

Updated Information from FDA on Donation of CCP, Blood Components and HCT/Ps, Including Information on COVID-19 Vaccines, Treatment with CCP or Monoclonals

1) 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](#).

2) CCP and ROUTINE BLOOD DONOR ELIGIBILITY:

2-1. Blood donor eligibility following COVID-19 vaccine

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" – see the full document [on page 2 below](#).

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.
- **In response to our April 14, 2021 request on behalf of AABB members regarding FDA's pause of the Johnson & Johnson vaccine, FDA confirmed:**
FDA does not require deferral after receipt of the Johnson & Johnson vaccine of blood donors who meet all other eligibility requirements.

2-2. Blood donor eligibility following CCP transfusion

Blood donor deferral following CCP transfusion is required.

- Blood donor and CCP donors must meet all allogeneic blood donor criteria and deferral requirements, including the 3-month deferral from the date of CCP transfusion or any other blood transfusion – [Feb 2021 CCP guidance](#), p. 6

2-3. CCP donor eligibility following vaccination if never infected

Individuals who have never been infected with COVID-19 and have received a COVID-19 vaccine are not eligible to donate CCP – [FDA's Feb 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.

2-4. CCP donor eligibility if recovered patient later receives a COVID-19 vaccine

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 Feb 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.*

2-5. CCP donor eligibility after treatment with monoclonals

CCP donors are deferred for at least 3 months following receipt of :

- investigational COVID-19 monoclonal antibody therapy as a participant in a clinical trial, **or**
- an authorized or licensed COVID-19 monoclonal antibody therapy."

TRACKING CHANGES IN FDA's JAN 19 2021 [Updated Information for Blood Establishments Regarding the COVID-19 Pandemic and Blood Donation](#)

January 19, 2021

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).

It is imperative that healthy individuals continue to donate blood and blood components, including Source Plasma.

Considerations

- FDA does not recommend using COVID-19 laboratory tests to screen routine blood donors.
- 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 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),
- 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.

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](#)