Updated Information for Human Cell, Tissue, or Cellular or Tissue-based Product (HCT/P) Establishments Regarding the Coronavirus Disease 2019 Pandemic

April 1, 2020

FDA continues to work closely with CDC and other federal and international agencies to monitor the evolving outbreak of the 2019 coronavirus that was first identified in Wuhan, Hubei Province, China. The virus has been named "SARS-CoV-2" and the disease it causes has been named coronavirus disease 2019 (abbreviated COVID-19). 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 and testing measures in response to the COVID-19 outbreak.

At this time, FDA does not recommend establishments use laboratory tests to screen asymptomatic HCT/P donors. Based on available information, it appears that SARS-CoV2 has only been detected in blood samples of a small percentage of severely ill patients.

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, 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
- been diagnosed with or suspected of having COVID-19 infection.

For HCT/Ps regulated as biological products under Section 351 of the Public Health Service Act, FDA is continually assessing available scientific evidence, and evaluating benefits and risks, to determine whether SARS-CoV-2 testing is warranted on certain types of HCT/Ps used in the manufacture of a biological product and/or warranted for the final product.

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 (https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19)
- FDA: Important Information for Human Cell, Tissue, or Cellular or Tissue-based Product (HCT/P) Establishments Regarding the 2019 Novel Coronavirus Outbreak (https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/important-information-human-cell-tissue-or-cellular-or-tissue-based-product-hctp-establishments), February 14, 2020