



# Summary of Current Evidence and Information– Donor SARS-CoV-2 Testing & Organ Recovery from Donors with a History of COVID-19

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## Introduction

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Current practices related to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) donor screening and organ acceptance of donors with a history of Coronavirus Disease 2019 (COVID-19) vary nationally.

## Aim

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This document is a summary of evidence and information regarding donor screening for SARS-CoV-2 and considerations for organ acceptance from donors with a history of COVID-19. It is based on peer-reviewed literature and OPTN data to date. This resource is subject to revision as new data accumulate. It will be reviewed quarterly for currency. The overarching objective of this document is to compile the latest information known for minimizing the risk of donor derived COVID-19 while maximizing donor utilization.

## Terms to know

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- **Nucleic Acid Test (NAT):** Nucleic acid tests are laboratory tests that detect viral genetic material. These include nucleic acid amplification tests (NAAT), RNA tests, and Polymerase Chain Reaction (PCR) tests
- **Upper respiratory specimen:** This includes a nasopharyngeal (NP) swab, NP wash or NP aspirate, mid-turbinate swab (MT) or an oropharyngeal (OP) swab sample.
- **Lower respiratory specimen:** This includes a tracheal aspirate, bronchial suction or wash, or a sputum sample.

- **Date of disease onset:** In this document will refer to the date of onset of [COVID-19 symptoms](#) or the initial date of test positivity if onset of symptoms cannot be confirmed or if asymptomatic.
- **Asymptomatic COVID-19 Infection:** Detection of SARS-CoV-2 in a respiratory sample without current or past symptoms compatible with COVID-19. If a donor symptom history is unknown, this person should not be considered asymptomatic.
- **Mild COVID-19:** Detection of SARS-CoV-2 in a respiratory sample in patients with symptoms consistent with COVID-19 infection who did not require oxygen supplementation or inpatient hospitalization for COVID-19.
- **Severe COVID-19:** Detection of SARS-CoV-2 in a respiratory sample in patients with symptoms consistent with COVID-19 infection who required oxygen supplementation or inpatient hospitalization for COVID-19.
- **Resolved COVID-19:** An immunocompetent donor with a history of confirmed COVID-19, with resolution of symptoms and more than 21 days from the date of onset of symptoms.
- **Active COVID-19:**
  - An immunocompetent donor with a history of confirmed COVID-19, less than 21 days from the date of disease onset and SARS-CoV-2 detected in a respiratory sample OR
  - An asymptomatic donor with detection of SARS-CoV-2 in a respiratory sample without a reliable history to determine the timeline of past symptoms of COVID-19.

## Methods

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The OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) and relevant stakeholders from the Centers for Disease Control and Prevention (CDC), American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), Association of Organ Procurement Organizations (AOPO), and Health Resources & Services Administration (HRSA) reviewed published literature and data reported to the OPTN during the time period corresponding to the COVID-19 pandemic. Specifically, DTAC

and relevant stakeholders assessed the available evidence as it relates to living and deceased donor evaluation and testing and recovery of organs from living or deceased donors with a history of resolved or active COVID-19.

## Discussion

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### SARS-CoV-2 Deceased Donor Evaluation and Testing

1. OPOs and transplant teams should adhere to [CDC Infection Prevention and Control Recommendations for Health Care Personnel during the Coronavirus Disease 2019 \(COVID-19\) pandemic](#) to minimize the risk of disease transmission to the procurement and transplant teams.
2. Available evidence indicates that testing deceased donors for SARS-CoV-2 by NAT from a respiratory sample within 72 hours, but ideally as close as possible to organ recovery, could decrease the risk of unrecognized infection.
3. When lungs will be recovered for transplantation, testing for SARS-CoV-2 by NAT in a lower respiratory sample likely decreases the risk of unrecognized infection.
4. SARS-CoV-2 antibody testing as a marker for assessing potential transmission risk to recipients has insufficient evidence to support its use for clinical evaluation of donors at this time.
5. NAT testing of non-respiratory samples is not standardized and has insufficient evidence to support its use for clinical evaluation of donors at this time.
6. Chest computed tomography (CT) and chest x-ray have many confounding factors, and evidence supports using radiographic imaging in conjunction with other testing methods for SARS-CoV-2 infection. Evidence does not support radiographic imaging as the sole diagnostic method for SARS-CoV-2 infection.
7. Available evidence supports an assessment for potential end-organ dysfunction if a donor has a history of COVID-19.

8. OPOs collecting a history and timeline of symptoms in a potential donor to understand if COVID-19 is *Resolved* or *Active* could lower the risk of undetected infection.
9. OPOs collecting a history of SARS-CoV-2 vaccination in a potential deceased donor could help further evaluate the risk of infection for potential transplant recipients.
10. The Food and Drug Administration (FDA) [has issued notification](#) of potential false positive and false negative results associated with certain SARS-CoV-2 testing platforms. [These notifications](#) can inform selection of testing platforms in order to minimize the possibility of donor deferral due to false test results.

## **Recovery of Organs from Deceased Donors with a History of Resolved COVID-19**

1. Deceased donors with resolved COVID-19 and a negative SARS-CoV-2 NAT test at the time of donor evaluation are unlikely to transmit infection. Evidence suggests the decision to recover and transplant organs in this case include the following:
  - The recipient risk of mortality or further complications while delaying transplantation and remaining on the waiting list.
  - Current unknown long-term outcomes from donors with a history of resolved COVID-19.
2. The safety of deceased donors with a history of mild COVID-19 more than 10 and less than 21 days after the date of disease onset and resolution of symptoms is unknown. It is believed that these donors are unlikely to transmit COVID-19 to non-lung recipients. Evidence suggests the decision in this case include the following:
  - The medical urgency of the candidate.
  - The recipient risk of mortality or further complications while delaying transplantation and remaining on the waiting list.
  - Current unknown long-term outcomes from donors with a history of resolved COVID-19.
  - Infectious diseases experts can offer subject matter expertise when accepting organs from these donors.

3. Donors with resolved COVID-19 and a positive SARS-CoV-2 NAT test 21-90 days after the date of disease onset are unlikely to transmit infection. A positive SARS-CoV-2 NAT test likely represents non-viable virus.

Evidence suggests the decision to recover organs in this case include the following:

- The recipient risk of mortality or further complications while delaying transplantation and remaining on the waiting list.
- Current unknown long-term outcomes from donors with a history of resolved COVID-19.
- Infectious diseases experts can offer subject matter expertise when accepting organs from these donors.

4. Donors with resolved COVID-19 and a positive SARS-CoV-2 NAT more than 90 days after the date of disease onset may reflect re-infection which may place the recipient at risk for disease transmission.

### **Recovery of Organs from Deceased Donors with Active COVID-19**

1. Donors with active COVID-19 carry an unknown but presumed risk of disease transmission to recipients as well as to individuals on the OPO and transplant teams. For recipients, the risk of disease transmission is likely higher for lung recipients.

### **SARS-CoV-2 Living Donor Testing and other precautions to minimize the risk of Donor-Derived COVID-19**

1. [CDC recommendations on infection control practices](#) can help living donors reduce the risk of SARS-CoV-2 infection prior to donation and during recovery.
2. Self-quarantine during the 14 days prior to organ recovery could reduce the risk of SARS-CoV-2 infection for living donors and recipients.
3. Testing for SARS-CoV-2 with NAT in a respiratory sample as close to organ recovery as possible, but within 72 hours prior to recovery could reduce the risk of undetected infection.

## Recovery of Organs from Living Donors with a History of Resolved COVID-19

1. Evidence suggests the decision to recover and transplant organs from living donors with resolved COVID-19 include the following:
  - Currently unknown long-term effects of COVID-19 infection for the living donor
  - The candidate risk of mortality or further complications while delaying transplantation and remaining on the waiting list.
  - The estimated risk of donor-derived COVID-19 transmission to the recipient
  - Currently unknown long-term outcomes of recipients of organs from living donors with resolved COVID-19
2. Living donation from donors with mild or asymptomatic COVID-19 is likely safe 21-28 days after the date of disease onset. There is unclear evidence on the need for a negative SARS-CoV-2 NAT for living donors with a history of COVID-19 prior to donation within 90 days of disease onset. It is always important to follow local infection prevention and control policies.
3. Infectious diseases experts can offer subject matter expertise when accepting organs from these donors.

## Themes

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- COVID-19
- SARS-CoV-2 donor testing

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