

Important Information for Human Cell, Tissue, or Cellular or Tissue-based Product (HCT/P) Establishments Regarding the 2019 Novel Coronavirus Outbreak

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FDA continues to work closely with CDC and other federal and international agencies to monitor the evolving outbreak of the 2019 novel coronavirus ([/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19](#)) (COVID-19) that was first identified in Wuhan, Hubei Province, China. While 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), the potential for transmission of COVID-19 by HCT/Ps is unknown at this time. 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 is aware that some HCT/P establishments in the U.S. are considering additional donor screening measures in response to the COVID-19 outbreak.

The HCT/P establishment's responsible person must evaluate a prospective donor and determine eligibility (21 CFR 1271.50). Based on the limited information available at this time, establishments may wish to consider the following donor history in the 28 days prior to HCT/P recovery for persons who have:

- traveled to areas with COVID-19 outbreaks, as defined by CDC
- lived with individuals diagnosed with or suspected of having COVID-19 infection; or
- been diagnosed with or suspected of having COVID-19 infection.

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

Additional Resources:

- CDC 2019 Novel Coronavirus web page (<https://www.cdc.gov/coronavirus/2019-ncov/index.html>)
- Novel coronavirus (COVID-19) web page ([/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19](#))