COVID-19 Convalescent Plasma (CCP) Circular of Information

Product: **COVID-19 Convalescent plasma with high titer SARS-CoV-2 antibodies**

1. Product description

COVID-19 convalescent plasma with high levels of SARS-CoV-2 antibodies (CCP) is human plasma collected by FDA registered or licensed blood establishments from individuals whose plasma contains high levels of anti-SARS-CoV-2 antibodies, and who meet all donor eligibility
requirements (21 CFR 630.10 and 21 CFR 630.15) and qualifications. Convalescent plasma is manufactured from individuals who have recovered from symptomatic SARS-CoV-2 infection in the last 6 months. Convalescent plasma is qualified and labeled as having high levels anti-SARS-CoV-2 antibodies based on testing accepted by FDA.

Qualification of COVID-19 convalescent plasma with high levels of SARS-CoV-2 antibodies is based on serologic correlates of neutralizing activity, i.e., the ability of the donor antibodies to block infection by reference strains of the SARS-CoV-2 virus in laboratory tests.

After meeting CCP donor questionnaire criteria, the donor sample is tested for high levels of antibodies by the GenScript cPass surrogate virus neutralization test with equal or greater than 80% inhibition of wild type RBD binding to ACE2.

The dating period for COVID-19 convalescent plasma should be 6 months from the date of collection. COVID-19 convalescent plasma may be stored frozen at -18°C or colder and has an expiration date of 6 months from the date of collection. Once thawed, it can be refrigerated for up to 5 days prior to patient transfusion.

2. Actions

This product serves as a source of nonlabile plasma proteins that is confirmed to have a high titer of anti-SARS-CoV-2 antibodies.

3. Indications for use

Treatment of COVID-19 in patients with immunocompromise-immunosuppressive disease/process or receiving immunosuppressive treatments at risk of severe disease progression in either the inpatient or outpatient setting.

4. Contraindications

COVID-19 convalescent plasma may be contraindicated in certain patients with a history of severe allergic reactions or anaphylaxis to plasma transfusion.

5. Dosing and Administration:

Clinical dosing may first consider starting with one unit of COVID-19 convalescent plasma (about 200 mL), with administration of additional convalescent plasma units based on the prescribing physician's medical judgment and the patient's clinical response.

Plasma must be ABO compatible with the recipient's red cells. Compatibility with Rh(D) is not necessary in plasma transfusion.

Health care providers will administer COVID-19 convalescent plasma according to standard hospital procedures and institutional medical and nursing practices.

Patients with impaired cardiac function and heart failure may require a smaller volume or more prolonged transfusion times. Administer COVID-19 convalescent plasma through a peripheral or central venous catheter according to standard institutional medical and nursing practices for the administration of plasma, including a slower initial rate.

6. Side Effects and Hazards

Do not use COVID-19 convalescent plasma if there is evidence of container breakage or of thawing during storage. Hazards that pertain to all transfusion components are described in the AABB Circular of Information section titled "Side Effects and Hazards for Whole Blood and All Blood Components" [i].

[i] AABB, the American Red Cross, America's Blood Centers, and the Armed Services Blood Program Circular of Information for the use of Human Blood and Blood Components, June 2024 (http://www.aabb.org/tm/coi/Documents/coi1017.pdf).