The Journey of a Plasma Donation

Did you know that you have gold in your veins?

Donating plasma is a simple process – much like donating blood. However, once the plasma is collected, it starts a long journey before ultimately becoming the main ingredient in a life-saving therapy for a person in need. The process utilizes an apheresis technology similar to that used by blood banks to collect platelets. As a result, the red cells and other cellular constituents are returned to the donor while the liquid plasma is retained. Plasma contains a large number of proteins that have potential therapeutic uses in both patients who lack those proteins (replacement therapy) and for disease modulation. The plasma that is collected is not for direct transfusion but rather for further manufacture. Therefore, many units from many donors are pooled in order to generate a therapy through a process called plasma fractionation.

The Plasma Donor

Healthy adults between the ages of 18-65 who weigh at least 110 pounds (50kg) are eligible to donate.

The potential donor must have a permanent address and consent to undergo a medical examination before their first donation. Donors also must have two tests performed in the plasma center to determine if they are healthy enough to donate before each donation (hematocrit and protein level). On the first visit they not only answer a lengthy questionnaire but undergo a brief physical examination. On subsequent visits, donors must answer a shorter health questionnaire. Product is only used for injectable product after two successful donations in a six-month period. The process assures the procedure is safe for the donor and the plasma collected will be safe for the patient.

The Plasma Donation Process

Two hundred fifty-one CSL Plasma collection centers across the U.S., Hungary, and Germany including five in Missouri, welcome donors every day. The donation process takes about 45 to 90 minutes. During that time, blood is drawn, plasma is separated from red blood cells and collected, and then the cells are returned to the donor. (A process called plasmapheresis)

- One-donation results in 21 to 30 oz. (625 to 880 ml.) of plasma, depending on the donor’s body weight.
- Because the donor’s cells are returned at each donation and the donor receives 500 ml of saline to help replace lost fluid, plasma donors are safely able to donate twice per week.

Testing and inventory hold

Samples from every plasma unit are sent to the CSL Plasma-owned laboratories in Göettingen, Germany or Knoxville, Tennessee to be tested for hepatitis parvovirus and human immunodeficiency virus. Plasma units can be released for after a 60-day hold if all tests were negative and all other qualifying criteria have been met. The hold allows us to remove all units collected from a donor in the prior 60 days if either a positive test occurs or
disqualifying information is obtained. The qualified units are shipped from our Plasma Logistic Center to a manufacturing facility. We have two logistics centers in the US (Indiana and Texas) and one in Germany.

Manufacturing

The frozen plasma units are shipped to CSL manufacturing sites in Illinois, Germany or Switzerland where it is fractionated into various proteins that are further purified into therapeutic products.

- Manufacturing biotherapies from plasma takes about 9 months

The Patient

It takes about 9 months for a donation to result in a therapy ready for patient use. Plasma therapies are used to treat bleeding disorders, primary immune deficiencies, hereditary angioedema, inherited respiratory disease, and neurological disorders. They are also used in cardiac surgery, organ transplantation, burn treatments and to prevent hemolytic diseases in newborns.

- More than 1,200 plasma donations are needed to treat one person with hemophilia for a one-year supply of medicine.
- More than 130 plasma donations are needed to treat one person with a primary immune deficiency for a one-year supply of medicine.

Ensuring Product Safety

To ensure the highest quality plasma-derived biotherapies, we apply four layers of safety in the manufacturing process:

- Careful plasma donor selection/screening
- Plasma testing that can detect viruses even before a donor has symptoms
- 60-day hold/quarantine
- Purification/viral reduction and elimination during manufacturing
- Pharmacovigilance which involves follow up of clinical experience with products

A plasma journey starts and ends with a single person – the donor and the patient. CSL Plasma is focused on ensuring that at every stop along the way, the plasma is treated with the same respect as the person it came from and the person it’s headed for.

1 Source: Plasma Protein Therapeutics Association