their donor testing protocols accordingly. They will need to ensure WNV NAT testing is conducted for all applicable donors during the July 1 – October 31 seasonal window.

The OPTN Computer System will require updates. Implementation will proceed in a phased approach: deceased donor system changes will be implemented directly following Board consideration, and living donor system changes will follow Office of Management and Budget (OMB) review and approval under the Paperwork Reduction Act of 1995.

There is no expected impact on histocompatibility laboratories. Communications about the changes will be provided to OPTN members, as well as educational materials.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

Policy 2.9: Required Deceased Donor Infectious Disease Testing

The host OPO is responsible for ensuring that all of the following infectious disease testing is completed in Clinical Laboratory Improvement Amendments (CLIA) certified laboratories, or in laboratories meeting equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS):

1. Blood and urine cultures
2. Infectious disease testing for all potential deceased organ donors using FDA licensed, approved or cleared tests, as listed below:
    a. HIV antibody (anti-HIV) donor screening test or HIV antigen/antibody (Ag/Ab) combination test
    b. HIV ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
    c. Hepatitis B surface antigen (HBsAg) donor screening test
    d. Hepatitis B core antibody (total anti-HBc) donor screening test
    e. Hepatitis B deoxyribonucleic acid (DNA) by donor screening or diagnostic nucleic acid test (NAT)
    f. Hepatitis C antibody donor screening test (anti-HCV)
    g. Hepatitis C ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
    h. Cytomegalovirus (CMV) antibody (anti-CMV) donor screening or diagnostic test
    i. Epstein-Barr Virus (EBV) antibody (anti-EBV) donor screening or diagnostic test
    j. Syphilis donor screening or diagnostic test
    k. Toxoplasma Immunoglobulin G (IgG) antibody test

Donor samples for all required HIV, HBV, and HCV testing must be obtained within 96 hours prior to organ procurement.

3. Infectious disease testing for all potential deceased lung donors using an FDA licensed, approved, cleared, or emergency use authorized, lower respiratory specimen test for SARS-CoV-2 (COVID-19) by nucleic acid test (NAT)

   Lower respiratory specimen test results for SARS-CoV-2 by nucleic acid test (NAT) must be available pre-transplant of lungs.

4. Infectious disease testing for all potential deceased donors for *Strongyloides* antibody, using either:
   - an FDA licensed, approved, cleared, or Class 1, 510(k)-exempt test or
   - a Laboratory Developed Test (LDT), as described by the FDA.

5. Infectious disease testing for all potential deceased donors whose donor history reflects the donor's birthplace was in a country classified as endemic for Chagas disease by the CDC at the time of testing. The OPTN maintains a list of countries currently classified as endemic for Chagas disease by the CDC. This testing must be performed using an FDA licensed, approved, or cleared donor screening test for *T. cruzi* antibody.

   Within 72 hours of receipt of a positive *T. cruzi* antibody donor screening test, the host OPO must submit a sample for confirmatory testing. Confirmatory testing requires either:

   - submission through the CDC or
   - performance of at least two different FDA licensed, approved, or cleared antibody diagnostic tests.

6. <u>For potential deceased donors with planned organ recovery between July 1st and October 31st, infectious disease testing using an FDA licensed, approved, or cleared test for West Nile Virus by nucleic acid test (NAT).</u>

   <u>NAT results for West Nile Virus must be available prior to implantation.</u>

Policy 14.4: Medical Evaluation Requirements for Living Donors

14.4.A Living Donor Medical Evaluation Requirements

A medical evaluation of the living donor must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. Documentation of the medical evaluation must be maintained in the donor medical record.

The medical evaluation must include all of the components in Tables 14-6 through 14-10 below.

Table 14-6: Requirements for Living Donor Medical Evaluations

This evaluation must be completed:	Including evaluation for and assessment of this information:
General donor history	1. A personal history of significant medical conditions which include but are not limited to: a. Hypertension b. Diabetes c. Lung disease d. Heart disease e. Gastrointestinal disease f. Autoimmune disease g. Neurologic disease h. Genitourinary disease i. Hematologic disorders j. Bleeding or clotting disorders k. History of cancer including melanoma 2. History of infections 3. Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication 4. Allergies 5. An evaluation for coronary artery disease

This evaluation must be completed:	Including evaluation for and assessment of this information:
General family history	• Coronary artery disease • Cancer
Social history	• Occupation • Employment status • Health insurance status • Living arrangements • Social support • Smoking, alcohol and drug use and abuse • Psychiatric illness, depression, suicide attempts • Risk criteria for acute HIV, HBV, and HCV infection according to the *U.S. Public Health Services (PHS) Guideline*
Physical Exam	• Height • Weight • BMI • Vital signs • Examination of all major organ systems
General laboratory and imaging tests	• Complete blood count (CBC) with platelet count • Blood type and subtype as specified in OPTN *Policy 14.5: Living Donor Blood Type Determination and Reporting* and its subsections

This evaluation must be completed:	Including evaluation for and assessment of this information:
	• Prothrombin Time (PT) or International Normalized Ratio (INR) • Partial Thromboplastin Time (PTT) • Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin) • HCG quantitative pregnancy test for premenopausal women without surgical sterilization • Chest X-Ray • Electrocardiogram (ECG)
Transmissible disease screening	Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include *all* the following: 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 3. HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery 4. HIV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 5. Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery

This evaluation must be completed:	Including evaluation for and assessment of this information:
	6. Hepatitis B core antibody (total anti-HBc) testing as close as possible, but within 28 days prior to organ recovery 7. HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 8. Hepatitis C antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery 9. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 10. Syphilis testing For tuberculosis (TB), living donor recovery hospitals must determine if the donor is at increased risk for this infection. If TB risk is suspected, testing must include screening for latent infection using *either*: • Intradermal PPD • Interferon Gamma Release Assay (IGRA) <u>For West Nile Virus (WNV), living donor recovery hospitals must test all potential donors with planned organ recovery between July 1st and October 31st for WNV by nucleic acid test (NAT), as close as possible, but within 14 days prior to organ recovery. WNV test results must be obtained prior to organ recovery.</u>
Endemic transmissible diseases	Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation.
Cancer screening	Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventive Services Task Force to screen for:

This evaluation must be completed:	Including evaluation for and assessment of this information:
	• Cervical cancer • Breast cancer • Prostate cancer • Colon cancer • Lung cancer