SUMMARY: DONATION OF CCP, BLOOD COMPONENTS and HCT/Ps
FOLLOWING COVID-19 VACCINES OR TREATMENT WITH CCP OR MONOCLONALS

HCT/P DONOR ELIGIBILITY:
For the agency’s current thinking on HCT/P donation during the pandemic, including donor eligibility following vaccination to prevent COVID-19, refer to FDA’s January 4th Safety and Availability communication, Updated Information for Human Cell, Tissue, or Cellular or Tissue-based Product (HCT/P) Establishments Regarding the COVID-19 Pandemic.

CCP and ROUTINE BLOOD DONOR ELIGIBILITY:
1-Blood donor deferral following COVID-19 vaccines is not required. Consider the following information on FDA’s web page Updated Information for Blood Establishments Regarding the COVID-19 Pandemic and Blood Donation last updated 01/19/21”

The blood establishment’s responsible physician must evaluate prospective donors and determine eligibility (21 CFR 630.5). The donor must be in good health and meet all donor eligibility criteria on the day of donation (21 CFR 630.10). The responsible physician may wish to consider the following:

- individuals who received a nonreplicating, inactivated, or mRNA-based COVID-19 vaccine can donate blood without a waiting period,
- individuals who received a live-attenuated viral COVID-19 vaccine, refrain from donating blood for a short waiting period (e.g., 14 days) after receipt of the vaccine,
- individuals who are uncertain about which COVID-19 vaccine was administered, refrain from donating for a short waiting period (e.g., 14 days) if it is possible that the individual received a live-attenuated viral vaccine.

Any decision to update policies for deferral following COVID vaccines is left to the discretion of the Medical Director.

2-Donation following CCP transfusion requires deferral.
- CCP donors must meet all allogeneic blood donor criteria and deferral requirements, including the 3-month deferral from the date of CCP transfusion.

3-Individuals who have never been infected with COVID-19 and have received a COVID-19 vaccine are not eligible to donate CCP – FDA’s Jan 2021 CCP EUA guidance (page 7) FDA states:

“This is to ensure that COVID-19 convalescent plasma collected from donors contains sufficient antibodies directly related to their immune response to COVID-19 infection.

Administration of COVID-19 vaccines for the purpose of boosting immunity of convalescent plasma donors would need to be conducted within a clinical trial under IND [21 CFR Part 312].”

Note: This is not a change from earlier recommendations.

4-Recovered COVID-19 patients who are eligible to donate CCP and also receive an investigational, authorized or licensed COVID-19 vaccine after recovery are eligible to donate only if they (page 7 of FDA’s Jan 2021 CCP EUA guidance):

1) had symptoms of COVID-19 and a positive test result from a diagnostic test approved, cleared, or authorized by FDA (i.e., individuals who meet the qualification for evidence of COVID-19 described in section III.B.1.a.1. above), AND
2) received the COVID-19 vaccine after diagnosis of COVID-19, AND
3) are within 6 months after complete resolution of COVID-19 symptoms.

5-FDA confirmed that deferral following receipt of monoclonal antibodies is at the discretion of the physician oversight.

### TRACKING CHANGES IN FDA’s JAN 19 2021 Updated Information for Blood Establishments Regarding the COVID-19 Pandemic and Blood Donation

<table>
<thead>
<tr>
<th>FDA’S MAY 11th UPDATE</th>
<th>REVISED TO</th>
<th>UPDATED JAN 19, 2021 COMMUNICATION</th>
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<tbody>
<tr>
<td>Deleted information is in strikeout</td>
<td><strong>REVISED TO</strong></td>
<td>New information is highlighted in yellow</td>
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<td><strong>Most significant change:</strong> Addition of vaccine deferral considerations.</td>
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- 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:

- 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 and blood components, including Source Plasma.
| AABB: [www.aabb.org](http://www.aabb.org) (External Link Disclaimer) | FDA does not recommend using laboratory tests to screen asymptomatic blood donors. |
| +1.301.907.6977 |
| America’s Blood Centers: [www.americasblood.org](http://www.americasblood.org) (External Link Disclaimer) | FDA does not recommend using COVID-19 laboratory tests to screen routine blood donors. |
| +1.800.RED CROSS (+1.800.733.2767) |
| American Red Cross: [www.redcrossblood.org](http://www.redcrossblood.org) (External Link Disclaimer) | +1.703.681.8024 |
| Armed Services Blood Program: [www.militaryblood.dod.mil](http://www.militaryblood.dod.mil) (External Link Disclaimer) |

**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).

New information on vaccine deferrals:
- individuals who received a nonreplicating, inactivated, or mRNA-based COVID-19 vaccine can donate blood without a waiting period,

- individuals who received a live-attenuated viral COVID-19 vaccine, refrain from donating blood for a short waiting period (e.g., 14 days) after receipt of the vaccine,

- individuals who are uncertain about which COVID-19 vaccine was administered, refrain from donating for a short waiting period (e.g., 14 days) if it is possible that the individual received a live-attenuated viral vaccine.

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)
FDA: Coronavirus Disease 2019 (COVID-19)
FDA: Donate COVID-19 Plasma
FDA/CBER: Coronavirus (COVID-19) | CBER-Regulated Biologics