

Updated Information for Blood Establishments Regarding the Novel Coronavirus (COVID-19) Outbreak







May 11, 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 blood transfusion. There have been no reported cases of transfusion-transmitted coronavirus, including SARS-CoV-2, worldwide.

Routine measures used to determine blood donor eligibility 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).

As communities are affected, it is imperative that healthy individuals continue to donate blood.

Considerations

- FDA supports the recommendations of AABB's Interorganizational Task Force encouraging healthy individuals to make plans to donate blood to maintain the adequacy of the nation's blood supply.
 - Those interested in donating blood may contact the following organizations to find a local blood collection site and to schedule an appointment:
 - AABB: www.aabb.org (<http://www.aabb.org>) 
(<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)
(<http://aabb.org>) (<http://aabb.org>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)); +1.301.907.6977
 - America's Blood Centers: www.americasblood.org
(<http://www.americasblood.org>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) (<https://americasblood.org/>)
(<https://americasblood.org/>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>))
 - American Red Cross: www.redcrossblood.org
(<https://www.redcrossblood.org>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) (<https://www.redcrossblood.org/>)
(<https://www.redcrossblood.org/>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)) +1.800.RED CROSS
(+1.800.733.2767)

- Armed Services Blood Program: www.militaryblood.dod.mil
(<https://www.militaryblood.dod.mil>) ↗ (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)
(<https://www.militaryblood.dod.mil/>
(<https://www.militaryblood.dod.mil/>) ↗ (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)) +1.703.681.8024
- FDA does not recommend using laboratory tests to screen asymptomatic blood donors.
- FDA is aware that some blood establishments have introduced donor education and/or donor deferral measures in response to COVID-19.
- FDA recognizes that deferral for travel to areas with cases of COVID-19 is not feasible.
- Blood establishments may wish to consider donor educational materials to instruct individuals to self-defer and refrain from blood donation if they have:
 - been diagnosed with COVID-19 and had symptomatic disease,
 - are suspected to have COVID-19, or
 - had a positive diagnostic test (e.g., nasopharyngeal swab) for SARS-CoV-2 but never developed symptoms.

You may wish to consider instructing these individuals not to donate for at least 14 days after complete resolution of symptoms or the date of the positive diagnostic test, whichever period is longer.

- The blood establishment's responsible physician must evaluate the prospective donor and determine eligibility (21 CFR 630.5). The responsible physician may want to consider the following:
 - individuals diagnosed with COVID-19 or who are suspected of having COVID-19, and who had symptomatic disease, refrain from donating blood for at least 14 days after complete resolution of symptoms,
 - individuals who had a positive diagnostic test for SARS-CoV-2 (e.g., nasopharyngeal swab), but never developed symptoms, refrain from donating at least 14 days after the date of the positive test result,
 - individuals who are tested and found positive for SARS-CoV-2 antibodies, but who did not have prior diagnostic testing and never developed symptoms, can donate without a waiting period and without performing a diagnostic test (e.g., nasopharyngeal swab).
- 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 COVID-19 as soon as possible to the blood establishment. Blood establishments may wish to consider retrieval and quarantine of blood and blood

components if donors report onset of fever, symptoms or a diagnosis of COVID-19 within 48 hours after their donation.

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

Resources:

- CDC: Coronavirus disease 2019 (COVID-19) (<https://www.cdc.gov/coronavirus/2019-ncov/index.html>)
- FDA: Coronavirus Disease 2019 (COVID-19) (<https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>)
- FDA: Donate COVID-19 Plasma (<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/donate-covid-19-plasma>)
- FDA/CBER: Coronavirus (COVID-19) | CBER-Regulated Biologics (<https://www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics>)
- AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism: www.aabb.org (<http://www.aabb.org>) ↗ (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)