

# Updated Information for Human Cell, Tissue, or Cellular or Tissue-based Product (HCT/P) Establishments Regarding the COVID-19 Pandemic

**July 2, 2020**

FDA continues to work closely with CDC and other federal and international agencies to monitor the coronavirus disease 2019 (COVID-19) pandemic caused by the virus, SARS-CoV-2. Respiratory viruses, in general, are not known to be transmitted by implantation, transplantation, infusion, or transfer of human cells, tissues, or cellular or tissue-based products (HCT/Ps). To date, there have been no reported cases of transmission of COVID-19 via these products.

Routine screening measures are already in place for evaluating clinical evidence of infection in HCT/P donors.

## **Considerations**

FDA does not recommend using laboratory tests to screen asymptomatic HCT/P donors.

FDA is aware that some HCT/P establishments in the U.S. are considering additional donor screening and testing measures in response to the COVID-19 pandemic.

The HCT/P establishment's responsible person must determine and document the eligibility of a cell or tissue donor (21 CFR 1271.50). Based on information available at this time, establishments may wish to consider, whether, in the 28 days prior to HCT/P recovery, the donor

- cared for, lived with, or otherwise had close contact with individuals diagnosed with or suspected of having COVID-19 infection; or
- had been diagnosed with or suspected of having COVID-19 infection; or
- had a positive diagnostic test (e.g., nasopharyngeal swab) for SARS-CoV-2 but never developed symptoms.

FDA will continue to monitor the situation and will issue updates as information becomes available.

## **Additional Resources:**

- CDC: Coronavirus Disease 2019 (COVID-19) web page (<https://www.cdc.gov/coronavirus/2019-ncov/index.html>)
- FDA: Coronavirus Disease 2019 (COVID-19) web page (</emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>)