Coronavirus (COVID-19) Convalescent Plasma Clinician Information

The information on this page is intended for clinicians and hospitals to obtain COVID-19 Convalescent Plasma for their patients. If you are an individual who has recovered from a COVID-19 infection and wish to be a convalescent plasma donor, please visit our COVID-19 Convalescent Plasma Donor Information Page. Hospitals and clinicians should refer potential donors to this site as well. If you currently have or suspect that you have COVID-19 and have questions about your health, please contact your healthcare professional.

In partnership with the U.S. Food and Drug Administration (FDA), the American Red Cross has developed a process to identify and qualify individuals who have recovered from coronavirus disease 2019 (COVID-19) and to collect their COVID-19 convalescent plasma. The program will work with clinicians to enable rapid access to a new experimental plasma treatment for the most seriously ill patients. Because this is still an Investigational New Drug (IND) program, requesting and receiving convalescent plasma occurs outside the routine product ordering processes. Though still experimental, this move will quickly make this potentially disease-modifying therapy more accessible to treating physicians and COVID-19 patients in need.

FDA has allowed for three pathways through which hospitals can acquire convalescent plasma. Hospitals can pursue the Expanded Access Protocol (EAP), a Single Patient Emergency Investigational New Drug (eIND) application, or another Investigator-Initiated Research IND. Specific information can be found at **Recommendations for Investigational COVID-19 Convalescent Plasma.** Clinicians participating via the EAP and eIND pathways to receive COVID-19 convalescent plasma for their currently ill patients can register them through their respective sites below.

The American Red Cross is encouraging hospitals to pursue registration under Mayo's Expanded Access Protocol (EAP). The Biomedical Advanced Research and Development Authority (BARDA) will be funding all units of COVID-19 convalescent plasma transfused under this protocol so there will be no charge to

hospitals operating under the EAP. Once a hospital registers under this protocol, an unlimited number of patients can be added and the EAP inclusion criteria capture a broader range of patients who clinically qualify for treatment with convalescent plasma.

In line with our mission to prevent and alleviate human suffering in the face of emergencies, the Red Cross is committed to assisting with the plasma collections of carefully screened COVID-19-recovered donors necessary to help enable rapid access to this treatment.

Expanded Access Protocol

The **Expanded Access Protocol (EAP)** is administered by Mayo Clinic. Hospitals must register their institution and enroll patients into the site under Mayo Clinic's IRB. Hospitals will not be required to complete a separate IRB if enrolled in the EAP. Products under this program may be supplied by Red Cross or other participating blood centers (e.g., OneBlood, Vitalant, or other blood center). The goal is that over time the EAP would allow hospitals to stock convalescent plasma for anticipated need.

Registration: Hospitals can join the EAP **here**.

Ordering Convalescent Plasma: Hospitals should contact their regular blood supplier for requests for COVID-19 Convalescent Plasma (CCP). For Red Cross customers, all convalescent plasma orders should be placed directly in Connect.

The blood community has collaborated to utilize a central resource sharing platform to ensure the need for CCP is met throughout the United States. Blood centers will use this network to seek available supplies should they be unable to fill an order directly. Only hospitals that do not have a regular blood supplier should contact 844-633-3226 or covidplasma@bca.coop to request product, all other hospitals should place orders with their provider.

Order fulfillment will be managed on first in, first out basis with the oldest orders being shipped first.

For further information: National Extended Access Protocol

Single Patient Emergency Investigational New Drug (eIND)

The **Single Patient Emergency Investigational New Drug (eIND)** is an alternate option. FDA has also facilitated access to convalescent plasma for use in individual patients with serious or immediately life-threatening COVID-19 infections through an **eIND**. This process allows the use of an investigational drug (i.e., convalescent plasma) for the treatment of an individual patient by a licensed physician upon FDA authorization. The eIND process is not for the use of COVID-19 convalescent plasma for the prevention of infection. FDA approval should be obtained by the patient's physician prior to requesting products from their blood supplier, however urgent needs may be communicated to us while awaiting FDA approval. Hospitals pursuing the eIND process should follow their institutional criteria to determine if an IRB is required or if they require the consent of the patient or patient representative prior to treatment.

Registration: Hospitals should request approval from FDA by visiting **Recommendations for Investigational COVID-19 Convalescent Plasma**. FDA has indicated they will respond within four (4) to eight (8) hours.

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For further information: FDA eIND

Investigator-Initiated Research IND

We are also providing Convalescent Plasma to facilities who have their own research IND.

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We want to share with you that, through all of the above processes, we understand the urgency and that there are patients who are in need.

Thank you for all your efforts to help patients during this unprecedented time. The Red Cross looks forward to supporting you through participation in this program.

We look forward to working together with our hospital partners to support this new development in the fight against COVID-19.

Individuals who have fully recovered from coronavirus infection can **learn how to be a convalescent plasma donor here .**

Frequently Asked Questions

Q. Which patients are candidates for COVID-19 Convalescent Plasma?

A. Patient Eligibility:

- Laboratory-confirmed COVID-19 testing
- Severe or immediately life-threatening COVID-19, for example,
- Severe disease is defined as one or more of the following:
- shortness of breath (dyspnea),
- respiratory frequency ≥ 30/min,
- blood oxygen saturation ≤ 93%,
- partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300,
- lung infiltrates > 50% within 24 to 48 hours
- Life-threatening disease is defined as one or more of the following:
- respiratory failure,
- eptic shock,
- multiple organ dysfunction or failure
- Informed consent provided by the patient or healthcare proxy.

Q. Who qualifies as a Donor for COVID-19 Convalescent Plasma?

A. Donor Qualifications:

- **Evidence of COVID-19 infection**
- Diagnostic test (Nasopharyngeal swab) at time of illness

OR

- Positive serological test for COVID-19 antibodies after recovery, if prior testing was not performed. The American Red Cross is now performing antibody testing on collections from donors who received a diagnosis of presumptive positive but never received a positive confirmatory test.

*List of approved testing can be found **here**.*

AND

- **Resolution of COVID-19 symptoms (return to base-line health status).**

- 14 - 27 days with negative COVID-19 test results

OR

- 28+ days: no further testing required

AND

- **Defined COVID-19 neutralizing antibody titer** (e.g. > 1:80)

- If neutralizing antibody titers cannot be obtained in advance, obtain a sample of the plasma and store for a later test date

- Donor must meet all routine allogeneic apheresis donor criteria per DHQ

- TRALI Mitigation: Males, females who are negative for anti-HLA antibodies (ARC performs this test)

- Aspirin restrictions apply if donor is undergoing a platelet/plasma-type collection (Determined at time of collection)

- Allowable collection every 28 days

Individuals who have fully recovered from coronavirus infection can **learn how to be a convalescent plasma donor here.**

If you are an individual and you currently have or suspect that you have COVID-19 and have questions about your health, please contact your healthcare professional.

Q. What type of Convalescent Plasma Products will be available? −

A. FFP; FP24; Can be extended to 5 days as thawed plasma.

Q. What are the ISBT Codes? +

Q. What is the expiration date of these products? −

A. Just as for 'regular' frozen plasma the shelf life is one year frozen and 5 days post-thaw.

Q. What is the volume of a COVID-19 Convalescent Plasma unit?

A. Units of convalescent plasma will be approximately 200 mL.

Q. What is considered a therapeutic dose of COVID-19 Convalescent Plasma?

A. There is limited data but published reports support the transfusion of one unit of convalescent plasma.

Q. Will the COVID-19 Convalescent Plasma products be pathogen-reduced?

A. No, but the donors will undergo the same screening process and infectious disease testing as our regular donors

Q. What is the therapeutic titer?

A. The FDA recommends neutralizing antibody titers of at least 1:160. A titer of 1:80 may be considered acceptable if an alternative matched unit is not available.

Q. Is the titer level required prior to donating?

A. Not at this time. A specimen will be obtained at the time of collection and will be frozen for later testing.

Q. Can hospitals who have the capability, collect COVID-19 Convalescent Plasma?

A. Yes, but they must still register for an eIND or through the EAP in order to transfuse.

Q. How many convalescent plasma products should be requested per patient?

A. One convalescent plasma product per patient should be ordered, by patient ABO type.

Q. When can my hospital expect to receive products?

A. Once the convalescent plasma program is fully operational by mid-May, products will be dispatched from the nearest available distribution site or blood center. At that time, hospitals should expect to receive products within 24 hours of their online order. Until then, order times may be delayed and we appreciate your patience as the Red Cross works to qualify and collect from recovered COVID-19 donors in order to build inventories of convalescent plasma. The Red Cross is committed to helping patients and will strive to provide product for your orders as soon as possible.

Q. Is liquid convalescent plasma available?

A. The Red Cross is not currently making liquid convalescent plasma available. Program participants and Red Cross customers will be promptly notified if Red Cross convalescent product offerings change.

Q. My hospital would like to request convalescent plasma for research, will the Red Cross supply it?

A. Yes, we are providing COVID convalescent plasma for the EAP, eINDs and other approved investigator-initiated INDs.

Q. Must my hospital register a qualified donor in order to receive convalescent plasma?

A. No, hospitals participating in the EAP or requesting product for a patient for whom they have obtained an eIND are not required to provide a COVID-recovered donor. We are requesting that hospitals and clinicians please direct potential donors to our ***COVID-19 Convalescent Plasma Donor Information Page*.**

Q. My hospital has ordered a unit of convalescent plasma for a patient who no longer needs it. Can this unit be transfused to another patient?

A. A hospital may transfuse a unit of convalescent plasma to any patient who has been registered via the EAP, eIND or other research pathways. The American Red Cross does not need to be notified of this.

Q. Can convalescent plasma be crossed over into our hospital's general plasma inventory?

A. No, convalescent plasma must be transfused to a patient who has been registered via the EAP, eIND or other research pathways.

Q. Can I cancel my order?

A. For order cancellations, please visit our **cancellation page**.

Q. Can I return my order?

A. Convalescent plasma, just like all frozen products, are not eligible for return.

Q. How is the American Red Cross implementing antibody testing?

A. The American Red Cross is performing antibody testing on collections from individuals who have been prequalified by our staff to donate convalescent plasma. Antibody testing is not available at collection sites, and will not be performed on the general population or on standard blood, platelet and plasma collections.

Key Scientific Resources:

- Possible Vertical Transmission of SARS-CoV-2 From an Infected Mother to Her Newborn (Dong et. al, 2020) (**PDF**)
- Estimating clinical severity of COVID-19 from the transmission dynamics in Wuhan, China (Wu et. al, 2020) (**PDF**)
- Coronavirus disease 2019 (COVID-19) and the supply of substances of human origin in the EU/EEA (Domanović, 2020) (**PDF**)
- Convalescent plasma as a potential therapy for COVID-19 (Chen et. al, 2020) (**PDF**)
- Effectiveness of convalescent plasma therapy in severe COVID-19 patients (Duan et. al, 2020) (**PDF**)