

## *Notice of OPTN Emergency Policy Change*

# Lower Respiratory SARS-CoV-2 Testing for Lung Donors

<b>Sponsoring Committee:</b>	<b>Ad Hoc Disease Transmission Advisory</b>
<b>Policies Affected:</b>	<b><i>Policy 1.2: Definitions</i></b> <b><i>Policy 2.9: Required Deceased Donor Infectious Disease Testing</i></b>
<b>Public Comment:</b>	<b>August 3, 2021-September 30, 2021</b>
<b>Board Approved:</b>	<b>April 26, 2021</b>
<b>Effective Date:</b>	<b>May 27, 2021</b>

### Summary of Changes

The policy change defines what a lower respiratory specimen is and requires that all lung donors receive lower respiratory specimen testing by nucleic acid test (NAT). The policy specifies that testing results must be available pre-transplant of lungs.

### Purpose of Policy Change

There has been accumulating evidence of a patient safety risk to lung recipients in four recent cases of deceased lung donors testing negative for SARS-CoV-2 by upper respiratory specimen and retrospectively testing positive by lower respiratory specimen. Three cases resulted in donor-derived transmission to lung recipients while the fourth resulted in lung discard. One lung recipient has died as a result of the donor-derived transmission. As of March 2021, only 60% of lung donors were tested by lower respiratory specimen.<sup>1</sup> Policy is needed to ensure organ procurement organizations (OPOs) perform and obtain results from lower respiratory specimen testing for all potential deceased lung donors to avoid SARS-CoV-2 (COVID-19) transmission to lung recipients. The policy change is emergent because of the significant patient safety implications of donor-derived COVID-19 and the subsequent risk of patient mortality. The policy change requires nucleic acid testing (NAT) for COVID-19 by lower respiratory specimen for all potential deceased lung donors, with results being available prior to lung transplantation.

### Proposal History

The OPTN ad hoc Disease Transmission Advisory Committee (DTAC) considered proposing emergency policy to be necessary after accumulating evidence in the first quarter 2021 of cases in which lung donors tested negative for SARS-CoV-2 by upper respiratory specimen and later tested positive by lower respiratory specimen. The DTAC reached out to OPTN stakeholder committees (OPO and Lung) and incorporated their feedback in a proposed solution to require lower respiratory testing on all lung donors.

---

<sup>1</sup> 2021 OPTN data.

The OPO Committee indicated requiring lower respiratory specimen test results pre-organ offer could negatively impact utilization, including utilization of donation by circulatory donation (DCD). The Lung Committee commented that requiring test results pre-procurement or pre-organ offer could avoid potential staff exposure peri-procurement, which indirectly impacts patient safety. However, the Lung Committee also indicated that requiring test results pre-transplant at the latest would be acceptable to address the main patient safety risk of COVID-19 transmission through donor lungs. In the initial DTAC proposal, the test results would have been required to be available pre-procurement to balance OPO and Lung Committee concerns related to patient safety and organ utilization. Both OPO and Lung Committees were supportive of the DTAC's efforts to address the accumulating evidence of patient safety risk with an emergency policy to require SARS-CoV-2 lower respiratory testing for all lung donors.

The OPTN Executive Committee supported the DTAC's effort to address an important patient safety risk with emergency policy requiring lower respiratory testing, but considered that the proposed change warranted an adjustment of the timing requirement. Specifically, several Executive Committee members expressed concern about the ability of OPOs to obtain results pre-procurement on DCD and other potential donors. The Executive Committee therefore modified the DTAC proposal to require that lower respiratory specimen test results be available pre-transplant instead of pre-procurement. This modified policy avoids a potential negative impact on organ utilization for certain donors including DCDs, while still addressing the important patient safety goal of ensuring that all lung donors have lower respiratory testing for SARS-CoV-2 completed prior to transplant. The Executive Committee unanimously approved policy language to require SARS-CoV-2 lower respiratory testing for all lung donors with results available pre-transplant of lungs.

## **Implementation**

Member Quality staff will review lung donor testing data reported in DonorNet® to verify that OPOs are testing all deceased lung donors for SARS-CoV-2 by nucleic acid test performed on a lower respiratory specimen. This policy change will not require programming in UNet<sup>SM</sup>.

Because this policy is emergent it will be evaluated monthly following implementation for 6-months and then again at 1-year post-implementation. The policy will expire a year from implementation unless the Board of Directors establishes the policy as permanent.

## Affected Policy Language

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

### 1.2 Definitions

#### Lower respiratory specimen

A sample taken from the respiratory system within the trachea or below. Sputum, tracheal aspirate, bronchial suction, bronchial wash, bronchoalveolar lavage (BAL), and lung biopsy are considered lower respiratory specimens.

### 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.