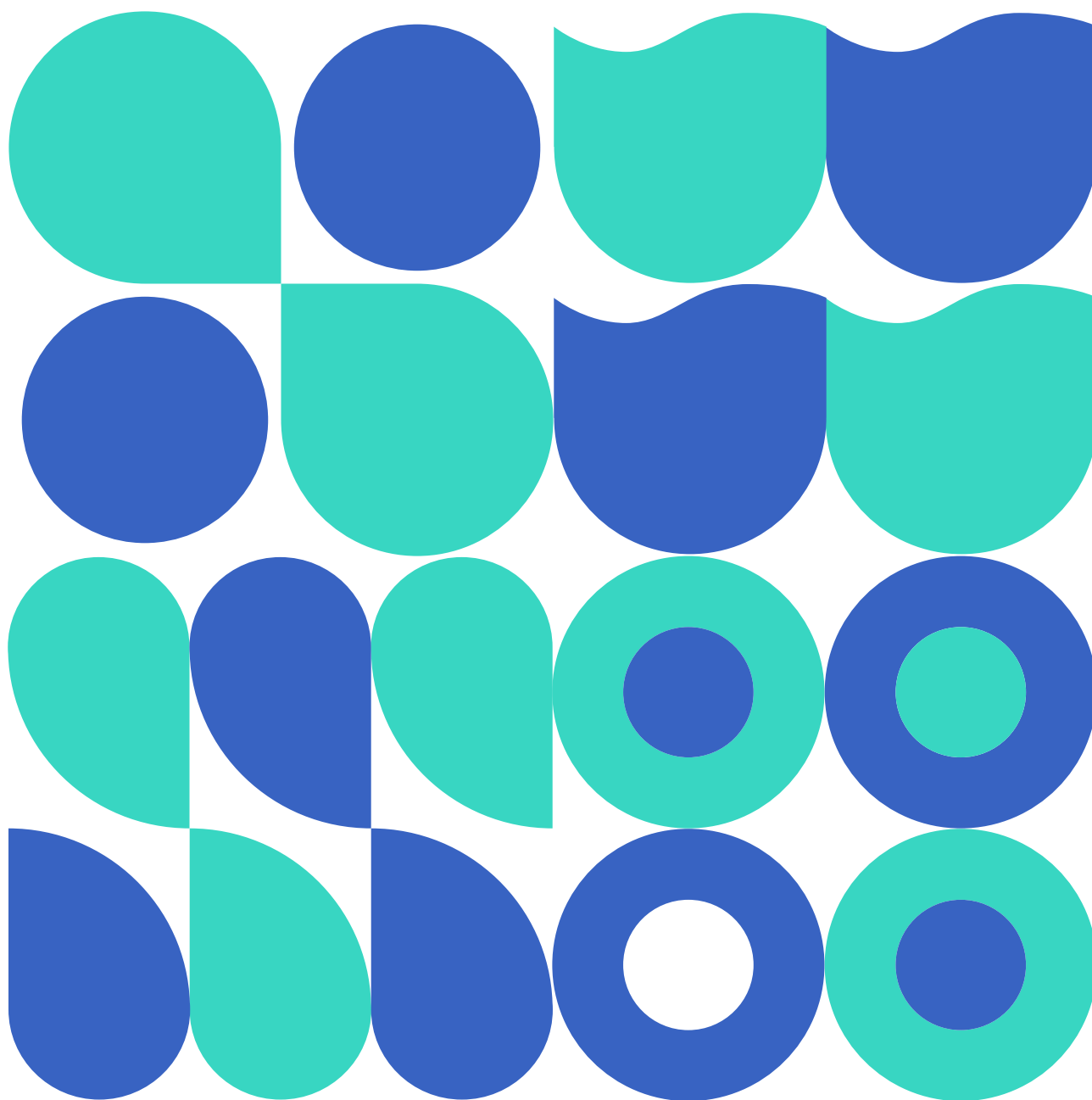


# Human raw materials for IVD manufacture

**BioSupplies**

Biological material solutions

**IVD Manufacture**



**GRIFOLS**

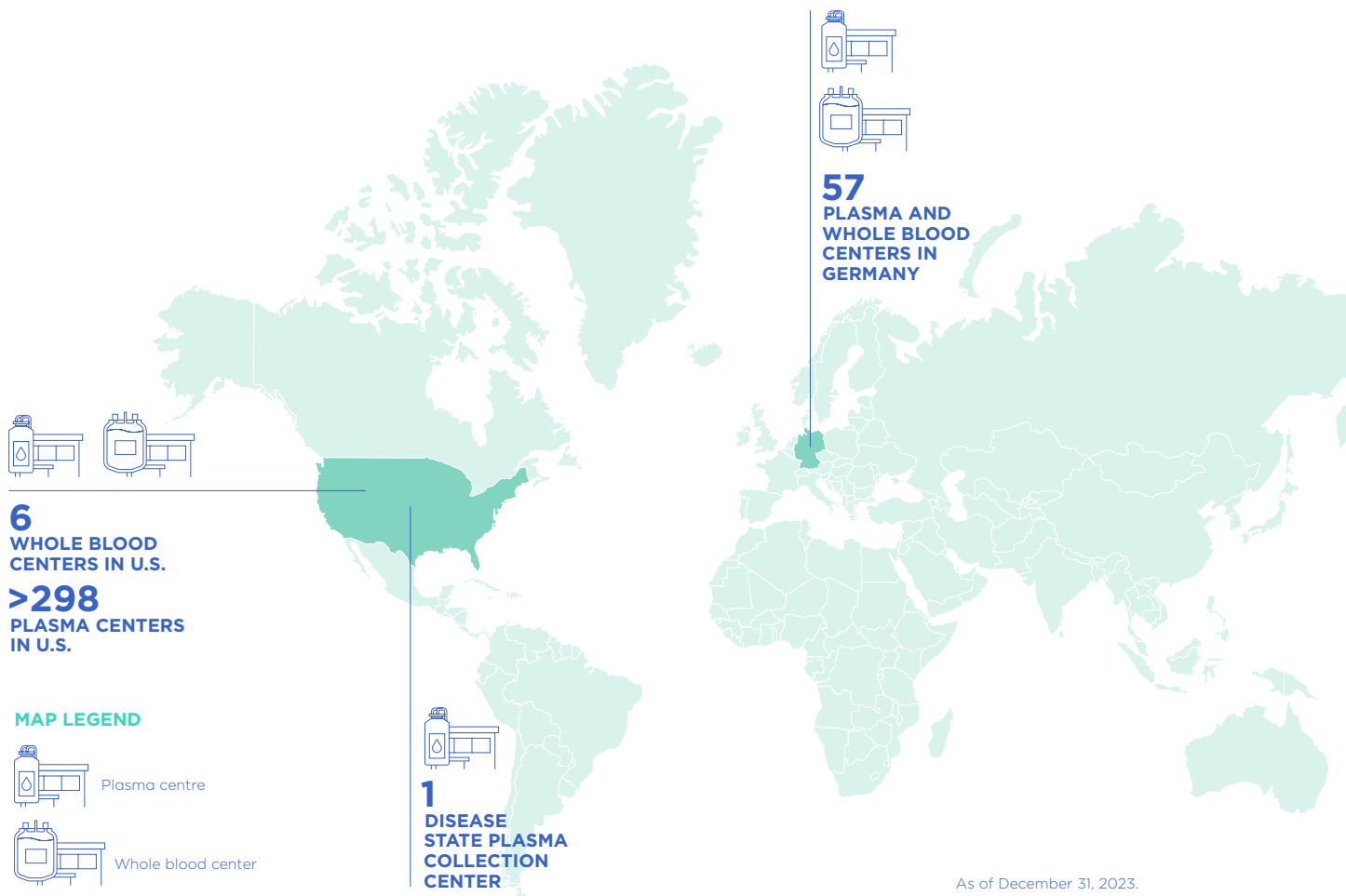
# Grifols Bio Supplies

Grifols is a global healthcare company founded in Barcelona in 1909 committed to improving the health and well-being of people around the world.

Through its Bio Supplies business unit, Grifols provides a comprehensive range of human biological materials, collected from its own network of blood and plasma centers in the U.S. and Europe. This ensures consistent quality and controls throughout the process.

**Researchers.** Grifols offers materials for life-science studies, including whole blood, blood cells, plasma, serum, and clinical samples.

**Diagnostic companies.** Grifols supplies human plasma and serum to manufacture reagents and controls. We can also process plasma to adapt to customer-specific needs, including defibrination, delipidation, and filtration among others.

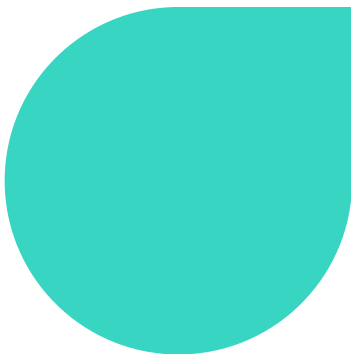


As of December 31, 2023.

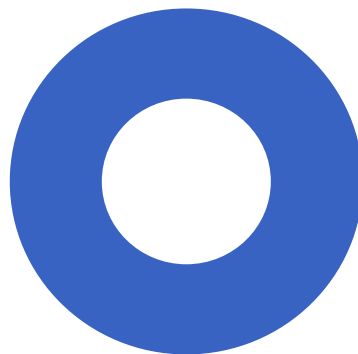
# Accelerate your research and development with Grifols:

Your supplier of choice  
for the procurement of  
human biological materials

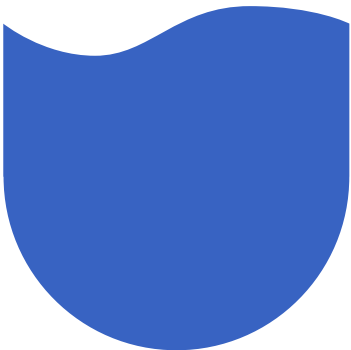
Plasma and  
Serum Products



Whole Blood  
and Blood Cells

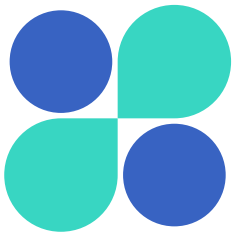


Biospecimens



Proteins





# Plasma and Serum Products

Grifols Bio Supplies offers high-quality human-derived products for use in the manufacturing of controls and calibrators for the IVD industry.

We can offer OTC serum, source plasma or processed plasma collected from healthy donors and from donors with special clinical conditions.

Human serum and plasma are essential in the production of calibrators and controls for the IVD industry. Their use guarantees the precision, reliability, and reproducibility of diagnostic tests.

## Applications:

- Calibrator and control manufacturing:
  - Offering a standard for normal analyte levels.
  - Mimicking patient samples for reliable diagnostic testing.
  - Human material from donors with specific clinical conditions can be used to produce disease-specific calibrators and controls, allowing for accurate quantification of disease-related parameters.
- Healthy donor blood (plasma/serum) acts as a natural matrix for calibrators and controls, mimicking patient samples to minimize test interference for accurate diagnoses.



## QUALITY ASSURANCE AND SAFETY

Our plasma and serum products are collected at FDA- and EMA-licensed centers and manufactured under strict quality assurance system enhancing the product quality.



## LARGE COLLECTION CAPABILITIES

- Grifols has the largest plasma donor center network worldwide with more than 390 plasma collection centers distributed across North America, Europe, Africa and the Middle East, and China.
- Large lot size production helps to have a better reproducibility.



## EXPERT SUPPORT

Our customer service team consists of skilled professionals who are committed to providing outstanding support at every stage of the process.



## CUSTOMIZATION SOLUTIONS

Our manufacturing processes are customizable to customer specifications.

# Processed Plasma Capabilities

Processed plasma is a great alternative to human serum for producing controls and calibrators, ensuring uniformity and consistency. It provides a base matrix for accurate analyte measurement and improves assay reliability.<sup>1,2</sup>

## OUR PLASMA PROCESSING TECHNIQUES INCLUDE:

Technique	Purpose	Use in calibrators and controls
<b>Defibrination</b>	Defibrinated plasma is plasma from which fibrinogen and other clotting factors have been removed, preventing coagulation	Stable matrix for controls and calibrators, preventing coagulation from affecting assay performance
<b>Charcoal stripping</b>	Charcoal stripping removes lipophilic substances like hormones and lipids from plasma by adsorbing them onto activated charcoal	Charcoal stripped plasma is free of lipophilic substances that may interfere with assays, enhancing specificity and accuracy, particularly in hormone and lipid assays
<b>Filtration</b>	Filtration eliminates particulate matter and aggregates from plasma, producing a clear and particle-free solution.  Filtration can be customized to as low as 0.1 µm	Filtered plasma provides a clean matrix for controls and calibrators, ensuring reliable assay performance and improving diagnostic test accuracy and precision by removing interference from particulate matter
<b>Delipidation</b>	Delipidation is the process of removing lipids (fats) from plasma, which reduces lipid interference in assays	Delipidated plasma provides a clean matrix for controls and calibrators, reducing lipid interference in assays and ensuring accurate measurement of analyte
<b>Dialysis</b>	Eliminates the excess of calcium used in the defibrination step	It ensures more stable and normalized parameters

# Products Available

## NORMAL HUMAN SERUM AND PLASMA

All normal human serum units are collected from donors who have been tested according to the U.S. FDA or EMA regulations to ensure the highest standards of quality and safety.



### OTC SERUM

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

- Formats available: fresh and frozen
- Packaging: bags (>250 mL) and bottles (300 mL, 500 mL, 650 mL, 1 L or 3.5 L)
- Option to be offered: dating specific
- Donor collections from U.S. and Europe
- Customizations based on donor demographics and testing



### SOURCE PLASMA

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

- Formats available: fresh and frozen
- Packaging: bottles (~0.8 L)
- Option to be offered: dated specific
- Donor collections available from U.S. and Europe
- Customizations based on donor demographics



### STANDARD HUMAN SERUM (PROCESSED PLASMA)

SHS is produced from a defibrinated plasma that undergoes a special high purification process that reduces citrate levels to physiological values

- Formats available: fresh and frozen
- Packaging: bottles (1 L and 3 L)
- Pooling options with large sizes
- Option to be offered: dated specific
- Donor collections available from U.S.
- Product can be adapted according to donor demographics, parameter specifications or final product format

## DISEASE STATE MATERIALS

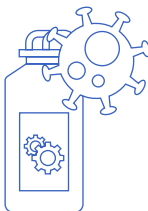
Human plasma collected from individuals with the presence or absence of specific markers used to diagnose different medical conditions (autoimmune diseases, infectious diseases, inflammatory or other conditions). These markers may be antibodies, enzymes, hormones, and others. Plasma can be provided in individual bottles, pooled and adjusted to specific titers and/or further processed as defibrinated plasma.



### SOURCE PLASMA

Plasma sourced from donors with or with the absence of specific clinical conditions and collected with plasmapheresis

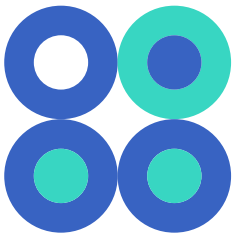
- Formats available: fresh and frozen
- Packaging: bottles (~0.8 L)
- Option to be offered: dated specific and packaging specific size
- Customizations based on donor demographics



### PROCESSED PLASMA

Plasma is sourced from donors, with or without the absence of specific clinical conditions. It is collected through plasmapheresis and processed to modify its composition, by removing unwanted components, or enhancing its suitability for various applications.

- Formats available: fresh and frozen
- Packaging: bottles (1 L and 3 L)
- Processing techniques available: defibrination, charcoal stripping, filtration, delipidation, heat inactivation, and gamma irradiation
- Custom processing and custom fill sizes available



# Whole blood and Blood Cells Products

Grifols Bio Supplies is specialized in providing whole blood-derived products for IVD development and manufacturing processes, including assays, instruments, and test kits.

## Applications:

- Assay development to detect biomarkers associated with specific clinical conditions.
- Clinical validation to assess the performance of the diagnostic products, including their accuracy, precision, and clinical utility.
- Stability studies to evaluate the stability of diagnostic products under various storage conditions, such as temperature and time.
- Quality control to monitor the performance of diagnostic products over time.
- Reference materials for calibrating and standardizing diagnostic assays.



## QUALITY ASSURANCE AND SAFETY

- All units are collected from donors who have an approved consent for donating blood and are tested according to FDA or EMA regulations
- Additional tests can be provided upon request



## ROBUST SUPPLY CHAIN

- We ensure timely delivery through our robust supply chain to meet customer schedules
- Grifols Bio Supplies operates multiple whole blood collection centers in the U.S. (6) and Germany (32), allowing us to oversee every step, from donor selection to blood collection, ensuring consistency and traceability



## CUSTOMIZATION SOLUTIONS

We offer customizable solutions to meet specific customer requirements, including donor demographics (age, gender, race...), storage temperature, packaging size, pooled donors or dating specifics.



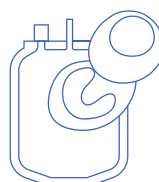
# Products Available



## WHOLE BLOOD

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

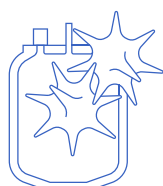
- Formats available: fresh and frozen
- Packaging: bags (>250 mL)
- Option to be offered: dated specific
- Donor collection available from U.S. and EU (Germany)
- Customizations: anticoagulant options, donor demographic, and specific testing options



## RED BLOOD CELLS (RBC)

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

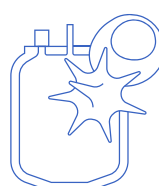
- Formats available: fresh and frozen
- Packaging: bags (>250 mL)
- RBC extended phenotype is available
- Option to be offered: dated specific and leukoreduced
- Donor collections available from U.S. and EU (Germany)
- Customizations: anticoagulant options, donor demographic, and specific testing options



## PLATELETS

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

- Formats available: fresh (<5 days after collection) and frozen
- Packaging: bags (>60 mL)
- Option to be offered: dated specific and concentrated.
- Donor collections available from Europe (Germany)
- Pools options



## BUFFY COATS

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

- Formats available: fresh and frozen
- Packaging: bags (20-50 mL)
- Donor collections available from Europe (Germany)



# Biospecimens

Human biospecimens obtained from both healthy donors and individuals with specific clinical conditions for research, development, and testing in the field of in vitro diagnostic (IVD) assays and life sciences. Additionally, we supply human biospecimen panels to aid in the development, evaluation, and troubleshooting of IVD assays.



## REGULATORY COMPLIANCE

Our collections are collected ethically and are HIPAA compliant with informed consent and/or IRB.



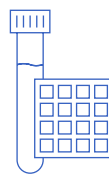
## BIOSPECIMEN ACQUISITION

Through our broad network of physicians and laboratories, we access a diverse range of specimens, supporting researchers by offering varied samples and maximizing information from each.



## CLINICAL SAMPLES

- Different matrices available
  - Blood: whole blood, plasma, and serum
  - Swabs: nasal, buccal, throat
  - Urine, saliva, and others under request
- Sourcing:
  - Prospective collections of different disease states and clinical data available, including the option to select samples based on donor characteristics.
  - Remnant clinical samples also available
- Collection types:
  - Individual or matched sets
  - Fresh (same day collection)
- Shipping temperature: room temperature, 2-8 °C, -20 °C, -80 °C
- Clinical conditions: disease free, infectious disease, endocrinology, oncology, cardiac, pregnancy, diabetes, autoimmune, virology...



## BIOSPECIMEN PANELS

- Seroconversion panels: Each panel contains unique plasma samples collected during the early stages of a virus or infection.
  - Panels available: COVID-19, COVID-19 vaccine, Epstein-Barr virus, HAV, human parvovirus B19
  - Other panels available under request
- Validation panels: range of samples covering a variety of concentrations of the analyte.
  - Panels available: COVID-19 positive and negative, antinuclear antibody (ANA), anti-cyclic citrullinated peptide (anti-CCP), APLS, celiac, HSV-1 and HSV-2, interference panel, measles, mumps, rubella, and varicella (MMRV), SARS-CoV-2 crossover panel, ToRC, vasculitis, and vitamin D
  - Other panels available under request

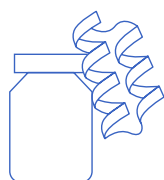


# Proteins

## High Manufacturing Standards

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

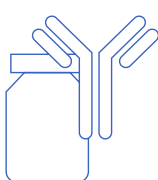
Our plasma proteins are manufactured from plasma originating from our own U.S. and EU plasmapheresis centers, conforming to the good manufacturing practices (**GMP**), the International Quality Plasma Program (**IQPP**) of the Plasma Protein Therapeutic Association (**PPTA**) and fulfilling additional requirements set by Grifols.



### HUMAN SERUM ALBUMIN

Diagnostic grade human serum albumin (HSA)

- Formats available: liquid
- Packaging: 3.5 L or customized
- Concentration: 20% or 25% - customized concentration under request



### IMMUNOGLOBULINS

Diagnostic grade immunoglobulins

- Formats available: liquid
- Packaging: 3.5 L or customized
- Concentration: 10% or customized concentration under request



## QUALITY ASSURANCE AND SAFETY

- Production processes and facilities are certified according to the U.S. FDA and EU regulations.
- Our donors have an approved consent for donating blood and are tested non-reactive for the required viral markers



## PRACTICAL PACKAGING OPTIONS

Our Proteins are offered in liquid format at different concentrations and volumes.



The products presented here are not for therapeutic use

**References:**

1. Nouri MZ, Kroll KJ, Webb M, Denslow ND. Quantification of steroid hormones in low volume plasma Wand tissue homogenates of fish using LC-MS/MS. *Gen Comp Endocrinol.* 2020;296:113543.
2. Panteghini M, Forest JC. Standardization in laboratory medicine: new challenges. *Clin Chim Acta.* 2005;355(1-2):1-12.

For ordering information,  
contact us here:



[biosupplies\\_custserv@grifols.com](mailto:biosupplies_custserv@grifols.com)  
[www.biosuppliesproducts.com](http://www.biosuppliesproducts.com)

**GRIFOLS**

**Grifols Bio Supplies Inc**  
2410 Grifols Way  
Los Angeles, CA 90032  
Tel. 323-405-0600  
[biosupplies\\_custserv@grifols.com](mailto:biosupplies_custserv@grifols.com)  
[www.biosuppliesproducts.com](http://www.biosuppliesproducts.com)