

Important Information for Blood Establishments Regarding the Novel Coronavirus Outbreak

February 4, 2020

FDA is working closely with CDC and other federal and international agencies to monitor the evolving outbreak of the 2019 novel coronavirus (2019-nCoV) that was first identified in Wuhan, Hubei Province, China. The potential for transmission of 2019-nCoV by blood and blood components is unknown at this time. However, respiratory viruses, in general, are not known to be transmitted by blood transfusion, and there have been no reported cases of transfusion-transmitted coronavirus.

Routine blood donor screening measures that are already in place should prevent individuals with clinical respiratory infections from donating blood. For example, blood donors must be in good health and have a normal temperature on the day of donation (21 CFR 630.10).

Considerations

FDA is aware that some blood establishments are considering donor education and/or donor deferral measures in response to 2019-nCoV. As a precaution, blood establishments may wish to consider whether to provide donor education, encourage self-deferral, and manage post-donation information about 2019-nCoV.

- Blood establishments may wish to consider updating donor educational materials to instruct individuals to self-defer and refrain from blood donation if they have:
 - traveled to areas with 2019-nCoV outbreaks, as defined by CDC;
 - lived with individuals diagnosed with or suspected of having 2019-nCoV infection;
 - been diagnosed with or suspected of having 2019-nCoV infection.

The blood establishment's responsible physician must evaluate the prospective donor and determine eligibility (21 CFR 630.5). Based on the limited information available at this time, we suggest individuals refrain from donating blood at least 28 days after resolution of symptoms after a diagnosis of 2019-nCoV infection or 28 days after the date of departure from an outbreak area or the last possible close contact exposure to a person with 2019-nCoV infection.

- Blood establishments may wish to consider updating post-donation instructions provided to all donors of blood and blood components to ask donors to report a subsequent diagnosis of 2019-nCoV infection as soon as possible to the blood establishment. Blood establishments may wish to consider retrieval and quarantine of blood and blood components collected in the 28 days prior to or after 2019-nCoV

disease onset; or collected in the 28 days prior to or after possible exposure to patients with 2019-nCoV infection.

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

Additional Resources:

- CDC 2019 Novel Coronavirus web page (<https://www.cdc.gov/coronavirus/2019-ncov/index.html>)
- FDA Novel coronavirus (2019-nCoV) web page (</emergency-preparedness-and-response/mcm-issues/novel-coronavirus-2019-ncov>)