



To: Carter BloodCare Customers
From: Hospital Relations Department
Date: November 19, 2020
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 mandates that beginning March 1, 2021 CCP units must be labeled as high or low titer.

Carter BloodCare will proceed with its intended plan to distribute high and low titer CCP prior to the FDA's earlier deadline of December 1, 2020. While we expected to implement next Monday, the persistent limited availability of convalescent plasma has prompted Carter BloodCare to label and distribute anti-SARS CoV-2 IgG tested CCP units that had been in stockpile inventory on November 19. 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.

Background

On August 23, 2020, the FDA issued emergency use authorization for COVID-19 convalescent plasma (CCP) for the treatment of hospitalized patients with coronavirus disease. The FDA had required that blood centers distributing CCP should by December 1, 2020, test for anti-SARS CoV-2 IgG titers and label the product accordingly.

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.

Please review the September 2nd issued FDA guidance in its entirety at <https://www.fda.gov/media/136798/download>.

Impact to Client

- Effective November 23, 2020, Carter BloodCare will distribute anti-SARS CoV-2 IgG tested CCP units.
- The units will be labeled on the lower right hand quadrant as high or low titer for SARS-CoV – 2 antibodies (see examples below). Please note the CCP product codes currently in use are not changing.
- The distinction of “limited by federal law to investigational use” will no longer be present on the label.

- Carter BloodCare’s preliminary data, as well as that of others in the industry, shows that the majority ($\geq 70\%$) of the CCP units have a low antibody titer. We can conclude that, since March, majority of patients have received CCP with low titer.
- Given the very limited availability of high titer CCP, and very limited opportunities to import this product, orders for high titer CCP, will, inevitably, 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. Carter BloodCare Medical director consultation can be requested if this approach needs to be discussed. .
- Depending on the availability of CCP, stock orders will have to be limited.
- On November 5, 2020, ICCBBA released high and low product codes (list attached for your reference). Carter BloodCare is evaluating the need to implement.
- Continue to request CCP via the fax order form.
- Continue to encourage recovered COVID-19 patients to donate convalescent plasma www.carterbloodcare.org

High and Low Titer label examples

