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

September 11, 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, 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 September 2nd, provides further recommendations on the collection of convalescent plasma.

BBA, along with blood centers across the nation, is working quickly to implement EUA and updated guidance recommendations. The FDA has allowed a 90-day period (active through December 1, 2020) to reach compliance with these new recommendations. Convalescent plasma units may still be collected and distributed during this period, however they must be labeled as investigational until compliance is met.

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 either have never been pregnant or else test negative for HLA antibodies (HLA antibody tests performed by BBA at time of donation). Donors must have complete resolution of symptoms (if present) at least 14 days before donating.

According to the FDA, donors must provide evidence of COVID-19 documented by a laboratory test either by:

- Individuals who had symptoms of COVID-19 and positive test result from a diagnostic test approved, cleared, or authorized by FDA.

OR

- Individuals who did not have a prior positive diagnostic test and/or never had symptoms of COVID-19 may be qualified to donate if they have had reactive (positive) results in two different tests approved, cleared, or authorized by FDA to detect SARS-CoV-2 antibodies.

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: Laboratory reports 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

- 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 Heath Care Providers:
  https://www.fda.gov/media/141478/download
- Fact Sheet for Patients and Parents/Caregivers:
  https://www.fda.gov/media/141479/download

Note: While the EUA went into effect on August 23rd, BBA is still in the process of meeting these new recommendations. Until compliance is met, convalescent plasma units will be labeled as investigational.

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

907-222-5674| mritter@bbak.org

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#Pathways%20for