# THE PLASMA POOL

### What Does the COVID-19 Vaccine Mean for Plasma Donation?

Abigail Glaser March 2021

March 11, 2021 marked the one-year anniversary of when the World Health Organization (WHO) declared the COVID-19 outbreak a pandemic. Since then, it has been a year of breaking news, mask-wearing, social distancing, and questions. The latest of which seems to be, if I received the COVID-19 vaccine, can I donate plasma?

The short answer is yes.

The U.S. Food and Drug Administration (FDA) has stated that persons who are healthy and meet certain eligibility criteria can donate source plasma.

### What is Source Plasma?

Chances are you have heard a lot about convalescent plasma in the past year, but convalescent plasma and source plasma are two very different things.

Convalescent plasma is plasma that is collected from people who have recovered from a disease, COVID-19 for example, and developed antibodies designed to defend the body against the virus, coronavirus SARS-CoV-2 in the case of COVID-19, that causes that disease. Once collected, convalescent plasma is given to patients currently fighting the disease as a therapy to help them ward off the virus. This therapeutic intervention is called passive immunization.

Recent FDA guidance states that vaccinated individuals cannot donate convalescent plasma to treat COVID-19; however, vaccinated persons can donate source plasma.

**Source plasma** is plasma collected through a process called plasmapheresis and it is used exclusively for further manufacturing into a variety of final therapies, which are used as a treatment for people living with rare diseases such a primary immunodeficiency, hemophilia, other protein deficiencies, certain neurological diseases, Kawasaki disease and other medical conditions. Plasmapheresis is a sterile, self-contained, automated process where plasma is separated from red blood cells and other cellular components of blood which are then returned to the donor.

### FDA Guidance on Donating Source Plasma After Getting the COVID-19 Vaccine:

As of January 2021, according to the FDA, individuals who meet the general donor requirements and have gotten the COVID-19 vaccine can donate source plasma if the following applies:

- Individuals who received a non-replicating, inactivated or mRNA-based COVID-19 vaccine can donate without a waiting period;
- 2. Individuals who received a live-attenuated viral COVID-19\* vaccine should refrain from donating for a short waiting period (e.g., 14 days) after receipt of the vaccine; and
- 3. Individuals who are uncertain about which COVID-19 vaccine was administered, should refrain from donating for a short waiting period (e.g., 14 days) if it is possible that the individual received a live-attenuated viral vaccine.<sup>1</sup>

<sup>\*</sup> At this time there are no live-attenuated viral COVID-19 vaccines approved for use in the U.S. or EU.

https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/updated-information-blood-establishments-regarding-covid-19-pandemic-and-blood-donation

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### **How COVID-19 Vaccine Type Impacts Donation**

As of today, there are five COVID-19 vaccines that have made it to the third phase of clinical trials. In the U.S., the Pfizer/BioNTech, Moderna, and Johnson & Johnson vaccines received Emergency Use Authorization by the FDA. In the European Union, the Pfizer/BioNTech, Moderna, AstraZeneca and Johnson & Johnson vaccines were authorized by the European Commission under conditional marketing authorization following evaluation by the European Medicines Agency (EMA). The fifth vaccine, produced by Novavax, has successfully completed Phase 3 clinical trial, but it has not yet been authorized for use in the U.S. or EU.

Based on guidance from the FDA and the European Center for Disease Prevention and Control (ECDC),<sup>2</sup> individuals who received a non-replicating, inactivated or mRNA-based COVID-19 vaccine can donate source plasma without observing a waiting period.

In the U.S. this includes the Johnson & Johnson (non-replicating), Pfizer (mRNA-based), or Moderna (mRNA-based) vaccines. In Europe this includes the AstraZeneca vaccine (non-replicating) as well as the Johnson & Johnson (non-replicating), Pfizer (mRNA-based) or Moderna (mRNA-based) vaccines.

According to the ECDC, individuals who received a live-attenuated viral vaccine (e.g., replication competent virus vector-based vaccines, live-attenuated virus vaccines) should be deferred for a period of four weeks from vaccination. The FDA guidance instructs individuals who received a live-attenuated viral vaccine for COVID-19 to observe a 14-day waiting period.

## The Importance of Donating Source Plasma

Source plasma is essential to the manufacture of lifesaving therapies. People living with rare and life-threatening diseases rely on these therapies to live healthier and more productive lives. The pandemic has caused a decline in plasma collections, so that now, more than ever, there is a greater need for plasma donations.

"The COVID-19 crisis has highlighted that need even more given [Europe's] strong reliance on third countries for plasma. Medicines made from donated plasma are critical for the treatment of a large number of patients," said Stella Kyriakides, Commissioner of health and Food Safety for the European Commission.

With an increasing number of patients diagnosed with life-threatening diseases reliant on plasma-derived therapies and the impacts of the global COVID-19 pandemic on patients and donors, the need for plasma donation is vital. So, whether you have been vaccinated or not, please consider donating plasma.

For more information on donor health screening criteria or to locate a plasma collection center near you, go to www.donatingplasma.org.

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 $<sup>^2\</sup> https://www.ecdc.europa.eu/sites/default/files/documents/Supply-SoHO-COVID-19--second-update-erratum-Feb-2021.pdf$