Blood Bank of Alaska
Helping Alaska patients in need

1215 Airport Heights Dr. • Anchorage, AK 99508 • Tel: 907-222-5600 • Fax: 907-222-5683 • www.bloodbankofalaska.org

December 17, 2020

Dear Medical Community,

Blood Bank of Alaska (BBA) would like to thank you for your caring service during this pandemic. COVID-19 (Coronavirus Disease 2019) has affected each of us in varying ways and we greatly appreciate the work that you are doing on the front lines to treat patients.

We have been carefully following developing updates from the FDA regarding the use of COVID-19 convalescent plasma to treat COVID-19 patients. On August 23, 2020, the FDA announced an Emergency Use Authorization (EUA) for investigational convalescent plasma for the treatment of COVID-19 in hospitalized patients. This EUA, along with the updated FDA guidance document released on November 16th, 2020 provides further recommendations on the collection of convalescent plasma. The EUA was updated on November 30, 2020 to include approval of an antibody test for determining product suitability before product release.

Blood centers across the nation have been working to implement EUA and updated guidance recommendations. The FDA has allowed a 180-day period (active through February 28, 2021) to reach compliance with these new recommendations. Convalescent plasma units collected by BBA on November 16th, 2020 or later are compliant under the EUA, however, imported units may not be. All blood centers must be compliant under the EUA by February 28, 2021.

We remain in need of your help in recruiting prospective convalescent plasma donors. Your help is appreciated.

**Who is Eligible to Donate?**

Prospective convalescent plasma donors must meet all screening and eligibility requirements for regular blood donation. Female donors must test negative for HLA antibodies (HLA antibody tests performed by BBA at time of donation).

Donors who experienced symptoms from COVID-19 must have had a complete resolution of symptoms at least 14 days before donating **AND** have a positive test result from a diagnostic test approved, cleared, or authorized by the FDA.

Donors who were asymptomatic (did not experience symptoms from COVID-19) may be qualified to donate if they provide positive results from two different antibody tests*.

Donors who did experience symptoms but **did not** have a prior positive diagnostic test may also provide positive results from two different antibody tests.

> ***Donors must provide evidence of COVID-19 documented by a laboratory test approved, cleared, or authorized by FDA.** A list of all current COVID-19 in vitro diagnostics is available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidinvitrodev.

Note: Test results must include the donor's name and date of birth and where the test was performed.

**How to Recommend a Prospective Donor**

If you have a recovered COVID-19 patient that you feel would be an appropriate donor for convalescent plasma, please encourage them to visit our website at https://www.bloodbankofalaska.org and click on the COVID-19 banner.

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**Convalescent Plasma Resources for Providers**

The following resources pertain only to the FDA's EUA. They do not apply to imported convalescent plasma units that are non-compliant under the EUA.

- FDA's Emergency Use Authorization (EUA) for emergency use of COVID-19 convalescent plasma for the treatment of hospitalized patients with Coronavirus Disease 2019*: https://www.fda.gov/media/141477/download
- Fact Sheet for Health Care Providers: https://www.fda.gov/media/141478/download
- Fact Sheet for Patients and Parents/Caregivers: https://www.fda.gov/media/141479/download

The success of our collection of convalescent plasma relies heavily on your assistance with recruiting suitable prospective donors. Thank you for your help and dedicated patient care.

Sincerely,

Megan Ritter, M.D.
Medical Director
Blood Bank of Alaska

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**References:**

1. FDA: Investigational COVID-19 Convalescent Plasma – Guidance for Industry https://www.fda.gov/media/136798/download
2. FDA: Recommendations for Investigational COVID-19 Convalescent Plasma: https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma