

Blood Safety and Vaccinated Blood Donors – simple explanations for patients and health care providers

1. What happens during the blood donation process?

In an AABB-accredited facility:

- Every donor must meet the safety requirements set by AABB and the US Food and Drug Administration (FDA).
- Every donor undergoes extensive screening in a confidential setting using more than 40 questions that are designed to detect a potential risk for infection.
- Every donor must be tested for a long list of infectious diseases before their blood is considered safe for use with a patient. These complex donor testing methods are highly accurate and must have FDA approval before they can be used to protect blood safety.
- The blood supply is collected primarily from volunteers who donate many times in their lives because they understand the importance of having a safe blood supply ready whenever a patient needs a transfusion. These volunteers have a proven test record demonstrating safety.
- There are many complex safety systems in place to help ensure that blood transfusions are as safe as possible.

2. How we know blood donation is safe following vaccination for COVID-19:

- The FDA established the safety of COVID-19 vaccines. AABB-accredited facilities follow all FDA regulations and recommendations related to blood donation safety.
- Refer to the [AABB Vaccination and Blood Donation Flyer](#) for more information.

3. Is it possible to know if blood comes from an individual who was not vaccinated against COVID-19?

- No, there is no way to know if blood comes from an unvaccinated individual.

4. Why don't we know if blood comes from an individual who was not vaccinated against COVID-19?

- In February 2024, FDA provided this clarification about requests for vaccine-free blood donations: "As noted in our October 23, 2023 communication ([Important Information About Directed Blood Donations that are Not Medically Indicated | FDA](#)), the justification for such requests and services may be based on misinformation and is not supported by any medical or scientific evidence. In addition, there is no validated method or test to determine whether a donor received an mRNA vaccine. Blood establishments must label blood components according to the requirements of 21 CFR Part 606.121 and 606.122. Blood and blood components labeled in a manner that is false or misleading are misbranded and are in violation of section 502(a) of the Federal Food, Drug, and Cosmetic Act."
- Refer to page 2 for the FDA notice.

FDA's Safety and Availability Notice, October 23, 2023: Important Information About Directed Donations that are Not Medically Indicated

The Food and Drug Administration (FDA) is advising consumers and health care providers that directed blood donations requested for certain donor characteristics (e.g., vaccination status, gender, sexual orientation, religion) lack scientific support and to be cautious about websites that offer memberships for delivery of blood and blood components from individuals who have not been vaccinated for COVID-19.

Summary of the Issue

FDA is aware that some blood establishments and hospitals have received requests from patients who need a blood transfusion and wish to receive directed donations only from personally chosen relatives, friends, or other individuals with certain characteristics (e.g., specific gender, sexual orientation, vaccination status, or religion). Such directed blood donations lack scientific support.

There is no evidence that directed donation provides safer blood and blood components for transfusion. All blood donors must be found eligible to donate blood for others under FDA regulations (21 CFR Part 630) and all donations intended for transfusion are tested for relevant transfusion transmitted infections (21 CFR 610.40). Studies suggest that directed donations may carry greater risk of transmitting infectious diseases than the general blood supply¹. In addition, the selection of blood or blood components based on donor characteristics that are not supported by scientific evidence might delay or interfere with appropriate medical intervention and life-saving blood transfusion.

This issue has recently received increased attention due to requests for directed blood donations from individuals who have not received COVID-19 vaccines. In addition, FDA is aware of several different websites purporting to offer blood and blood components from donors who have not been vaccinated against COVID-19 and charging individuals for membership to receive such services in the future. The justification for such requests and services may be based on misinformation and is not supported by any medical or scientific evidence. In addition, such practice has been denounced in a joint statement by the American Red Cross, the American Association of Blood and Biotherapies and America's Blood Centers.²

Information for Healthcare Providers, Consumers and Blood Establishments

We advise consumers and health care professionals to exercise caution about websites offering memberships for delivery of blood and blood components from COVID-19 unvaccinated blood donors. Further, FDA reminds all owners or operators of establishments that manufacture blood products that they must register with the FDA, pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act, and must comply with the requirements for registration and blood product listing in FDA regulations (21 CFR Part 607). Blood and blood components must be labeled according to the requirements of 21 CFR Part 606.121 and 606.122. Blood and blood components labeled in a manner that is false or misleading are misbranded and are in violation of section 502(a) of the Federal Food, Drug, and Cosmetic Act.

The agency will continue to closely monitor this issue and take additional actions, as appropriate.

Consumers and health care providers who have questions may contact FDA's Center for Biologics Evaluation and Research (CBER) at ocod@fda.hhs.gov.

Establishments that wish to manufacture blood and blood components and have questions about FDA regulations may contact CBER at industry.biologics@fda.hhs.gov.

¹ Dorsey KA, Moritz ED, Steele W, Eder AF and Stramer SL. A comparison of human immunodeficiency virus, hepatitis C virus, hepatitis B virus and human T-lymphotropic virus marker rates for directed versus volunteer blood donations to the American Red Cross during 2005 to 2010, *Transfusion* 2013;53:1250-1256.

² Joint Statement: Blood Community Reiterates the Safety of America's Blood Supply for Patients, <https://www.redcross.org/about-us/news-and-events/press-release/2023/blood-community-reiterates-the-safety-of-america-s-blood-supply.html>[External Link Disclaimer](#)