

To: Carter BloodCare Customers
From: Hospital Relations
Date: April 9, 2020
Re: UPDATE- COVID-19 Convalescent Plasma

Background

Convalescent plasma is being investigated for the treatment of COVID-19 because there is early information that suggests it might help some patients recover from COVID-19. As communicated on March 30, 2020, Carter BloodCare (CBC) has a process for the *collection* of Convalescent COVID-19 Plasma under single patient emergency IND (investigational new drug).

Please review the *Revised Recommendations for Investigational COVID-19 Convalescent Plasma* (April 8, 2020) <u>https://bit.lv/FDACOVID</u> for details:

Points to highlight:

Criteria for eligibility as convalescent plasma donor:

- 1. Evidence of COVID-19 documented by a laboratory test which must be:
 - A diagnostic test (e.g., nasopharyngeal swab) at the time of illness OR
 - A positive serological test for SARS-CoV-2 antibodies after recovery, if prior diagnostic testing was not performed at the time COVID-19 was suspected.
- 2. Additionally
 - There must be complete resolution of symptoms during 28 days prior to donation

OR

Complete resolution of symptoms during 14 days prior to donation along with negative results for COVID-19, either from one or more nasopharyngeal swab specimens or by a molecular diagnostic test from blood.

- Donors must be male, never pregnant females, or females who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies.
- There must be evidence of SARS-CoV-2 neutralizing antibody titers (e.g., greater than 1:80). (If neutralizing antibody titers cannot be obtained in advance, consider storing a retention sample from the convalescent plasma donation for determining antibody titers at a later date).

Carter BloodCare is recruiting recovered COVID-19 patients who are interested in donating their plasma.

Hospitals play a significant role by identifying and referring potential COVID-19 recovered donors. Inquiries and interest in donating convalescent plasma should be directed to <u>https://www.carterbloodcare.org/plasma-donations-for-treating-covid-19/</u>.

These donors will not need a negative COVID-19 test prior to donating plasma, per FDA rules. The donor collection is occurring on a mobile donor coach at a location separate from normal blood donor collection. The plasma collected ranges from 650 to 825 mls depending on donor weight, gender, and hemoglobin. The final product is aliquotted into 3 or 4 individual units for ease of thawing and administration.

Many of you have also inquired about the Mayo Clinic National Program. This is another route (expanded access) for hospitals to gain use of convalescent plasma using the IRB of the Mayo Clinic. Physicians, facilities and individual patients must still be registered prior to use. Additional information and details can be reviewed at <u>https://www.uscovidplasma.org</u>.

Please do not hesitate to contact us with any questions or concerns.