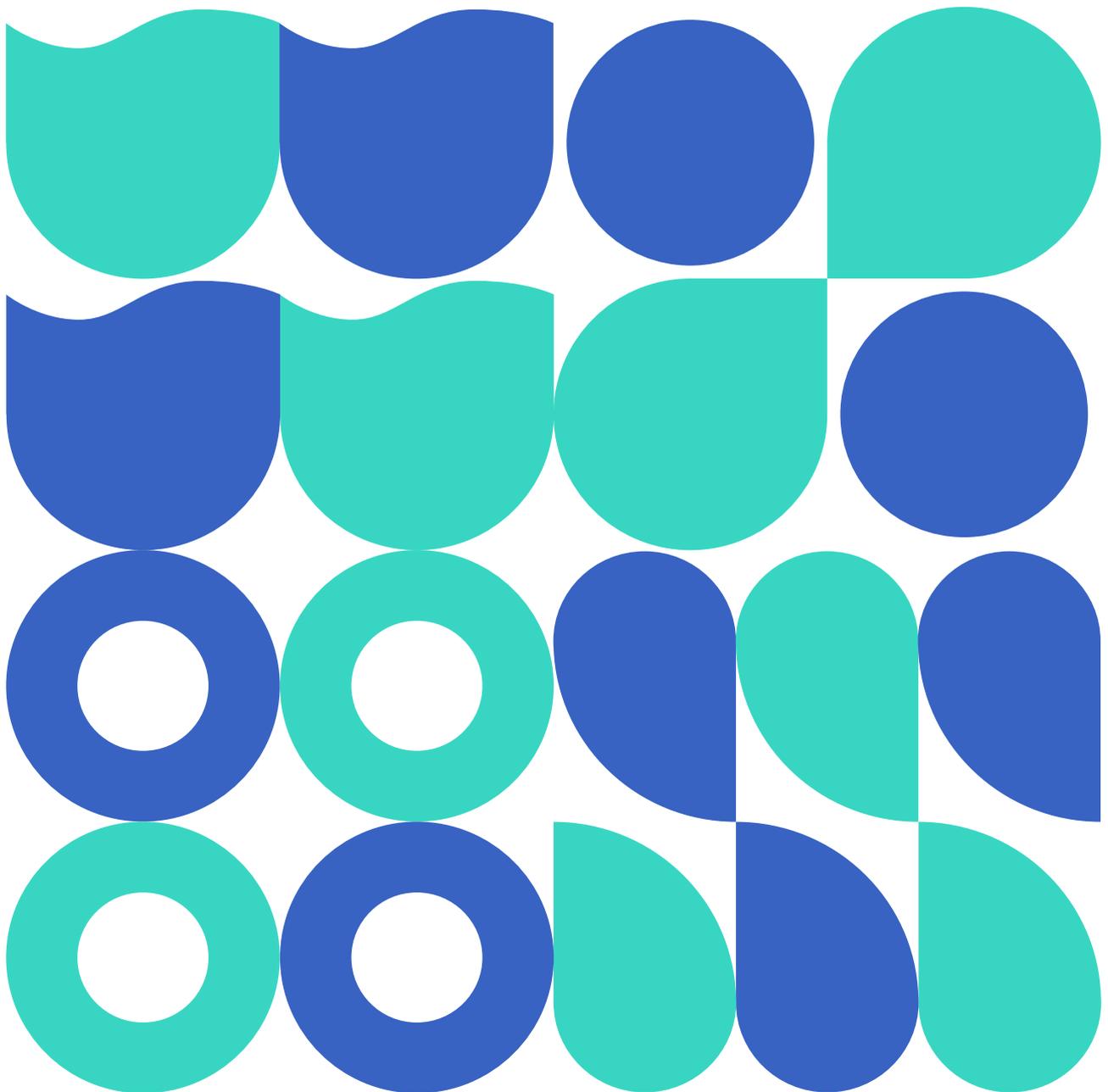


# Bio Supplies Diagnostic Catalogue

**BioSupplies**  
Biological material solutions  
**Diagnostic**



**GRIFOLS**



**BioSupplies**  
Biological material solutions

# Grifols Bio Supplies

Grifols is a global healthcare company that since 1909 has enhanced the health and well-being of people around the world. Our four divisions – Bioscience, Diagnostic, Hospital and Bio Supplies – develop, produce and market innovative solutions and services in more than 100 countries.

The Bio Supplies Diagnostic Product Line provides a portfolio of biological materials collected from our own network of blood and plasma centers to be used for life science research and in vitro diagnostic companies in research, development and manufacturing of reagents and controls.



## **SAFETY**

Source control of all materials is directly linked to safety.



## **COMMITMENT**

Our commitment to our customers inspires us to maintain the very high standards of quality in our products facilitating the development of diagnostics and therapeutics.



## **EXCELLENCE**

Bio Supplies provides excellence and a reliable supply of human biological material collected ethically and with consent from the largest plasma collection network in the world and whole blood centers.



## **LEGACY OF INNOVATION**

Our ongoing innovation has helped shape industry standards in the plasma sector.

# Bio Supplies Solutions

## Consistent attributes qualified Grifols Bio Supplies as your supplier of choice for the procurement of human-derived blood materials:

### LARGE COLLECTION CAPABILITIES

- Grifols has the largest worldwide plasma donor center network worldwide with more than 350 plasma collection centers distributed across the US and Europe with more than 45,000 daily donations
- Multiple whole blood collection centers located in the US and Germany provide Grifols Bio Supplies with access to a large amount of qualified human raw material
- One dedicated donor collection center for non-injectable blood products
- Leading suppliers and collectors of blood components for the in vitro diagnostic (IVD) industry are now part of, or have a partnership with, Grifols Bio Supplies, growing the Grifols collection and supplier capabilities

IBBI

GRIFOLS

Haema.

Access Biologicals  
A Grifols Company



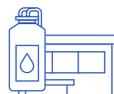
**1**  
DISEASE  
STATE PLASMA  
COLLECTION  
CENTER



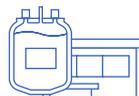
**10**  
WHOLE BLOOD  
CENTERS IN USA

**> 300**  
PLASMA CENTERS  
IN USA

### MAP LEGEND



Plasma centre



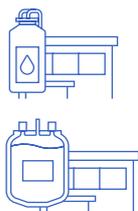
Whole blood center

400 +

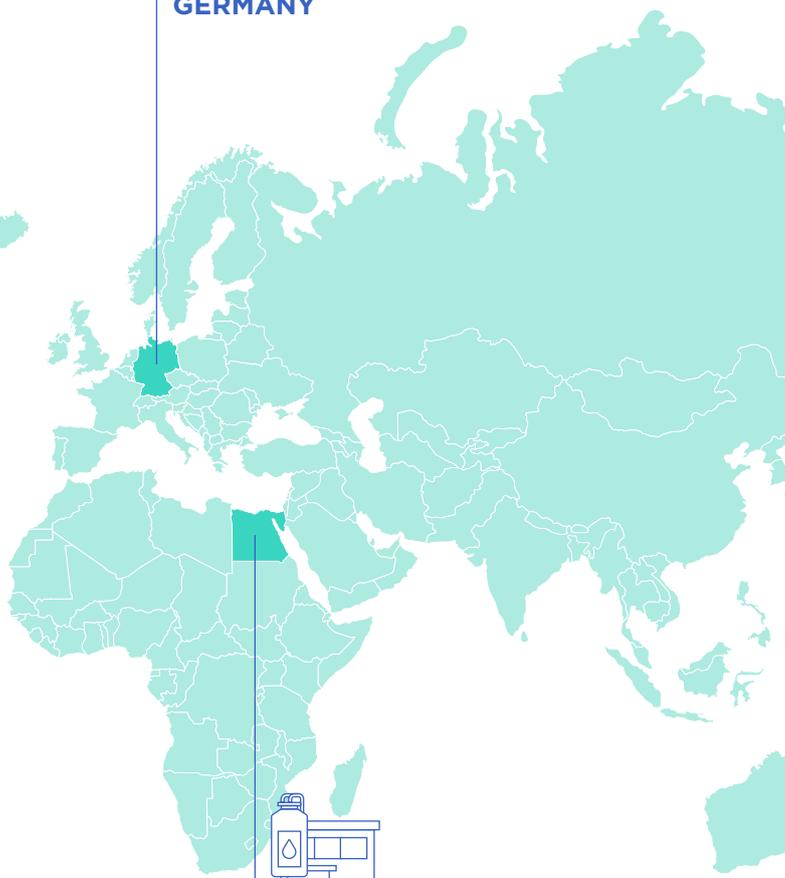
PLASMA CENTERS  
WORLDWIDE

10 M

PLASMA DONATIONS  
ANNUALLY



32  
PLASMA AND  
WHOLE BLOOD  
CENTERS IN  
GERMANY



1  
PLASMA CENTER  
IN EGYPT



### HIGH QUALITY

- All of our collection centers located in the USA are FDA-licensed facilities
- All of our collection centers located in Germany are all under full GMP compliance facilities



### DONOR DATA

- Age
- Race
- Gender
- Blood group
- (Non)smoker



### PRODUCT CUSTOMIZATION

Customizable product capabilities to align with the customer needs and specifications:

- Anticoagulants
- Processing
- Packaging
- Storage Temperature



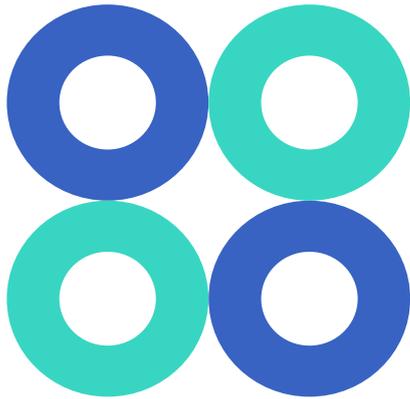
### VIRAL DONOR TESTING

All units are tested according to local regulations to ensure they are negative for infectious diseases.

Additional tests can be provided by customer demand.

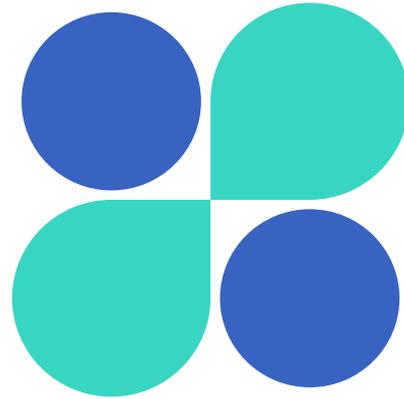
# **Your Partner in Biological Material Supply**

# Table of Contents



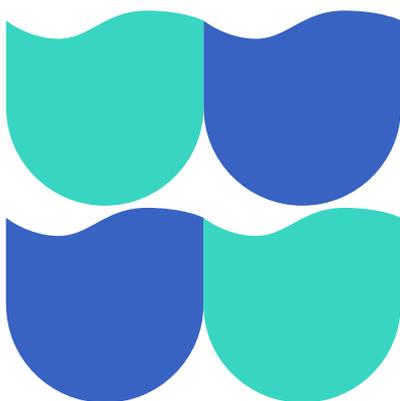
---

Blood Cells  
Products  
08



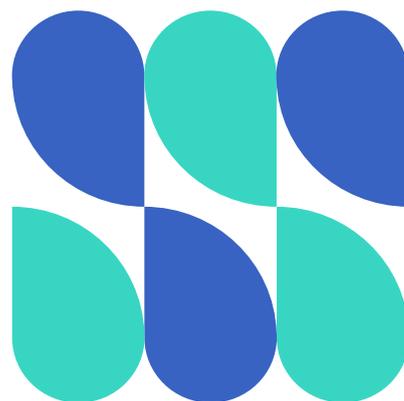
---

Plasma and Serum  
Products  
12



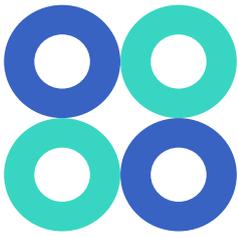
---

Human Biospecimen  
Samples  
14



---

Bioproducts  
16



# Blood Cells Products

Grifols Bio Supplies has an extensive collection of human blood products for research and development needs.

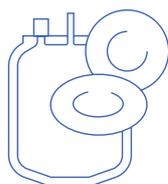
All of products are collected from donors who have an approved consent for donating blood. All donors are screened to ensure that each of them is in good health and that products are not collected from a high-risk population for blood-borne infections.

The donor data provided are age, gender, race and blood group. Moreover, for Red Blood Cells, an RBC extended phenotype is available.



## WHOLE BLOOD

Whole blood is human blood from a standard blood donation. It contains red blood, white blood and platelets suspended in plasma.



## RED BLOOD CELLS

Red blood cells are the most common type of blood cell and are prepared from whole blood by removing plasma.



## PLATELETS

Platelets, or thrombocytes, are small, colorless cell fragments in human blood that form clots and stop or prevent bleeding. They are prepared through blood donations or apheresis methods.



## BUFFY COATS

The buffy coat is the fraction of uncoagulated blood that contains most of the white blood cells and platelets after a density gradient centrifugation process.

## SPECIFICATIONS

PRODUCT	WHOLE BLOOD		RED BLOOD CELLS		PLATELETS		BUFFY COATS	
Source region	USA	EU	USA	EU	USA	EU	USA	EU
Collection method	Blood donation	Blood donation	Blood donation	Blood donation	Blood donation	Apheresis	Blood donation	Blood donation

### FORMAT

>60 mL - Bag					•	•	•	•
>250 mL - Bag	•	•	•	•				
Bulk - Bottle	•	•	•	•	•	•	•	•

### DONOR VIRAL TESTING

HIV-1-NAT	•	•	•	•	•	•	•	•
HCV-NAT	•	•	•	•	•	•	•	•
HBV-NAT	•	•	•	•	•	•	•	•
HEV-NAT		•		•		•		•
HAV-NAT		•		•		•		•
WNV-NAT	•	•	•	•	•	•	•	•
PVB19-NAT		•		•		•		•
anti-HIV 1/2	•	•	•	•	•	•	•	•
anti-HCV	•	•	•	•	•	•	•	•
HBsAg	•	•	•	•	•	•	•	•
anti-HBc		•		•		•		•
Syphilis	•	•	•	•	•	•	•	•
Chagas	•		•		•		•	
Babesia	•		•		•		•	

### ANTICOAGULANT

ACD	•	•	•	•	•	•	•	•
AS-1 (additive solution)			•	•				
CPD	•	•	•	•				
CPDA-1	•	•	•	•			•	•
K2 EDTA	•	•						
K3 EDTA	•	•					•	•
Sodium citrate	•	•						
Sodium heparin	•	•						

### STORAGE TEMPERATURE

Refrigerated 2-8 °C	•	•	•	•	•	•	•	•
Room temperature 15-30 °C	•	•	•	•	•	•	•	•
Frozen <20 °C	•	•	•	•	•	•	•	•

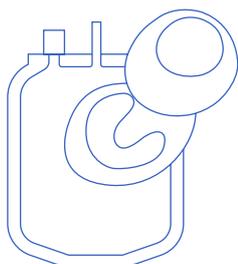
### OTHER CUSTOMIZATIONS

Dating specific	•	•	•	•	•	•	•	•
Leukoreduced			•	•		•		
Concentrated					•	•		
Pooled			•		•	•		

For more information on product availability or customization, please contact us: [biosuppliesdx@grifols.com](mailto:biosuppliesdx@grifols.com)

# Fresh Leukopak

High concentration of leukocytes, collected from European donors under GMP procedures



A leukopak is a blood-derived product rich in mononuclear leukocytes (i.e., lymphocytes and monocytes)<sup>1</sup>. Leukopaks are useful for researchers looking for a large number of leukocytes to cover large scale needs.

Our leukopaks are obtained through leukapheresis following GMP procedures.



## SPECIFICATIONS

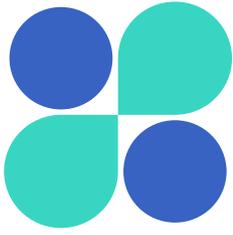
PARAMETER	SPECIFICATION
Origin of leukopaks	Europe (Germany)
Package volume	170 to 240 mL/Bag
Obtention method	Leukapheresis (Spectra Optia system)
Leukocyte concentration	$\geq 40 \times 10^9$ cells/L
Virus testing	HBsAg, Anti-HBc, HIV-1/2-Ab, HCV-Ab, HIV-1-NAT, HCV-NAT, HBV-NAT, HAV-NAT, PVB19-NAT, HEV-NAT, WNV-NAT* and syphilis
Platelet concentration	$1600$ to $5200 \times 10^9$ /L
Hemoglobin concentration	$\leq 0.5$ mmol/L
Hematocrit	$\leq 0.07$ L/L
Monocyte concentration	$\geq 5 \times 10^9$ cells/L
Lymphocyte concentration	$\geq 28 \times 10^9$ cells/L

\*WNV-NAT: Seasonal testing from June 1 to November 30.

1. Garcia A, Keinonen S, Sanchez AM, et al. Leukopak PBMC sample processing for preparing quality control material to support proficiency testing programs. J Immunol Methods. 2014;409:99-106. doi:10.1016/j.jim.2014.05.01

Leukapheresis is a specific apheresis process in which white blood cells are separated from the blood sample and the remainder is returned to the circulation.





# Plasma and Serum Products

Grifols Bio Supplies offers high-quality human reagent grade plasma collected from healthy donors for use in manufacturing of controls and calibrators for the in vitro diagnostic industry.

All of healthy state products are collected from donors who have an approved consent for donating blood. All donors are screened to ensure that each of them is in good health and that products are not collected from a high-risk population for blood-borne infections.

The donor data provided are age, gender, race and blood group.



## RECOVERED PLASMA

Plasma produced by separating donated whole blood into cellular components and plasma.



## SOURCE PLASMA

Plasma collected through apheresis, a process that takes only plasma from the donor while the cellular components are returned.



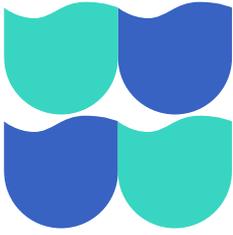
## OTC SERUM

Off-the-clot serum collected from whole blood and allowed to coagulate naturally without anticoagulants.

## SPECIFICATIONS

PRODUCT	RECOVERED PLASMA		SOURCE PLASMA		OTC SERUM
	USA	EU	USA	EU	USA
<b>Source region</b>	USA	EU	USA	EU	USA
<b>Collection method</b>	Blood donation	Blood donation	Plasmapheresis	Plasmapheresis	Blood donation
<b>FORMAT</b>					
>250 mL - Bag	•	•			•
300 mL - Bottle					•
500 mL - Bottle					•
650 mL - Bottle					•
0,8 L - Bottle			•	•	
1 L - Bottle					•
3,5 L - Bottle					•
<b>DONOR VIRAL TESTING</b>					
HIV-1-NAT	•	•	•	•	•
HCV-NAT	•	•	•	•	•
HBV-NAT	•	•	•	•	•
HEV-NAT		•		•	
HAV-NAT		•		•	
WNV-NAT	•	•	•	•	•
PVB19-NAT		•		•	
anti-HIV 1/2	•	•	•	•	•
anti-HCV	•	•	•	•	•
HBsAg	•	•	•	•	•
anti-HBc		•		•	
Syphilis	•	•	•	•	•
Chagas	•		•		•
Babesia	•		•		•
<b>ANTICOAGULANT</b>					
ACD	•	•			
CPD	•	•			
CPDA-1	•	•			
K2 EDTA	•	•			
K3 EDTA	•	•			
Lithium heparin	•	•			
Sodium citrate	•	•	•	•	
Sodium EDTA	•	•			
Sodium heparin	•	•			
<b>STORAGE TEMPERATURE</b>					
Refrigerated 2-8 °C	•	•	•	•	•
Room temperature 15-30 °C	•	•			•
Frozen <20 °C	•	•	•	•	•
<b>OTHER CUSTOMIZATIONS</b>					
Dating specific	•	•	•	•	•

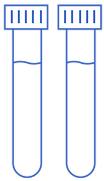
For more information on product availability or customization, please contact us: [biosuppliesdx@grifols.com](mailto:biosuppliesdx@grifols.com)



# Human Biospecimen Samples

Grifols collects human biospecimen (samples) from healthy donors to be used in the research, development and testing of in vitro diagnostic (IVD) assays and life science.

Grifols offering includes the option to select samples based on donor characteristics.



## BLOOD SAMPLES

Institutional Review Board (IRB) approved biospecimens/samples collected from healthy donors.

## PRODUCTS

<b>Oral specimens (Saliva)</b>	Samples collected with oral collection device
<b>Oropharyngeal specimens (OP)</b>	Samples collected with oropharyngeal (throat) swab
<b>Nasopharyngeal specimens (NP)</b>	Samples collected with nasopharyngeal swab
<b>Serum</b>	Off-the-clot serum
<b>Plasma</b>	Variety of different anticoagulants including ACD, CPD, CPDA-1, heparin and EDTA. Additional anticoagulants on request.
<b>Whole blood</b>	Variety of different anticoagulants including ACD, CPD, CPDA-1, heparin and EDTA. Additional anticoagulants on request.
<b>Matched sets</b>	Matched saliva, NP, OP, serum, plasma (with different anticoagulants) and whole blood samples sets for being used in equivalency matrix studies

## SPECIFICATIONS

Human specimens can be used in existing or future diagnostic studies that evaluate the performance and clinical utility of IVD assays.

All materials are single donation tested according to methods cleared in compliance with the US Food and Drug Administration (FDA) regulations, collected under an IRB-approved protocol.

## CRITERIA FOR DONORS



All samples will come from routine blood donors.



Donors are consented with an FDA-approved consent for blood donation.

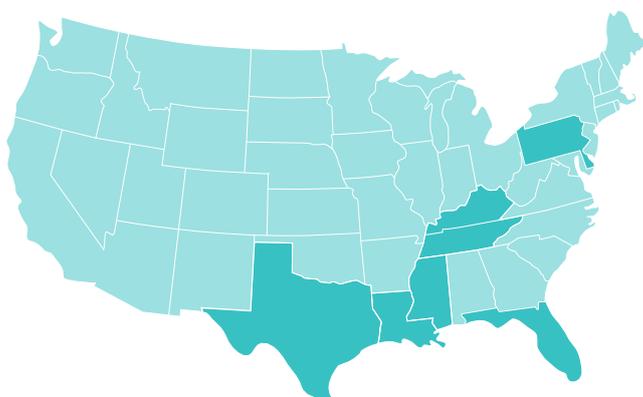


All donors are screened to ensure that each of them is under good health conditions and that samples are not collected from a high-risk population for blood-borne infections.



All donors are tested negative for infectious diseases according to FDA regulations.

## DATA PROVIDED



### Donor data provided

Age, race, gender and blood type

### Geographical location

Donor centers located in different regions in USA (Memphis, Miami, Philadelphia, Baltimore, Jackson, Temple, Louisville and Indianapolis).

We can also provide samples collected at one of our more than 30 blood collection centers located in Germany.

For more information on product availability or customization, please contact us: [biosuppliesdx@grifols.com](mailto:biosuppliesdx@grifols.com)

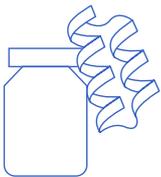


## Bio Products

Diagnostic grade plasma proteins obtained from human source plasma as part of the fractionation process for further protein purification.

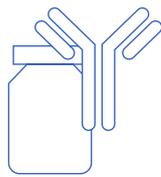
Our plasma proteins are manufactured from plasma originating from our own US and EU plasmapheresis centers, conforming to Good Manufacturing Practices (GMP), International Quality Plasma Program (IQPP) of the Plasma Protein Therapeutic Association (PPTA) and fulfilling additional requirements set by Grifols.

- Production processes and facilities are certified according to the US FDA and EU regulations.
- Our Proteins are offered in liquid format at different concentrations and volumes.
- Our donors have an approved consent for donating blood and are screened to ensure that each of them is in good health and that products are not collected from a high-risk population for blood-borne infections.



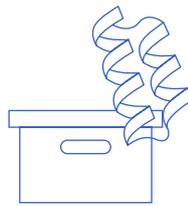
### **HUMAN SERUM ALBUMIN**

Diagnostic grade human serum albumin (HSA) obtained from human source plasma



### **IMMUNOGLOBULINS**

Diagnostic grade immunoglobulins obtained from human source plasma



### **PLASMA PRODUCTS FOR FURTHER MANUFACTURING**

Several fractions from the plasma fractionation process containing a range of different proteins available for R&D purposes and/or for being utilized to purify specific proteins contained within them

**Human serum albumin is the most abundant protein in human blood plasma, constituting about half of all serum proteins.**



## SPECIFICATIONS

PRODUCT	SOURCE PLASMA
Source region	USA and EU
Collection method	Plasmapheresis

### FORMAT

Liquid format at different concentrations and volumes

### DONOR VIRAL TESTING

HIV-1-NAT	•
HCV-NAT	•
HBV-NAT	•
WNV-NAT	•
anti-HIV 1/2	•
anti-HCV	•
HBsAg	•
Syphilis	•
Chagas	•
Babesia	•

## HIGH MANUFACTURING STANDARDS



Product obtained from plasma collected at FDA-approved collection centers



Fully tested according to FDA regulations to ensure that the products are found negative for required tests



Manufactured in GMP grade facilities

# Contact and Order Information

## **General Contact Information**

+34 93 571 05 00

[biosuppliesdx@grifols.com](mailto:biosuppliesdx@grifols.com)

## **US Order Information**

+1 901 384 6250

[ibbicustserv@grifols.com](mailto:ibbicustserv@grifols.com)

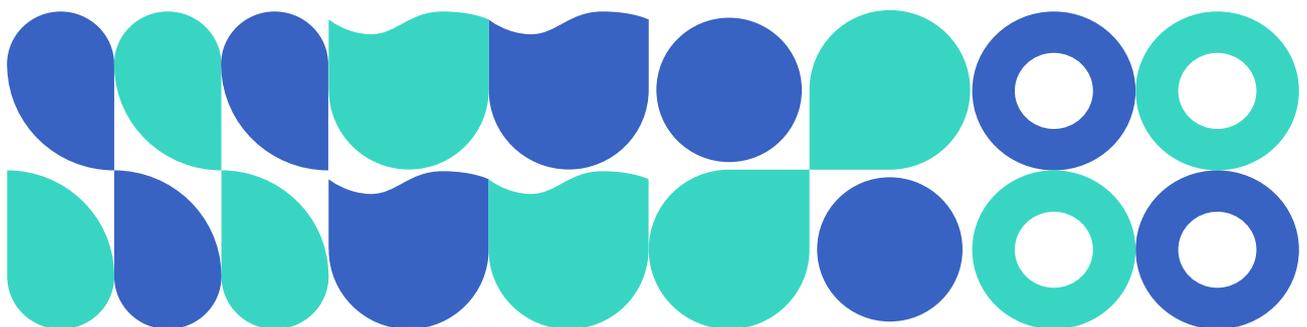
## **EU Order Information**

+49 341 478 30 0

[HAGbiosupplies@haema.de](mailto:HAGbiosupplies@haema.de)

**For further product information, you can also visit our website:**

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





**GRIFOLS**  
**CPD - 63 ml para extracción/For extraction/**  
**450 ml ± 10%**  
 Para preservar el componente de plasma de sangre humana o uno de sus componentes. No utilizar para plasma. Visible de detección. No utilizar fuera de aire. Contiene fluido estéril y apirógeno.  
 Bag for collection or preservation of human blood or one of its components. Do not use if liquid is visible sign of deterioration. Do not use. Sterile and non pyrogenous fluid pathway.  
 Saccos per la raccolta o per la conservazione di sangue umano o di uno dei suoi componenti. Non usare se sono visibili segni di deterioramento. Non usare se sono visibili segni di deterioramento. Non fare entrare aria nella sacca. Contiene fluido sterile ed apirogeno.  
 Σάκκοι για συλλογή ή διατήρηση ανθρώπινου αίματος ή ενός από τα συστατικά του. Μην χρησιμοποιείτε αν υπάρχουν εμφανείς σημάδια φθοράς. Μην σφίξετε. Στείρα και μη πυρετογόνος διαόδος υγρού.

**CPD - 450**  
 N°No./Ap.:  
 Fecha extracción/Extraction date/Дата от приготовления раствора/ Ημερομηνία Λιμόνησης:  
 Caducidad/Expiry date/Scadenza/Data de caducidad/ Ημερομηνία Λήξης:  
 Centro de transfusión/transfusion center/Centro de transfusão/ Centro de transfusão/Κέντρο Αιμοδοσίας:  
 ABO: Rh:  
 Formula 100 ml: Acid. citric. anhydr. 0.29% g. Natri. dihydr. 2.63 g. Natri. dihydrogenophosphas monohydr. 0.20% g. Glucose. monohydr. 2.55 g. Aqua ad iniect. ad 100 ml.  
 Laboratorios Grifols, S.A.  
 Can Guasch, 2 - Parets del Vallès 08150 Barcelona - Spain

REF 722190 LOT L0001#01  
 1LG0722190 2020-01  
 00000L0001

**GRIFOLS**

**Grifols Bio Supplies Division**  
Parc Empresarial Can Sant Joan  
Av. de la Generalitat, 152-158  
08174 Sant Cugat del Vallès  
Barcelona, España  
Tel: +34 935 710 500  
biosuppliesdx@grifols.com

**Interstate Blood Bank, Inc.**  
5125 Elmore Road  
Memphis, TN 38134  
Tel: +1 901 384 6250  
ibbicustserv@grifols.com

**Haema AG**  
Landsteinerstrasse 1  
04103 Leipzig  
Deutschland  
Tel: +49 341 478 30 0  
HAGbiosupplies@haema.de