



**Statement on COVID-19 Convalescent Plasma**  
*(January 10, 2022)*

America's Blood Centers (ABC) and its network of not-for-profit community blood centers remain committed to supporting the nation's COVID-19 pandemic response. In light of clinical trials showing positive efficacy of COVID-19 Convalescent Plasma (CCP) when administered early in the course of treatment, the Food and Drug Administration (FDA) recently updated the Emergency Use Authorization (EUA) for CCP to expand the administration of CCP to the outpatient environment. This expansion is especially important as COVID-19 cases rise across the country, leaving existing therapeutics in limited supply. Based on recent data, the updated EUA also limits the administration of CCP to patients with immunosuppressive disease or those receiving immunosuppressive treatment.

ABC supports FDA's continued interest in convalescent plasma as a treatment for COVID-19 patients. However, we stress that operational considerations must be accounted for before CCP can be a readily available treatment for those patients in need. These considerations, include, but are not limited to:

- while the FDA recently updated guidance for blood centers to allow for individuals with breakthrough cases of COVID-19 following vaccination to donate CCP, the process to identify eligible donors remains onerous. Additional changes would need to occur before centers could operationalize a large-scale collection of CCP once again;
- due to recent changes by FDA to the list of approved antibody screening tests as well as a previous wane in hospital demand for CCP, a very limited supply of CCP currently exists. Given that the newly approved tests are not currently in wide distribution, it will take weeks for participating testing laboratories, suppliers, and blood centers to be ready to resume CCP production;
- the costs to resume CCP collections are significant and the long-term demand for CCP remains uncertain. The United States Government must play a role in ensuring cost recovery funding to blood centers for CCP collections and production as it has in the past and continues to do with other therapies; and
- the nation continues to face blood shortages brought on by challenges in conducting traditional blood drives and the same staffing shortages seen in other healthcare settings. The need to produce CCP must be balanced by the need to continue to provide blood components to patients facing a variety of acute and ongoing medical conditions.

ABC and its members look forward to continuing to work with our government, hospital, physician, and community partners to meet the current and future needs of the patients we serve.