Carter BloodCare

To: Carter BloodCare Customers
From: Hospital Relations
Date: January 3, 2022
Re: UPDATE: FDA revisions affecting the use of COVID-19 Convalescent Plasma Usage

Update

According to the FDA revisions, CCP units previously collected and tested by Carter BloodCare do *not* qualify as high titer. Please be advised and do not transfuse any previously collected CCP units you may have in storage. Please notify distribution of the intent to return these frozen products.

Background

On December 28, 2021, the FDA revised the emergency use authorization (EUA) associated with COVID-19 Convalescent Plasma (CCP) restricting the use of CCP with high titers of anti-SARS-COV-2 antibodies for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment in the inpatient or outpatient setting; revised the acceptable tests and increased qualifying antibody test result cutoffs to be used for manufacturing CCP, and made corresponding changes to the authorized Fact Sheets.

Effective immediately, Carter BloodCare will discontinue distribution of CCP until we can confirm that any previously collected units meet the new high titer requirements. We will notify you if and when CCP distribution is resumed. Please review the revisions to the EUA here.

Client Action

- Notify appropriate personnel that CCP distribution is discontinued effective immediately.