

Convalescent Plasma Clinician Drop-in Newsletter



U.S. FOOD & DRUG
ADMINISTRATION

FDA ENCOURAGES AMERICANS TO DONATE COVID-19 PLASMA AND BLOOD

The U.S. Food and Drug Administration continues to play a critical role in accelerating medical countermeasures to treat and prevent COVID-19. The agency is taking the lead on a national effort to facilitate the development of, and access to, two investigational therapies derived from human blood. These are called convalescent plasma and hyperimmune globulin, antibody-rich blood products made from plasma donated by people who have recovered from the virus.

Prior experience with respiratory viruses and limited data suggest that convalescent plasma has the potential to lessen the severity or shorten the length of illness caused by COVID-19. This treatment must be evaluated in the context of clinical trials. Convalescent plasma is being investigated for the treatment of COVID-19 because there is no FDA-approved treatment for this disease and there is some information that suggests it might help some patients recover from COVID-19.

However, further investigation is still necessary to determine if convalescent plasma might shorten the duration of illness, reduce morbidity, or prevent deaths associated with COVID-19. Plasma transfusions are generally safe and well-tolerated by most patients but can cause allergic reactions and other side effects.

COVID-19 convalescent plasma has not yet been approved. The following pathways are available for administering or studying the use of COVID-19 convalescent plasma:

- single patient investigational new drug applications (INDs),
- expanded access, and
- clinical trials.

Please see the [Recommendations for Investigational COVID-19 Convalescent Plasma](#) posted on FDA's web site. Convalescent plasma is not yet widely available from blood centers, although many are starting to collect it. Health care providers or acute care facilities should obtain COVID-19 convalescent plasma from an FDA-registered blood establishment. FDA does not provide COVID-19 convalescent plasma to hospitals.

Additionally, COVID-19 convalescent plasma must only be collected from recovered individuals if they are eligible to donate blood. Qualifications for such donors also include a prior diagnosis of COVID-19 documented by a laboratory test at the time of illness, or a positive serological test for SARS-CoV-2 antibodies after recovery, if prior diagnostic testing was not performed at the time COVID-19 was suspected.

[For more information on donor eligibility please access the FDA website.](#)

Potential donors should be fully recovered from COVID-19, with complete resolution of symptoms for at least 14 days before donation of COVID-19 convalescent plasma. Health care providers may wish to encourage their patients who have recovered to consider donating. Information about donating may be found on [FDA's website](#).