

A woman with long, light-colored hair is lying in a hospital bed, smiling. She is wearing a light-colored hospital gown. A black blood pressure cuff is wrapped around her upper left arm, with the brand name 'WelchAllyn' and 'ADULT DURA BLE TWO-PIECE Blood Pressure Cuff' visible. Several white IV lines are secured to her forearm with white tape. The background shows a hospital room with medical equipment and another person in a white coat partially visible.

# GRIFOLS' COMMITMENT TO OUR DONORS

GRIFOLS



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Plasma is the essential raw material in the production of life-saving plasma-based medicines. Grifols serves as the bridge between patients and donors, whose generosity makes these therapies possible

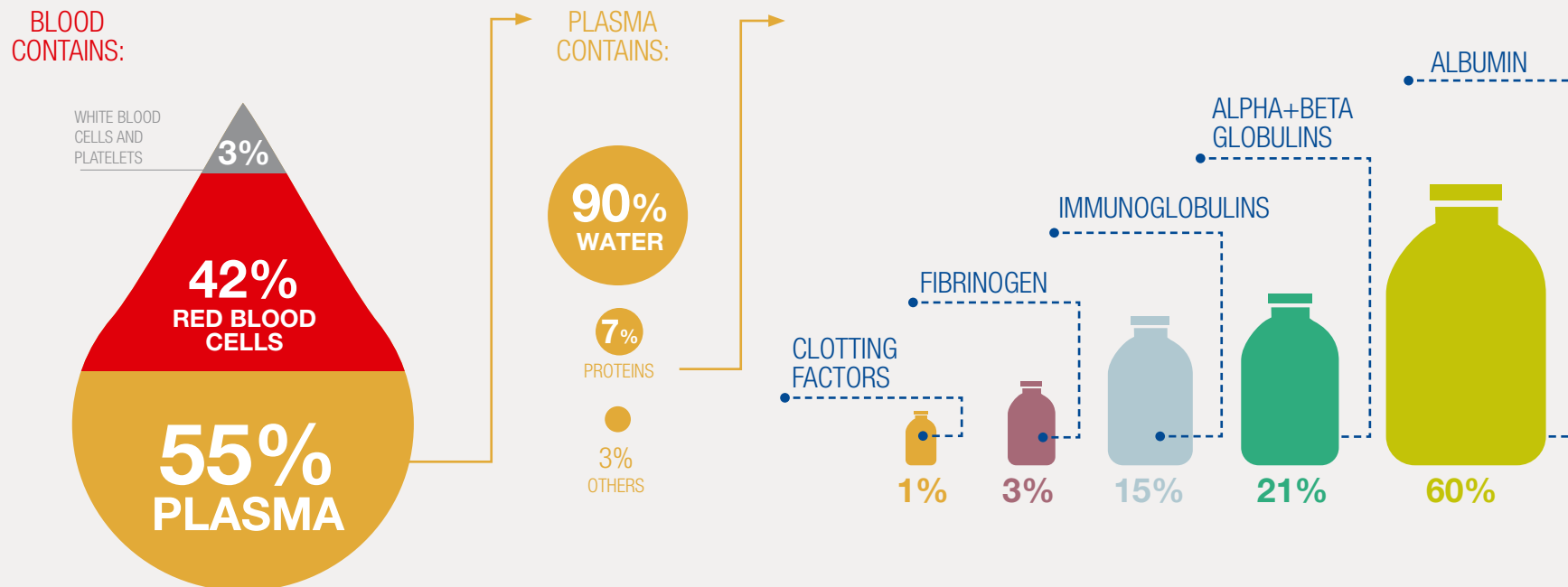


# PLASMA, DONATIONS AND DONORS

## WHAT IS PLASMA?

A clear and slightly yellowish liquid, plasma is the largest component of human blood, representing around 55% of total blood volume. A 70-kg person will have around five liters of blood, of which three are plasma.

Plasma includes the blood cells – red blood cells, white blood cells and platelets – as well as water (90%), mineral salts and essential proteins and antibodies, which are critical for the proper functioning of the body. These include immunoglobulins, clotting factors, albumin and alpha-1 antitrypsin, among others. A shortage of any of these plasma proteins can lead to serious and even life-threatening diseases.



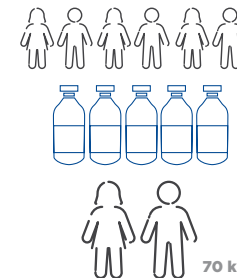
## THE GENEROSITY OF PLASMA DONORS MAKES PLASMA-DERIVED MEDICINES POSSIBLE

Plasma is an essential raw material in the manufacture of plasma-derived therapies, which are used to treat and prevent potentially life-threatening diseases and conditions for patients around the world.

It is impossible to artificially create or manufacture plasma in a lab. Plasma donations are the only means possible to produce plasma-derived medicines and enhance the quality of life of patients who require them. Hundreds of donations are needed to produce enough plasma-based medicine to treat one patient for a year.

In 2020, the importance of plasma, plasma-derived medicines and donors were brought to the forefront as a result of the COVID-19 pandemic. Plasma from recovered COVID-19 patients – known as convalescent plasma – contains antibodies to the SARS-CoV-2 virus that might prove effective in treating the disease. Grifols is working to find treatments from this plasma.

Hundreds of donations are needed to produce enough plasma-derived medicines to treat one patient for one year.



### PRIMARY IMMUNODEFICIENCIES

### ALPHA-1 ANTITRYPSIN DEFICIENCY



### CIDP\*

### HEMOPHILIA



2020 HIGHLIGHTED THE VITAL IMPORTANCE OF PLASMA, PLASMA-DERIVED TREATMENTS AND PLASMA DONORS

\*Chronic inflammatory demyelinating polyneuropathy

# DONATING PLASMA IS SAFE

## REGULATIONS FOR PLASMA DONATIONS

WITH A NORMAL DAILY DIET AND ADEQUATE INTAKE OF WATER, THE BODY CAN RECOVER THE PLASMA PROTEINS AND LIQUID EXTRACTED DURING DONATION WITHIN A DAY

There are two ways to obtain plasma: recovered plasma, derived from whole blood, and source plasma, obtained through plasmapheresis.

The collection of source plasma exclusively for fractionation purposes is regulated by the U.S. Food and Drug Administration (FDA) and other global health authorities. In addition to universal good manufacturing norms and procedures by health agencies, the Plasma Protein Therapeutics Association (PPTA) also defines and monitors additional voluntary standards as part of the voluntary IQPP (International Quality Plasma Program) certification. In Europe, it is regulated by the European Medicines Agency (EMA).

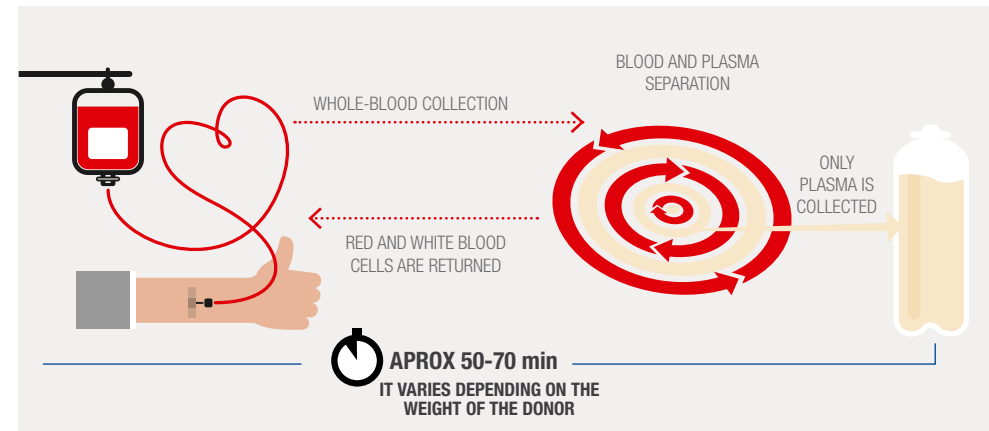
Plasmapheresis is a technique by which plasma is separated and removed and blood cells, platelets and other components are returned to the donor. The body is able to regenerate the volume of collected proteins in less than 24 hours following a plasma donation, a shorter recovery compared to that whole-blood donations.

The requirements for donating convalescent plasma are regulated by healthcare authorities, including the FDA and EMA.

## PLASMAPHERESIS: A SAFE WAY OF DONATING ONLY PLASMA

Plasmapheresis is an automatic plasma-extraction process used in all of Grifols' donation centers. A safe and sterile medical procedure, it involves separating plasma from the blood and returning the remaining components (including red and white blood cells) to

the donor. Plasmapheresis is the most effective way to remove plasma from the blood, shortening the recovery process and in turn, facilitating a higher frequency of plasma donations without impacting the donor's health.



More information visit  
<https://www.fda.gov/about-fda/fda-en-espanol/done-plasma-del-covid-19>  
[https://ec.europa.eu/health/blood\\_tissues\\_organ/covid-19\\_en](https://ec.europa.eu/health/blood_tissues_organ/covid-19_en)



## REASONS TO DONATE



### PLASMA DONATIONS SAVE LIVES

Plasma-derived medicines are used to treat or prevent severe conditions and diseases in various medical fields including pneumology, hematology, immunology, neurology, infectious diseases and traumatology. Plasma donors help save lives and improve the quality of life of thousands of patients worldwide.



### PLASMA CANNOT BE ARTIFICIALLY MANUFACTURED

Plasma cannot be created in a lab or produced synthetically. These life-saving medicines are possible thanks to the generosity of volunteer plasma donors.



### CONVALESCENT PLASMA CAN HELP IN THE FIGHT AGAINST COVID-19

Plasma from recovered COVID-19 patients – also known as convalescent or convalescent plasma – is a therapeutic option to combat the disease since it contains specific antibodies against SARS-CoV-2, the virus responsible for COVID-19. It can be used for both direct transfusions and to produce hyperimmune immunoglobulin.



## ONLY TRULY COMMITTED PEOPLE ARE QUALIFIED DONORS

Grifols only collects plasma from qualified and regular donors, who must undergo a physical exam and thorough medical evaluation to be classified as qualified donors and begin the donation process. In addition, they must also carry out two separate donations over a six-month period. Collected plasma is subject to rigorous analyses to screen for possible communicable diseases.

Collecting plasma from two different donations makes it easier to determine if the donor is healthy and suitable to donate plasma. Without a second donation, the first donation cannot be used and must be

discarded. Grifols never uses plasma from occasional or sporadic donors. Plasma donors commit themselves to undertake regular donations, and once they become qualified donors, they are subject to annual medical exams and routine health screenings before every donation.

THE COVID-19 PANDEMIC HIGHLIGHTED THE IMPORTANCE OF PEOPLE WHO HAVE RECOVERED FROM THE DISEASE IN DONATING PLASMA TO HELP OTHERS

CONVALESCENT PLASMA DONORS, IN ADDITION TO COMPLYING WITH ELIGIBILITY CRITERIA APPLICABLE TO ALL PLASMA DONORS, MUST BE CERTIFIED WITH A PREVIOUS COVID-19 DIAGNOSTIC AND THE ABSENCE OF SYMPTOMS FOR AT LEAST 28 DAYS BEFORE EACH DONATION

### WHEN IS DONATING PLASMA NOT ALLOWED?

Grifols goes beyond legal requirements in many cases by establishing additional criteria to determine eligibility. The individual's medical history is essential to evaluate eligibility. Recent surgeries, changes in medications, history of diabetes, heart diseases and autoimmune diseases, among others, are evaluated. Donors must postpone the donation process if their medical evaluations show abnormal levels or irregularities in certain parameters since these could be a sign of an underlying health issue. By conducting regular medical exams in its plasma donation centers, Grifols helps monitor the health of their donors, whose health is a topmost priority for the company.

- Irregular heart rate
- High body temperature
- High hematocrit
- Low hematocrit
- High total protein
- Low total protein
- Lipemic plasma



# REQUIREMENTS FOR PLASMA DONORS

## WHO ARE QUALIFIED DONORS?

- A qualified donor must donate at least twice over a six-month period
- A qualified donor can donate as often as twice in a seven-day period, with a full rest day in between in the U.S. and two days in Europe

## DOCUMENTATION

- Valid photo ID: Driver's license, state-issued ID, passport, military identification or student ID card
- Proof of Social Security Number
- Proof of residence

## VERIFICATION OF WEIGHT, BLOOD PRESSURE, PULSE AND TEMPERATURE, AND ANEMIA AND PROTEIN LEVELS CONTROL

NOT EVERYONE CAN DONATE PLASMA

18-68 YEARS (EUROPE)

18-69 YEARS (U.S.)

+50 KG

MEDICAL EXAM

## DONORS UNDERGO BLOOD TESTS FOR EVERY DONATION

- Screening for HAV, HBV, HCV, HIV and B19 virus using genomic amplification tests (Nucleic Amplified Testing; NAT)
- Serologic tests for HBsAg (Hepatitis B surface antigen), Hepatitis C antibodies (anti-HCV) and HIV antibodies
- Other periodic tests

PLASMA FROM FIRST-TIME DONORS WHO DO NOT RETURN FOR A SECOND DONATION IS NEVER USED TO MANUFACTURE PLASMA-DERIVED MEDICINES. THESE UNITS ARE DESTROYED OR USED FOR DIAGNOSTIC PURPOSES AS A REAGENT

## ■ ENSURING DONORS' SAFETY

Donating plasma is an extremely safe process with few-to-no side effects. In their first visit and at least once a year thereafter, donors undergo a physical exam and an in-depth evaluation of their medical, social and travel history. This information is recorded in the donor's file, (see Privacy and Data Protection section in Chapter 3, Corporate Governance in the 2020 Integrated Annual Report, for more detail). This process ensures the safety of both donors and patients treated with donor plasma therapies.

Before every donation, Grifols checks the donor's vital signs and inquires about their health and travel history since their last visit. Their levels of hematocrit (the percentage of red blood cells in blood, by volume) and plasma protein levels are also evaluated to ensure it is safe to donate.

The catheters and other materials used in the extraction process are sterilized and subsequently discarded. New and sterile materials are used with every single donation.

## ■ SAFETY AND QUALITY CONTROLS IN GRIFOLS DONATION CENTERS


Grifols donation centers adhere to the highest quality and safety standards to ensure donors' health and the quality of donated plasma.

### Regulatory inspections in Grifols plasma centers in 2020

Regulatory Body	Inspection Days	Administrative Actions**
FDA*	104	0
EMA	74	0
CLIA-COLA	51	0
PPTA	79	0
<b>TOTAL</b>	<b>308</b>	<b>0</b>

(\*) More than 95% of FDA inspections resulted in 0 observations

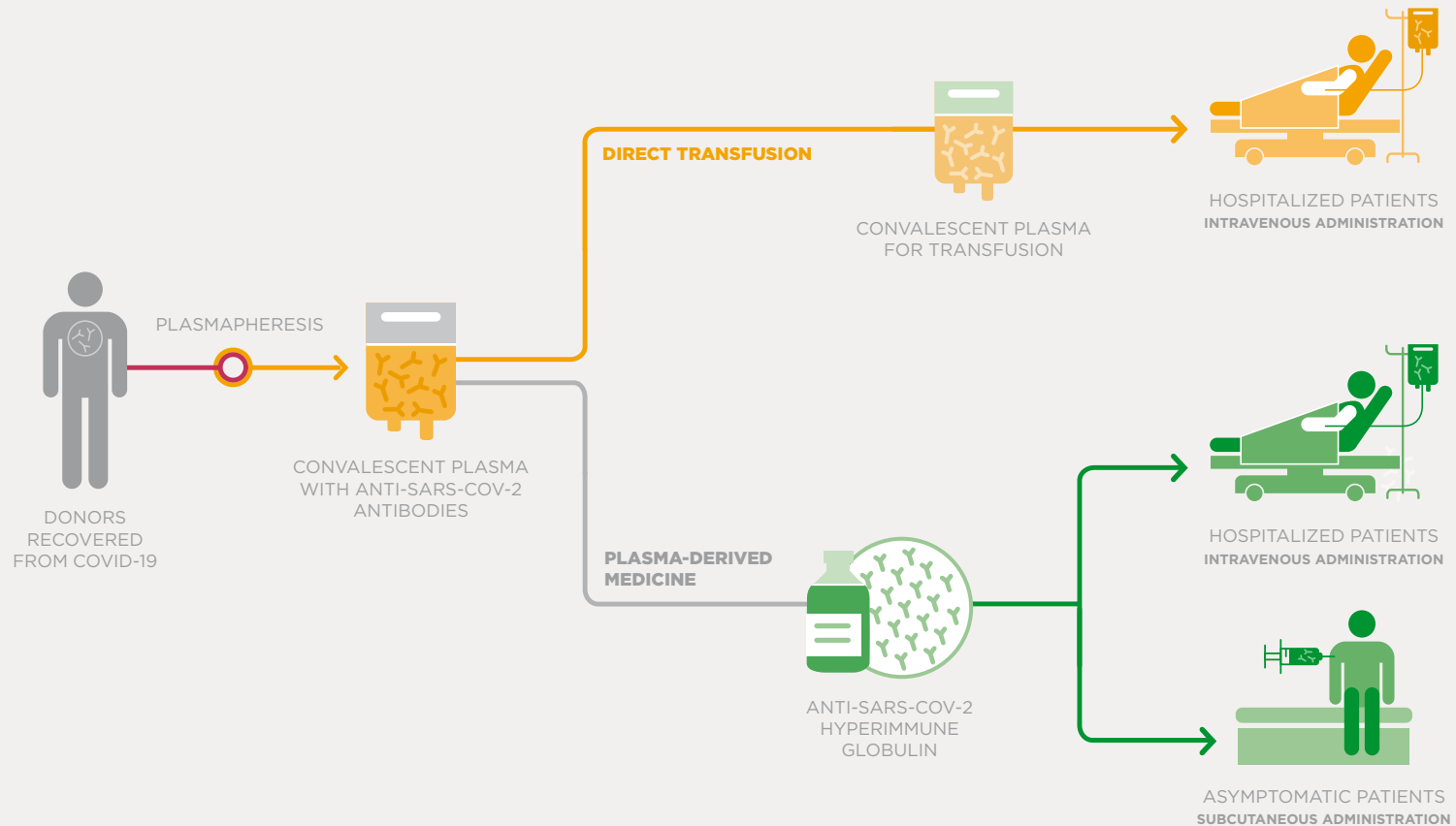
(\*\*) Suspension, revocation or loss of any license or certification; warning letter, imposed suspension of any regulated activity, etc.

 Grifols' requirements to carry out a safe donation, as well as detailed information on the donation process, are available at [www.grifolspasma.com](http://www.grifolspasma.com)

## CONVALESCENT-PLASMA DONORS ARE PLAYING A CRITICAL ROLE IN THE FIGHT AGAINST COVID-19

After recuperating from COVID-19, patients develop antibodies to defend themselves against the virus. For this reason, plasma from recovered COVID-19 patients – known as convalescent or convalescent plasma – might prove effective in treating the disease.

Since the discovery of the novel coronavirus, the use of convalescent plasma to treat infected people could be a promising treatment both for direct transfusion and to produce a specific medicine: hyperimmune immunoglobulins.



# GRIFOLS' COMMITMENT TO DONORS



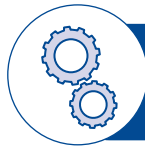
## BASED ON THE DECLARATION OF HUMAN RIGHTS

- Respect for human dignity and human rights are embedded in all Grifols operations, which support the fundamental pillars of the Universal Declaration of Human Rights (1948), the Helsinki Declaration (1964) and UNESCO's Universal Declaration on Bioethics and Human Rights (2005).
- Grifols does not discriminate donors based on their gender, race, ethnicity or socioeconomic status, although it only uses plasma from qualified donors to produce its plasma-derived medicines in accordance with the regulation of the countries where it operates.
- Ensuring the health, safety, well-being and dignity of plasma donors is Grifols' top priority.



## EQUAL TREATMENT

- Grifols adheres to the same quality and safety criteria in all of its plasma centers and for all of its donors.
- Donors throughout Grifols' network of plasma centers benefit from the same strict criteria of quality and safety, regardless of where they come from. There are no exceptions.

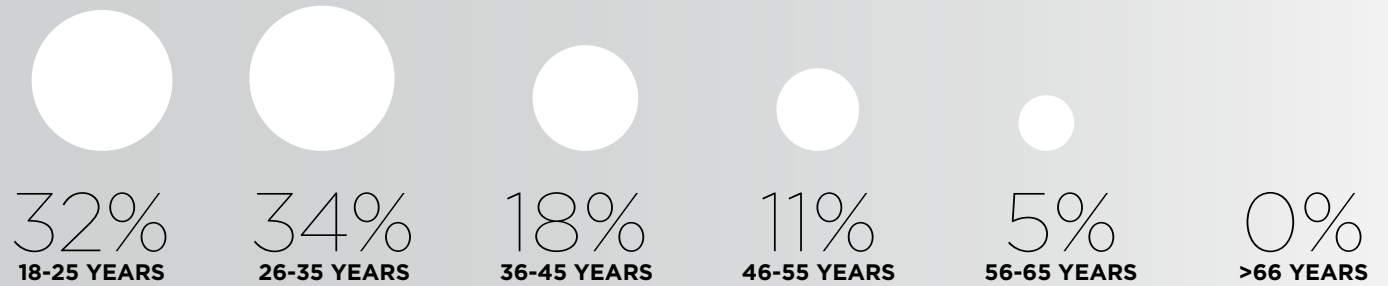


## RECOGNITION FOR DONORS' TIME AND COMMITMENT

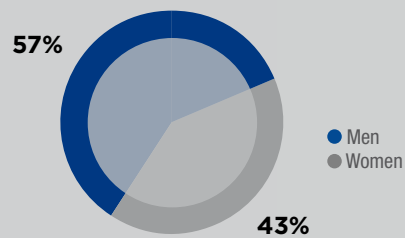
- Grifols recognizes the time and effort that it takes donors to donate plasma on a regular basis and compensates them for it. Grifols compensates donors for their commitment, which includes undergoing thorough health screenings, and for being regular plasma donor.
- The compensation serves as an incentive and fosters altruism. Thanks to its donor compensation policy, Grifols is able to collect plasma to provide patients worldwide with essential life-saving plasma-derived medicines.
- Grifols' compensation policy applies equally to all donors. No distinction is made in terms of the volume of plasma collected or donors' weight, although they must weigh at least 50 kg. to donate plasma.
- The compensation that Grifols' regular donors receive for their time supplements their monthly income and positively impacts the communities where donation centers are located. More information on the company's social impact on donors and local communities, please see the "Grifols' Social Impact" section.
- Plasma donors also have the option of waiving part or all of their compensation to support one of the non-profit organizations under the umbrella of Grifols' non-profit Plasma Possibilities program. Since the program was launched in 2017, Plasma Possibilities offers the chance to help twice: by donating plasma and by helping NGOs. It has helped raise more than USD 80,000 (USD 35,000 in 2020) for more than 40 U.S. non-profit charity organizations (19 in 2020).

## GRIFOLS PLASMA DONORS REPRESENT A CROSS-SECTION OF SOCIETY

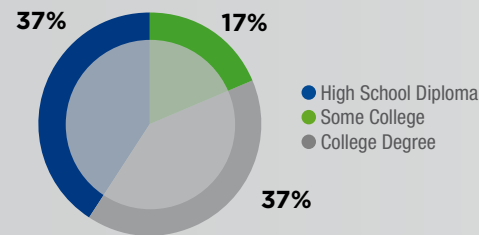
**+60% OF DONORS ARE BETWEEN 26 AND 55 YEARS OLD**



**DISTRIBUTION BETWEEN MEN AND WOMEN**



**73% OF DONORS HOLD UNIVERSITY DEGREES AND 90% HAVE A HIGH SCHOOL DEGREE**



**EMPLOYMENT**

**62%**  
**ARE EMPLOYED FULL-TIME**

# ENSURING THE HEALTH OF OUR DONORS IS OUR HIGHEST PRIORITY

## ■ PLASMA SURVEILLANCE DATA SUPPORTS THE SAFETY OF DONATIONS

In line with data from previous years, Grifols' plasma surveillance information from 2019 indicates that side effects in donors, or Donor Adverse Effects (DAEs), were very low.

Considering the 9 categories established by the Plasma Protein Therapeutics Association (PPTA) and as a percentage per 10,000 donations, only 0.2% of all donations in 2020 caused any side effects. With regard to serious adverse effects, including embolisms, anaphylaxis, severe reactions to immunization or cardiovascular events, none has been registered.

The predominant, but minimal, side effects are local injuries related to phlebotomy events, mainly hematomas, and hypotensive events, accounting for about 0.1% of total Grifols' donations each.



## STUDIES THAT CONFIRM DONOR SAFETY

As part of its commitment to the health and safety of plasma donors, Grifols spearheads a range of initiatives, both directly and through collaborations with scientific organizations, to support research on the potential residual effects of plasmapheresis on donors:

### STUDY ON BLOOD PRESSURE

Donating plasma through plasmapheresis involves the removal of a weight-adjusted volume of plasma and the return of cellular components to the donor. Although plasma volumes generally return to normal, a study was carried out to determine the possible residual effects of plasmapheresis on blood pressure.

The findings indicate that systolic and diastolic blood pressure may decrease following plasmapheresis used for plasma donations at less-than-14-day intervals in donors with high baseline blood pressure levels.

For donors with normal blood pressure, no reduction in blood pressure levels was observed.

**0** Research reference: The Effect of Plasmapheresis on Blood Pressure in Voluntary Plasma Donors - PubMed (nih.gov)

### STUDY ON CHOLESTEROL LEVELS

LDL apheresis is used to treat patients with familial hypercholesterolemia, and low-volume plasmapheresis for plasma donation may similarly lower cholesterol levels in some donors. This study was designed to assess the effect of plasmapheresis on total LDL and HDL cholesterol levels in a plasma donor population.

Based on the study's findings, total and LDL cholesterol levels in donors with elevated baseline cholesterol levels may decrease during routine voluntary plasmapheresis.

For donors with normal cholesterol levels, no reduction in those levels was observed.

**0** Reference: Prospective Multicentre Study of the Effect of Voluntary Plasmapheresis on Plasma Cholesterol Levels in Donors - PubMed (nih.gov)

### STUDY TO EVALUATE IRON LEVELS

Whole blood and red blood cell (RBC) donors are at risk of iron deficiency. In plasma donations using the plasmapheresis technique, only plasma is removed and red blood cells are returned to the donor, so the risk of iron depletion appears low. The study concludes that few source plasma donors have iron depletion and it is not higher in frequent donors. Frequent source plasma donation does not adversely impact iron stores, making it unnecessary to monitor donor iron status or iron supplementation.

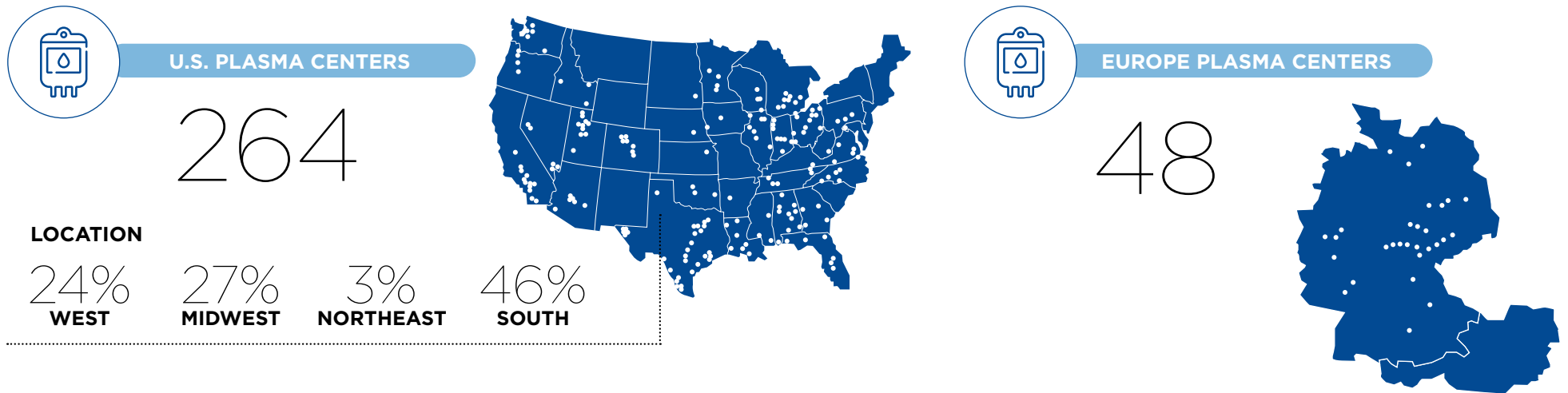
**0** Reference: Frequent Source Plasma Donors Are Not at Risk of Iron Depletion: The Ferritin Levels in Plasma Donor (FLIPD) Study - PubMed (nih.gov)





# GRIFOLS PLASMA DONATION CENTERS CREATE VALUE

## GRIFOLS PLASMA CENTERS ARE LOCATED IN COMMITTED COMMUNITIES



In 2020, Grifols' network included 264 plasma centers in the U.S. and 48 in Europe. Although donor communities are diverse, they all share a common commitment to continuous development. In the U.S., Grifols' centers are located throughout the country, with no particular concentration in a specific region.

When it comes to choosing a suitable site for its plasma centers, Grifols considers primarily small and medium-sized cities with a solid commitment to community progress, manifested by active chambers of commerce and ongoing initiatives to promote social progress. For Grifols, active community participation in the plasma donation process is key in order to guarantee a long-

term supply of this core raw material, essential to producing life-saving medications.

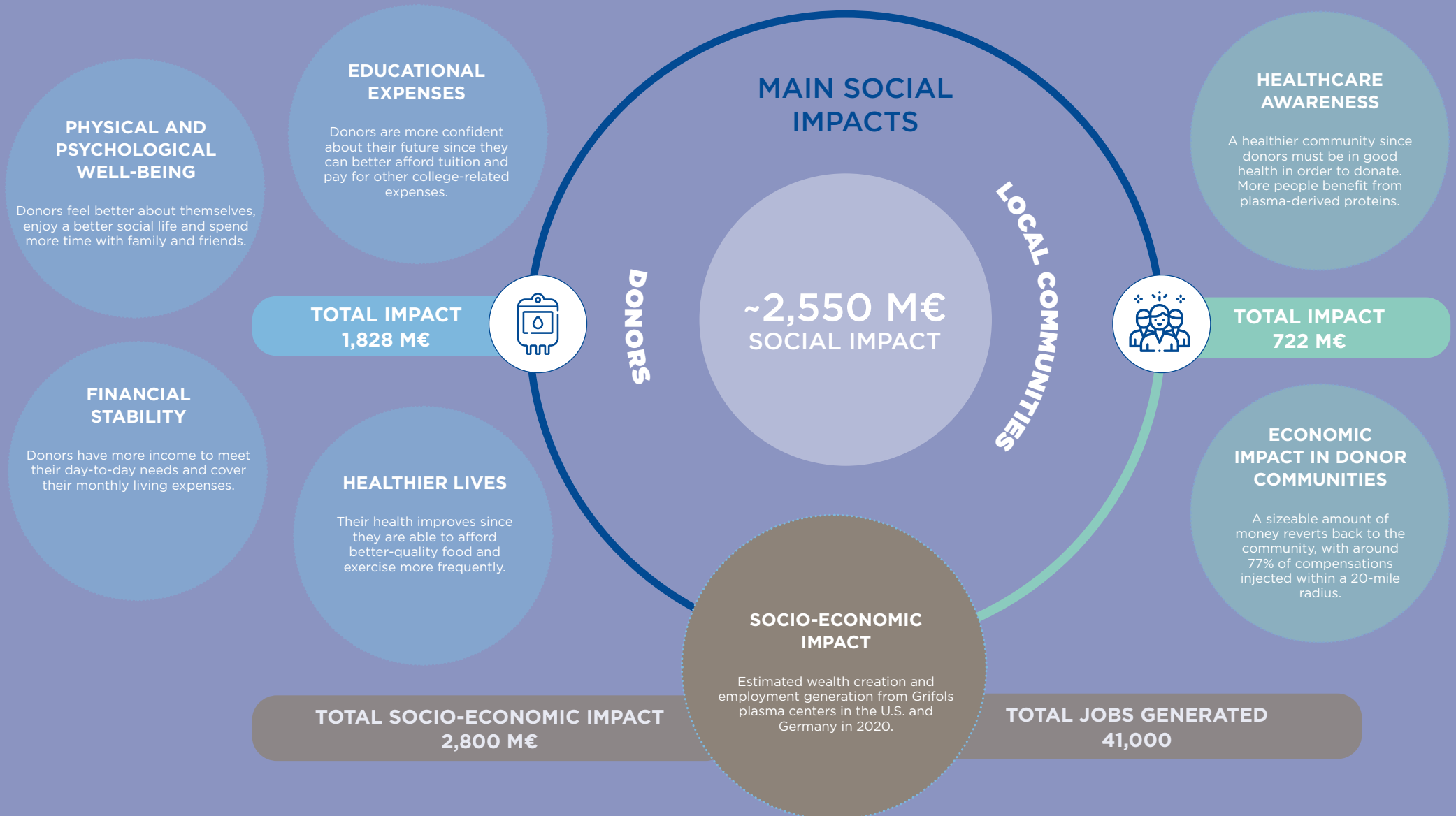
To this end, members of Grifols' plasma centers actively participate in their communities, taking proactive steps to get to know local residents and organizing educational and awareness events on the

vital role of plasma and the production of plasma-derived therapies.

When developing new centers, the company also seeks healthy communities with low viral markers, lower-than-average crime rates and heterogeneity among area residents to ensure a diverse donor pool, among other criteria.

## MEASURING THE SOCIAL VALUE OF GRIFOLS PLASMA DONATION CENTERS

In 2020, Grifols finalized its first study to measure the social value generated by its plasma centers. It followed the SROI methodology which enabled us to unveil the social value created for donors and communities in 2019.







**GRIFOLS**

[www.grifols.com](http://www.grifols.com)