



To: Carter BloodCare Customers
From: Hospital Relations Department
Date: February 5, 2021
Re: Low Titer COVID-19 Convalescent Plasma Update

UPDATE:

On February 4, 2021, the FDA revised the Letter of Authorization for COVID-19 convalescent plasma (CCP.) The revision removes the use of low titer COVID-19 CCP and limits the use of high titer COVID-19 CCP to hospitalized patients with COVID-19 early in disease course and to those hospitalized who have impaired humoral immunity and cannot produce an adequate antibody response. Included in the revision is a change to the cutoff of the Ortho VITROS Anti-SARS-CoV-2 IgG test from $S/C \geq 12.0$ to $S/C \geq 9.5$ for qualification of COVID-19 convalescent plasma as high titer.

A link to the February 4, 2021 update issued by the FDA is included for your reference <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-updates-emergency-use-authorization-covid-19-convalescent-plasma-reflect-new-data>.

Additional information will be forthcoming as Carter BloodCare continues to work through and implement updates.