



To: Carter BloodCare Customers
From: Hospital Relations Department
Date: January 21, 2021
Re: UPDATE: High and Low Titer COVID-19 Convalescent Plasma

UPDATE:

On November 16, 2020, the FDA granted an extension to the deadline for implementation of the Emergency Use Authorization (EUA) for Covid-19 convalescent plasma (CCP). The extension mandated that beginning March 1, 2021, CCP units must be labeled as high or low titer.

On January 15, 2021, the FDA again extended the deadline for implementation of the EUA for CCP mandating that beginning June 1, 2021, CCP units must be labeled as high or low titer. Please be advised that Carter BloodCare will be maintaining a dual inventory of CCP (investigational and titer tested) to ensure patient orders can be filled. Carter BloodCare will continue to label CCP units as high and low titer. Units that are imported to meet the current demand for CCP may or may not be labelled with the high and low titer designation until after the June 1, 2021 deadline.

Please review the January 15th issued FDA guidance in its entirety at <https://www.fda.gov/media/136798/download>.

Carter BloodCare CCP donations are tested by the Ortho VITROS SARS-CoV-2 IgG platform both to determine suitability of the CCP before release, and also for qualifying the unit as high titer or low titer. Units found to have a signal-to-cutoff (S/C) value of 12 or greater qualify the associated units as high titer COVID-19 convalescent plasma. Units found to contain anti-SARS-CoV-2 antibodies with an S/C value below 12 qualify the associated units as low titer COVID-19 convalescent plasma.

- Given the limited availability of high titer CCP, orders for high titer CCP might be placed on back order.
- When high titer CCP is not available, transfusion of more than one (perhaps two) unit of low titer CCP is at the clinician's discretion.
- Please consider implementing a substitution policy to meet patient needs when requesting groups B and AB CCP.
- Carter BloodCare Medical director consultation can be requested if multiple low titer CCP units, or ABO Incompatible CCP transfusion needs to be discussed.
- Depending on the availability of CCP, stock orders may have to be limited.
- Continue to request CCP via the fax order form.
- Continue to encourage recovered COVID-19 patients to donate convalescent plasma www.carterbloodcare.org