

THE **FACTS** ABOUT...

PLASMA USED TO PRODUCE LIFE-SAVING THERAPIES

Plasma-derived therapies and their recombinant analogs (collectively referred to as plasma protein therapies) are essential, life-saving treatments for a range of rare, chronic and genetic diseases including hemophilia, primary immunodeficiencies and alpha-1 antitrypsin deficiency, and acute conditions such as burns and shock.

It is important to understand that plasma used to manufacture protein therapies is intrinsically different from blood components used for transfusion. These differences include the way that the plasma is collected and the complexities of the production process of plasma therapies. Following are some additional facts and information about plasma collected and used for manufacturing plasma protein therapies.

PLASMA

Plasma is a clear, straw-colored liquid component of blood comprised mostly of water, salts and proteins. Plasma contains proteins for blood clotting and defending the body against infection and is quickly replenished by the body.

SOURCE PLASMA FOR THE PRODUCTION OF PLASMA THERAPIES

Plasma can be donated at one of over 400 government licensed and International Quality Plasma Program (IQPP)-certified source plasma collection centers located throughout the U.S., Europe and Canada through a process called plasmapheresis. During this process, whole blood is separated into cellular and other components by using specialized equipment called a plasmapheresis device. This sterile, self-contained, automated process separates red blood cells and other cellular components in the blood, which are then returned to the donor.

The first plasma donation can take up to three hours and involves completing health screenings, donor education, and the donation process itself. Subsequent plasma donations generally take approximately one-and-a-half to two hours. In order for the first donation to be used to produce therapies, the donor must make a second donation and both must test negatively for transmissible diseases.

To guarantee a safe and adequate supply of donated source plasma, it is standard industry practice to compensate donors for the significant commitment of personal time and effort required to donate. In the U.S., a person may donate plasma two times in a seven day period, with at least two days in between donations. In Europe, an individual may donate plasma up to twice a week, but may only make 33 plasmapheresis donations per year. The amount of plasma collected varies depending on the donor's weight. Plasma donors who donate on a regular basis are valued individuals who are committed to improving and saving lives. In 2008, 18.8 million plasma donations were made in the U.S. and more than 1.4 million in Europe.

RECOVERED PLASMA

Several PPTA member companies use recovered plasma that is derived from single units of whole blood as a byproduct of whole blood collection. Its use in the production of plasma protein therapies is regulated by government authorities, and it is different from source plasma in the way that it is collected.

PLASMA PROTEIN THERAPIES

Although plasma protein therapies and blood products for transfusion are both derived from human blood, they are different in almost every respect: the collection process, storage and processing, regulatory requirements and most importantly, the diseases and conditions they are used to treat.

Unlike collected blood and blood components used for transfusion purposes, plasma used for the production of plasma protein therapies is subject to additional and complex manufacturing processes. The time from when a donation is given to the time a plasma therapy is ready to be used by a patient often takes between seven-to-nine months. The development and production of plasma therapies relies heavily on a steady supply of donated plasma that is available to be produced into life-saving therapies. The following table outlines the most common uses for the major plasma protein therapies.

PLASMA-DERIVED THERAPY	TYPE OF DISEASE	TREATMENT OUTCOMES
Coagulation factors (essential to the blood clotting process)	Hemophilia A and B , which are disorders that prohibit a person's blood from clotting. Even the most minor injury can become life-threatening without a proper coagulation therapy. Von Willebrand disease is the most common inherited bleeding disorder and is usually milder than hemophilia.	Varies with severity. In acute cases, the treatment increases lifespan four-to-five times.
Immunoglobulins (proteins used by the immune system to neutralize foreign objects such as viruses and bacteria)	Primary immunodeficiencies (a life-threatening disease when part of the body's immune system, which fights infection, has a genetic defect); Secondary immunodeficiencies (the immune system is compromised by outside factors such as viruses or chemotherapy; and numerous other immune deficiencies and auto-immune disorders.) Chronic Idiopathic Demyelinating Polyneuropathy (CIDP) , a rare disorder of the peripheral nerves.	Improved lifespan and/or quality of life. Prevention of infections and protection of unborn babies.
Alpha-1 Proteinase Inhibitor (protects tissues from enzymes of inflammatory cells)	Alpha-1 Antitrypsin Deficiency (a genetic deficiency, which may result in serious, life-threatening lung disease in adults and/or liver disease in people of any age.)	Improved quality of life and stops the disease from progressing.
Albumin (a protein important in regulating blood volume)	Used to treat shock, severe burns and during surgery.	Life-saving in severe clinical situations such as intensive care.

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