



MARCH 14, 2022

UPDATED GUIDANCE AND COVID-19 SCREENING RECOMMENDATIONS

The Policy & Position Review Subcommittee of the EBAA Medical Advisory Board continues to update its guidance and screening recommendations as the COVID-19 pandemic evolves based on the latest guidelines from the FDA and CDC as well as available scientific evidence. The most current set of guidelines, designed for recipient and recovery technician safety, specify criteria for: 1) Donor ineligibility and 2) Donor eligibility requiring Medical Director review. In this second category, donors who have signs* and symptoms† possibly consistent with COVID-19 but that are reasonably explained by a plausible alternative etiology may be eligible for transplantation. Donors who are not excluded by one of the criteria listed below should be considered eligible if all other eligibility criteria are met.

1. Donors should be determined ineligible who in the 10 days prior to death:
 - a) were diagnosed with acute COVID-19; OR
 - b) tested positive for COVID-19 by direct viral testing methods (e.g., NAAT and/or antigen); OR
 - c) had close contact‡ with a person diagnosed with or suspected to have COVID-19 AND developed signs and symptoms of COVID-19, regardless of a plausible alternative etiology or vaccination history

2. Donors should be evaluated for eligibility by a Medical Director who:
 - a) in the 10 days prior to death, without a known close contact with a person diagnosed with or suspected to have COVID-19, developed new signs and/or symptoms consistent with acute COVID-19 not explained by a plausible alternative etiology; OR
 - b) in the 10 days prior to death, had a known close contact with a person diagnosed with or suspected to have COVID-19 AND was asymptomatic; OR
 - c) in the 11 to 20 days prior to death had a positive or reactive test for SARS-CoV-2§ AND had ongoing signs and/or symptoms of COVID-19, regardless of a plausible alternative etiology.

*COVID-19 Signs
Development of any of the following signs may be consistent with COVID-19 infection: <ul style="list-style-type: none">• ARDS• Pneumonia• Pulmonary computed tomography (CT) showing “ground glass opacities”

†COVID-19 Symptoms
Development of acute symptoms may be consistent with COVID-19 infection. People with COVID-19 have reported a wide range of symptoms, ranging from mild to severe. <ul style="list-style-type: none">• Fever or chills• Cough• Shortness of breath or difficulty breathing• Fatigue• Muscle or body aches

- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

Regarding persistent symptoms (extending beyond 10 days from symptom onset):

- People with “long COVID-19” or “post COVID-19 syndrome” may have symptoms that overlap with active (acute) COVID-19 infection including but not limited to: fatigue, shortness of breath, cough, joint pain, chest pain, memory loss, concentration or sleep problems, muscle pain, headache, fast or pounding heartbeat, loss of smell or taste, depression, anxiety, fever, dizziness upon standing, and/or worsened symptoms after physical or mental activities. These symptoms can persist long after active infection or any detectable viral load and do not make the donor ineligible outside of the screening recommendations.^{1,2}
- Immunocompromised people may have symptoms up to 20 days after symptom onset with a persistently high viral load. Care should be taken to exclude these individuals from transplant donation due to potential for transmission of viable SARS-CoV-2.

‡Close Contact

A close contact is defined by the CDC as someone who was within [6 feet of an infected person](#) (laboratory-confirmed or a [clinical diagnosis](#)) for a total of 15 minutes or more over a 24-hour period (for example, three individual 5-minute exposures for a total of 15 minutes). An infected person can spread COVID-19 starting from 2 days before they have any symptoms (or, if they are asymptomatic, 2 days before their specimen that tested positive was collected), until they meet the criteria for [ending isolation](#).

§SARS-CoV-2 Testing

Includes NAAT and antigen testing of nasal or nasopharyngeal specimens; excludes antibody testing. Donors who are severely ill (i.e., those requiring hospitalization, intensive care, or ventilation support) or [moderately to severely immunocompromised](#) may produce replication-competent virus beyond 20 days. The CDC recommends an isolation period of at least 20 days and ending isolation in conjunction with a test-based strategy and consultation with an infectious disease specialist. Therefore, extending the duration of precaution in this donor population up to 20 days after symptom onset may be warranted.

NOTES

The value of donor screening for SARS-CoV-2 is subject to ongoing assessment. This guidance provides the means to minimize COVID-19 transmission risk and will allow for the continued provision of safe corneal tissue to patients while minimizing the wastage of suitable donor corneal tissue. Eye bankers and corneal surgeons should continue to keep in mind the following with regard to the safety of corneal tissue and ocular tissue recovery:

1. Individuals who have received non-replicating, inactivated, or RNA-based COVID-19 vaccines are not precluded from donating cells, tissues, or cellular or tissue-based products.³ If the vaccination status of a donor is known, it must be communicated to end-users on Tissue Report Forms or other supporting documents.
2. Current EBAA Medical Standards require use of a double povidone iodine donor prep; povidone iodine has documented in vitro viricidal activity against coronaviruses.
3. The EBAA acknowledges that other associations, hospital systems, eye banks, departments of health, or governments may require that all donors be tested for COVID-

19. Eye banks must establish a protocol to ensure access to testing notification and results obtained by partner agencies to prevent discordant resulting and/or discovery of results after release of tissue for transplant use. Results of such testing must be communicated to end-users on Tissue Report Forms or other supporting documents.
4. Cadaveric PCR or antigen testing for SARS-CoV-2 may be an additional tool to assist Medical Directors in determining donor eligibility. However, currently available tests for detecting the SARS-CoV-2 virus have not been validated for postmortem use.⁴
 5. Medical Director review for final determination of donor eligibility in certain cases allows for further assessment of the full clinical picture and/or case specific scenarios.
 6. There have been no reported cases of transmission of SARS-CoV-2, MERS-CoV, or any other coronavirus via transplantation of ocular tissue.⁴

REFERENCES

¹ Mayo Clinic Staff. "COVID-19 (Coronavirus): Long-term Effects". Mayo Clinic Health System. October 22, 2021. <https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-long-term-effects/art-20490351>

² United States, Department of Health and Human Services, Centers for Disease Control and Prevention. "Post-COVID Conditions." Centers for Disease Control and Prevention (US CDC). September 16, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/long-term-effects/index.html>

³Updated Information for Human Cell, Tissue, or Cellular or Tissue-based Product (HCT/P) Establishments Regarding the Coronavirus Disease 2019 Pandemic". *US Food & Drug Administration*, US Department of Health & Human Services, January 4, 2021, <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/updated-information-human-cell-tissue-or-cellular-or-tissue-based-product-hctp-establishments>.

⁴Aldave AJ, DeMatteo J, Chamberlain WD, Philippy B, Farooq AV, Buckman N, Crosson A, Li J, Meinecke E, Kaufman AH. "COVID and the Cornea: From Controversies to Consensus: Report of the Eye Bank Association of America Medical Advisory Board Policy and Position Review Subcommittee." *Cornea*. 2021;40:809-816.