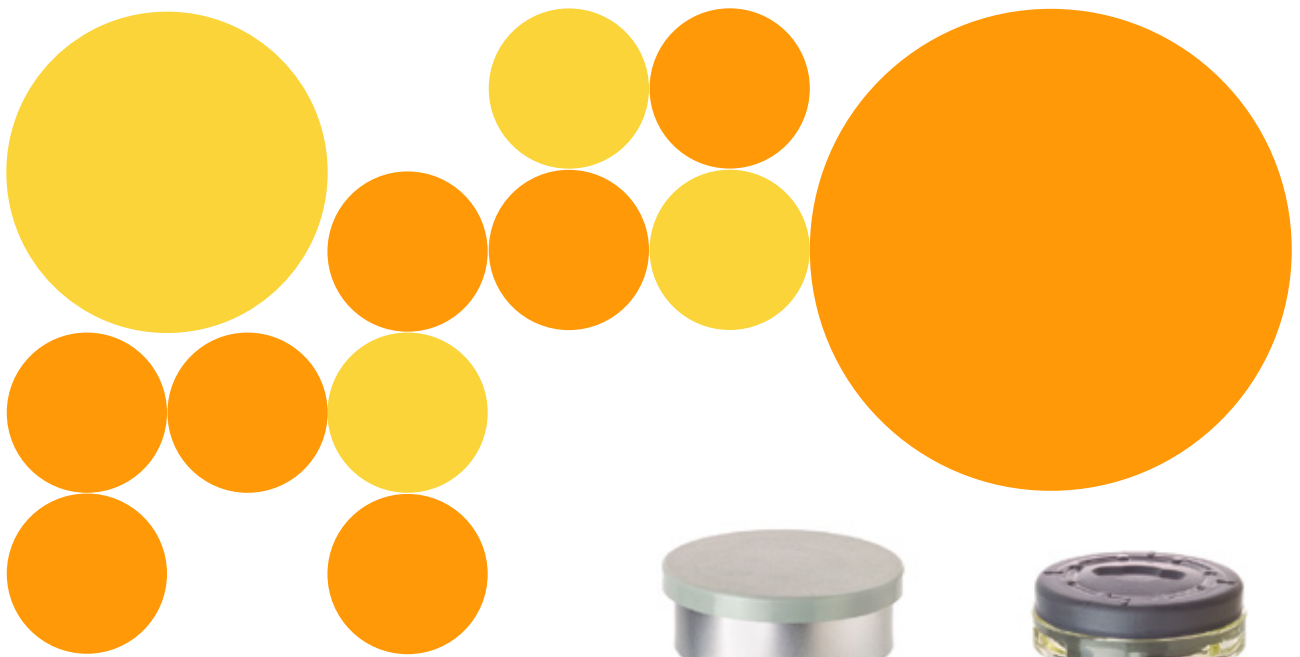


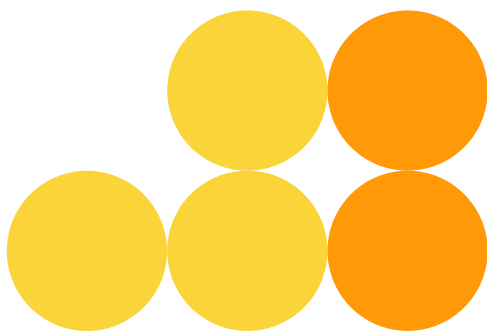
# The human plasma supplement for cell culture

**BioSupplies**  
**Biopharma**  
Cell Culture



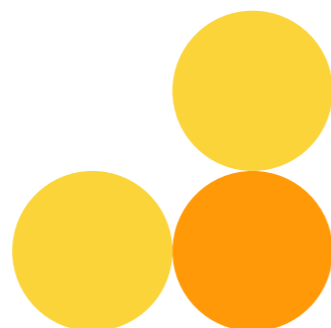
## PLASTEM®

GRIFOLS EXPERTISE  
IN HUMAN PLASMA  
AT YOUR SERVICE



**GRIFOLS**

**PLASTEM® is a pharmaceutical grade product of human origin that overcomes the limitations of many cell culture supplements including fetal bovine serum (FBS)<sup>1</sup>.**



**CONSISTENCY**

PLASTEM® has no batch-to-batch variation. Manufactured from plasma pools containing more than 1000 donations.

**QUALITY**

Grifols Quality System, EMA and FDA license for production and commercialization of plasma derivatives.

- GMP production.
- Quality and safety of a human plasma-derived medicine applied to PLASTEM®.
- Grifols' plasma derivatives are used in more than 90 countries.

**PERFORMANCE**

PLASTEM® is derived from human plasma which can be used for cell culture supplementation and supports the growth of several cell lines.

Cell lines grown with PLASTEM® include:

Human mesenchymal stem cells (hMSCs)<sup>2</sup>

Peripheral blood mononuclear cells (PBMCs)

Induced pluripotent stem cells (iPSCs)

Bone marrow mononuclear cells (BM-MNCs)

Primary cell cultures

African green monkey kidney (Vero)

Human fetal lung (MRC-5)

BALB/c mouse myeloma (P3X63Ag8.653)

Chinese hamster ovary (CHO) cells

T Cells

**SAFETY**

- Plasma is collected from healthy donors in US-based FDA-licensed plasma centers and European based plasma centers.
- Manufactured using the same safety standards as plasma-derived IV therapeutic products, e.g. Albumin and Immunoglobulins.
- Specific production steps with viral inactivation capacity.
- Gamma irradiation treatment.



1. EMA. 13 May 2013. Guideline on the use of bovine serum in the manufacture of human biological medicinal products. EMA/CHMP/BWP/457920/2012 rev 1. Committee for Medicinal Products for Human Use. European Medicines Agency.  
 2. Diez J.M., Bauman E., Gajardo R., et al., Culture of human mesenchymal stem cells using a candidate pharmaceutical grade xeno-free cell culture supplement derived from industrial human plasma pools. Stem Cell Res Ther, 2015;6(1): 28.



**PLASTEM® is an additive for the culture of different cell lines obtained from human plasma following a fractionation process based on the Cohn method.**

**CHARACTERISTICS**

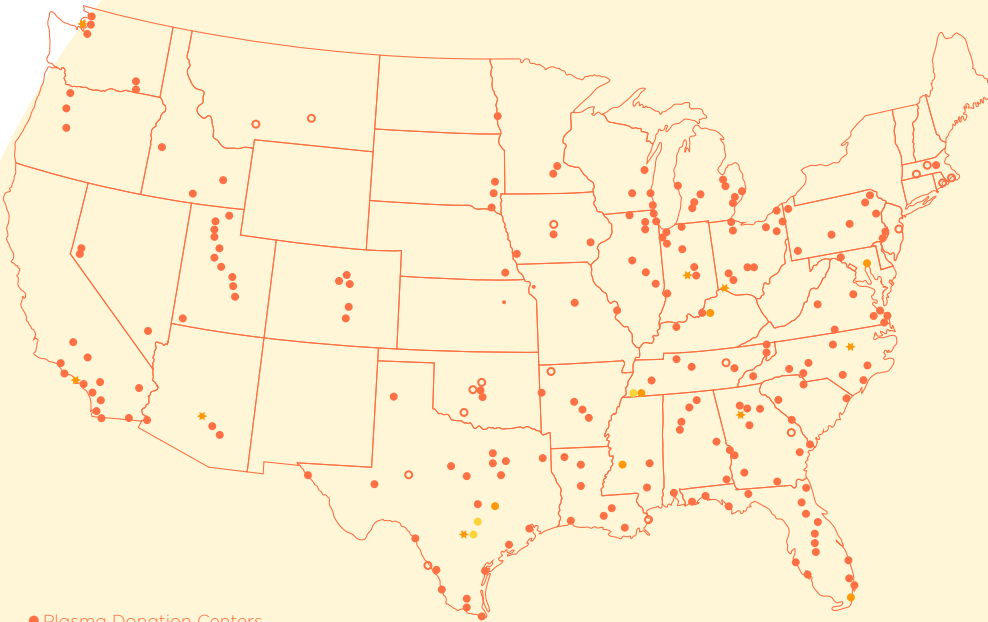
- Composition per vial: 1.5 g of human plasma proteins, mostly albumin
- Pharmaceutical grade
- No batch-to-batch variation since it is manufactured from plasma pools containing thousands of donations
- Easy to handle: Lyophilized product for reconstitution in cell culture media or water
- Shelf life of three years when stored within 2-30 °C

**APPLICATIONS**

- Suitable for cell culture media supplementation
- Cell culture research
  - Stem cell research
  - Cell therapy
  - Production of therapeutic monoclonal antibodies (mAbs)
  - Advanced therapy medicinal products (ATMPs)

## Grifols has a network of more than 300 US-based plasma donation centers.

Plastem is manufactured using the same quality standards as plasma-derived therapies.



- Plasma Donation Centers
- Plasma Testing Laboratories
- Whole Blood Donation Centers
- ★ The Grifols Academy of Plasmapheresis
- Plasma Centers coming soon

Around 13 million donations per year are made at Grifols Plasma Donor Centers across the US.

5 testing laboratories: 3 in the US (Austin, San Marcos and Memphis) and 2 in the EU (Spain and Germany). With the capacity to perform more than 120 million analyses per annum.

As part of our commitment to continuous learning and innovation **Grifols Academy of Plasmapheresis** offers education in the field of plasma science to all employees.

### STATE-OF-THE-ART FACILITIES AND RELIABLE SUPPLY

Grifols has the capacity to fractionate more than 17 million liters of plasma per year.

Our manufacturing plants are located in:



Barcelona, Spain



Clayton, US.



Los Angeles, US.



Dublin, Ireland.