

**SARS-CoV-2 (Coronavirus, 2019-nCoV):
Recommendations and Guidance for Organ Donor Testing**

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The AST's Infectious Disease Community of Practice has received queries regarding the novel coronavirus (SARS-CoV-2). The following FAQs were developed with input of members from both the organ donation and transplantation communities to relay information on the current state of knowledge. This document is subject to change as more information becomes available.

Also see UNOS information link: <https://unos.org/covid/>

SARS-CoV-2 Transmission and Implication for Healthcare Centers

The novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), can spread rapidly within healthcare settings and communities and poses a special challenge for organ transplantation. Person-to-person transmission of SARS-CoV-2 was recognized early in the pandemic and occurs during close exposure (<6 feet) to an infected person, primarily via respiratory droplets produced when the infected person coughs or sneezes. Shedding of high viral titers has been documented from the respiratory tract, including shedding before the onset of symptoms, and results in droplet transmission of SARS-CoV-2 (Zou et al NEJM 2020). Transmission via droplet spread can occur from both symptomatic and asymptomatic individuals who are infected with COVID-19 (Arons et al NEJM 2020). In addition, it appears that patients with COVID-19 have the highest viral loads early in the course of their infection. Thus, a reliance on symptom-based screening strategies alone are not sufficient to prevent or diagnose infection; consideration of symptoms and exposure history, along with testing is imperative.

Donor screening in the era of COVID-19

The epidemiology of SARS-CoV-2 is changing over time, and the knowledge base is rapidly expanding. The recommendations suggested below are to assist with specific considerations

regarding donor screening that may arise, but these are subject to revision as new data accumulate. Some screening considerations are pertinent to both living and deceased donation while other recommendations refer only to one or the other. Finally, it should also be recognized that no test is 100% sensitive or specific and both false positive and false negative results may occur. Accordingly, the risk: benefit ratio for an individual living donor and transplant candidate should always be taken into consideration when making the final decision to perform a transplant. This includes the risk of proceeding with a transplant as well as the risk of deferring and/or potentially foregoing transplantation.

Can SARS-CoV-2 be transmitted from living or deceased donors?

The risk of a COVID-19 infection from an infected living or deceased donor is unknown at this time, but to date, there have been no known proven cases of donor-derived transmission. In addition, transmission from blood banks has not been documented at this time, and blood banks currently screen by acute symptoms only. Factors that could impact the transmission of SARS-CoV-2 from an organ donor include viability of the virus within the blood and its viability within specific organ compartments of an infected donor. Epidemiologic exposures need to be considered when assessing a donor's risk for infection. Other factors to consider when assessing an organ for transplantation is the risk of the transplant candidate's mortality while on the transplant waitlist, as well as the impact that a COVID-19 donor-derived infection could have on the recipient's medical system and community.

How should deceased donors be screened and tested?

Donors should be screened epidemiologically, including for known contacts, and by clinical history for suspected COVID-19 infection. While ground glass opacification has been well described in patients with confirmed SARS-CoV-2 infection, it is a non-specific finding. Accordingly, a CT scan of the chest cannot be relied upon either to exclude or diagnose SARS-CoV-2 infection in potential deceased or living donors and should not be used as the sole diagnostic modality.

Donor testing recommendations (Table 1):

- Given ongoing, wide-spread community transmission, viral testing of at least one sample from the respiratory tract by NAT for SARS-CoV-2 should be performed within 3 days of procurement.
- In addition, some experts recommend a second viral test be performed 24-hours after the initial test and within 24-48 hours of procurement when feasible.
- For thoracic organ donors, we recommend obtaining testing of both the upper and lower respiratory tract (e.g. tracheal aspirate, bronchial wash, or bronchoalveolar lavage) when feasible.
- Additional testing for SARS-CoV-2 that may have been performed prior to donation should also be reviewed and made available to evaluating centers.

- For donors previously known to have had COVID-19, we currently recommend consideration for organ acceptance under the following circumstances:
 - Repeat NAT testing is negative, including upper and lower respiratory tract testing in potential lung donors.
 - Symptoms have resolved and the initial COVID infection occurred between 21 and 90 days prior to donor evaluation, irrespective of repeat NAT test results.
 - For individuals who have recovered from SARS-CoV-2 infection, another positive PCR within 90 days after the onset of illness likely reflects persistent shedding of viral RNA rather than active or new infection (CDC.gov).
 - Consultation with local ID experts should be considered prior to acceptance of those donors.
 - Following infection, reinfection with SARS-CoV-2 has been reported. Consequently, repeat positive PCR tests >90 days after the initial infection should be considered true positives. Consultation with local ID experts should be obtained prior to consideration of these donors.
 - Data regarding the safety of organ donation from donors with previous COVID-19 are extremely limited at this time. In this context, decisions regarding whether to proceed with transplantation must include discussions with the transplant candidate and his or her proxy, as well as consideration of the risk associated with not proceeding with transplantation. Given multiple organ involvement with SARS-CoV-2 infection and unclear long-term implications, close follow up will be required.

How should living donors be screened and tested?

- Once the surgery date is finalized, the living donors should be counseled to contact the transplant center if they or one of their close contacts develops COVID-19 so that the timing of the donation surgery can be reassessed in advance.
- Careful consideration should be given regarding recommending practices to minimize risk of infection, and these recommendations should be balanced against feasibility and practicality for donors. This strategy is vital for programs to continue live donor kidney and liver transplants during COVID-19 pandemic.
 - Living donors and their support persons should be counseled on and encouraged to use preventive strategies (e.g., masking, physical distancing, good hand hygiene), particularly in the 14 days prior to donation to avoid infection.
 - While self-quarantine is recommended as a preventive strategy, it should not be mandatory, as some donors may not have an option to work from home. However, self-quarantine is recommended after the pre-operative COVID-19 testing is performed (see below).

Donor testing recommendations (Table 2):

- Given ongoing, wide-spread community transmission, all living donors should have

- viral testing of at least one sample from the respiratory tract by NAT for SARS-CoV-2 within 3 days of donation.
- The exact timing should be guided by local transplant center and hospital policy and the turn-around time of the test. The test results should be available at least one day before surgery.
 - Living donors who are part of KPD programs should be tested based on the policy of the procuring transplant center.
 - We do not recommend using organs from a living donor with active COVID-19 at this time.
 - Consider delaying transplant for asymptomatic living donors with a known exposure history within the previous 14 days.
 - For living donors who were previously known to have had COVID-19, we would recommend only considering proceeding to transplant under the following circumstances:
 - Repeat NAT testing is negative.
 - Symptoms have resolved and the initial COVID infection occurred between 21 and 90 days prior to donation, irrespective of repeat NAT test results.
 - For individuals who have recovered from SARS-CoV-2 infection, another positive PCR within 90 days after the onset of illness most likely reflects persistent shedding of viral RNA rather than active or new infection (CDC.gov).
 - Consultation with local ID experts should be considered prior to acceptance of those donors.
 - Following infection, reinfection with SARS-CoV-2 has been reported. Consequently, repeat positive PCR tests >90 days after the initial infection should be considered true positives. Consultation with local ID experts should be obtained prior to consideration of these donors.
 - Given the renal dysfunction associated with SARS-CoV-2 infection and unclear long-term implications thereof, additional evaluation may be required when considering kidney transplantation from living donors with previous COVID-19.
 - Data regarding the safety of organ donation from donors with previous COVID-19 are extremely limited at this time. In this context, decisions regarding whether to proceed with transplantation must include discussions with the transplant candidate and his or her proxy, as well as consideration of the risk associated with not proceeding with transplantation.

Additional donor testing considerations

Recommendations for donor screening and testing may change over time as more data accumulate. It should be recognized that no test is 100% sensitive or specific and false positive and false negative results may occur. Positive and negative predictive values will be impacted by the amount of locally circulating virus, specimen quality, and assay performance.

We do not recommend use of NAT from blood, urine, or stool, nor antigen testing from

respiratory samples at this time.

Antibody testing

Serologic assays for SARS-CoV-2 are increasingly available. At this time, our understanding of the application and interpretation of serologic results is evolving but likely varies with the different testing platforms. Test specificity should be interpreted in the context of the prevalence of SARS-CoV-2 in the region. At this time, there is no recommendation to include these tests in the deceased or living donor screening process. If used, results should be viewed as adjunctive data points rather than as primary definitive information to determine final disposition of a potential donor. Issues to keep in mind include:

- IgM assays in general have a higher rate of false positive results compared to IgG assays. However, IgM true positive assays usually reflect recent infections, and in this setting the risk of transmission to the procurement team and the recipient must be considered.
- IgG positive assays may reflect passive antibody from blood products or immunoglobulin.
- It is anticipated that a person with prior COVID-19 disease who has recovered will be IgG positive, but it is not certain how long IgG positivity is maintained.

OPTN Policy 2.2 (OPO Responsibilities), #15, requires storage of blood for all deceased donors which could be used to retrospectively look for positive donor serology if needed.

- While not mandated, storage of respiratory or other specimens in a fashion suitable for PCR testing may also be valuable if subsequent donor-derived infection is suspected. Storage of donor lower respiratory tract specimens may be of particular value when thoracic organs are being procured.

Table 1: Deceased Donor Testing Recommendations

Screening:

- Viral testing of at least one sample from the respiratory tract by NAT for SARS-CoV-2 should be performed within 3 days of procurement.
- Some experts recommend a second viral test be performed 24-hours after the initial test and within 24-48 hours of procurement when feasible.

Thoracic Organs:

- One of the two screening NAT tests should be performed on a lower respiratory tract sample (e.g. tracheal aspirate or bronchial wash, or bronchoalveolar lavage sample), whenever feasible.

Deceased Donors with Previous COVID-19 Infection

- Data regarding the use of organs from donors with previous COVID-19 infection are limited at this time.
- For donors previously known to have had COVID-19, we currently recommend consideration for organ acceptance under the following circumstances:
 - Repeat NAT testing is negative, including upper and lower respiratory tract testing in potential lung donors.
 - Symptoms have resolved and the initial COVID infection occurred between 21 and 90 days prior to donor evaluation, irrespective of repeat NAT test results.
 - For individuals who have recovered from SARS-CoV-2 infection, another positive PCR within 90 days after the onset of illness most likely reflects persistent shedding of viral RNA rather than active or new infection (CDC.gov).
 - Consultation with local ID experts should be considered prior to acceptance of those donors.
 - Following infection, reinfection with SARS-CoV-2 has been reported. Consequently, repeat positive PCR tests >90 days after the initial infection should be considered true positives. Consultation with local ID experts should be obtained prior to consideration of these donors.
 - Data regarding the safety of organ donation from donors with previous COVID-19 are extremely limited at this time. In this context, decisions regarding whether to proceed with transplantation must include discussions with the transplant candidate and his or her proxy, as well as consideration of the risk associated with not proceeding with transplantation. Given multiple organ involvement with SARS-CoV-2 infection and unclear long-term implications close follow up will be required.

Table 2: Recommendations to Mitigate the Risk of COVID-19 Transmission from Living Donors

Screening:

- All living donors should have viral testing of at least one sample from the upper respiratory tract by NAT for SARS-CoV-2 as close to donation as possible, but no longer than 3 days prior to surgery.

Contraindications to Donation:

- Any living donor with active COVID-19 infection.
- Consider delaying transplant for asymptomatic living donors with a known exposure history within the previous 14 days.

Living Donors with Previous COVID-19 Infection

- Data regarding the use of organs from donors with previous COVID-19 are extremely limited at this time.
- For donors previously known to have had COVID-19, we currently recommend consideration for organ acceptance under the following circumstances:
 - Repeat NAT testing is negative.
 - Symptoms have resolved and the initial COVID infection occurred between 21 and 90 days prior to donor evaluation, irrespective of repeat NAT test results.
 - For individuals who have recovered from SARS-CoV-2 infection, another positive PCR within 90 days after the onset of illness likely reflects persistent shedding of viral RNA rather than active or new infection (CDC.gov).
 - Consultation with local ID experts should be considered prior to acceptance of those donors.
 - Following infection, reinfection with SARS-CoV-2 has been reported. Consequently, repeat positive PCR tests >90 days after the initial infection should be considered true positives. Consultation with local ID experts should be obtained prior to consideration of these donors.
 - Given the renal dysfunction associated with SARS-CoV-2 infection and unclear long-term implications thereof, additional evaluation may be required when considering kidney transplantation from living donors with previous COVID-19.
 - Data regarding the safety of organ donation from donors with previous COVID-19 are extremely limited at this time. In this context, decisions regarding whether to proceed with transplantation must include discussions with the transplant candidate and his or her proxy, as well as consideration of the risk associated with not proceeding with transplantation.

The current outbreak is unpredictable. During widespread community-transmission, healthcare infrastructure and capacity issues may have further impact on donation and transplantation. These recommendations will be regularly updated to account for the changing epidemiology and new information regarding treatment and testing.

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