OCTOBER 27, 2021

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. In this current version the decision table has been replaced by a simplified set of guidelines, designed for recipient and recovery technician safety, that specify criteria for: 1) Donor eligibility requiring Medical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 14 days prior to death:
   a) were diagnosed with 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 14 days prior to death, without a known close contact with a person diagnosed with or suspected to have COVID-19, experienced signs and/or symptoms consistent with COVID-19 not explained by a plausible alternative etiology; OR
   b) in the 14 days prior to death, had a known close contact with a person diagnosed with or suspected to have COVID-19 prior to death AND was asymptomatic; OR
   c) in the 15 to 28 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.

<table>
<thead>
<tr>
<th>COVID-19 Signs</th>
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<tbody>
<tr>
<td>Development of any of the following signs may be consistent with COVID-19 infection:</td>
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<tr>
<td>• ARDS</td>
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<td>• Pneumonia</td>
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<td>• Pulmonary computed tomography (CT) showing “ground glass opacities”</td>
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<table>
<thead>
<tr>
<th>COVID-19 Symptoms</th>
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<td>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 illness.</td>
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<tr>
<td>• Fever or chills</td>
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<td>• Cough</td>
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<td>• Shortness of breath or difficulty breathing</td>
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Fatigue
• Muscle or body aches
• Headache
• New loss of taste or smell
• Sore throat
• Congestion or runny nose
• Nausea or vomiting
• Diarrhea

Close Contact
A close contact is defined by 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 more than 20 days after symptom onset or, for those who were asymptomatic throughout their infection, the date of their first positive viral test. Therefore, extending the duration of precaution in this donor population up to 20 days after symptom onset may be warranted.

NOTES
Progression in our understanding of the utility of donor screening for the SARS-CoV-2 virus, the risk of transmission via corneal transplantation and means to minimize this risk 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:

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. 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.
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.
REFERENCES
