

# The human plasma supplement for cell culture

**BioSupplies**

Biological material solutions

**Proteins**

PLASTEM



## PLASTEM®

GRIFOLS EXPERTISE  
IN HUMAN PLASMA  
AT YOUR SERVICE

**GRIFOLS**

The product presented here is not for therapeutic use

# PLASTEM® is a GMP 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.

## 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

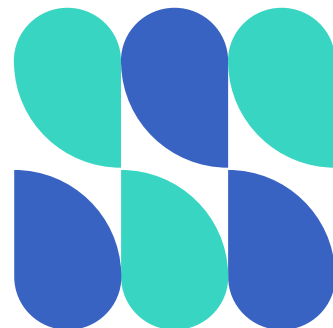
## QUALITY

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.

## 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

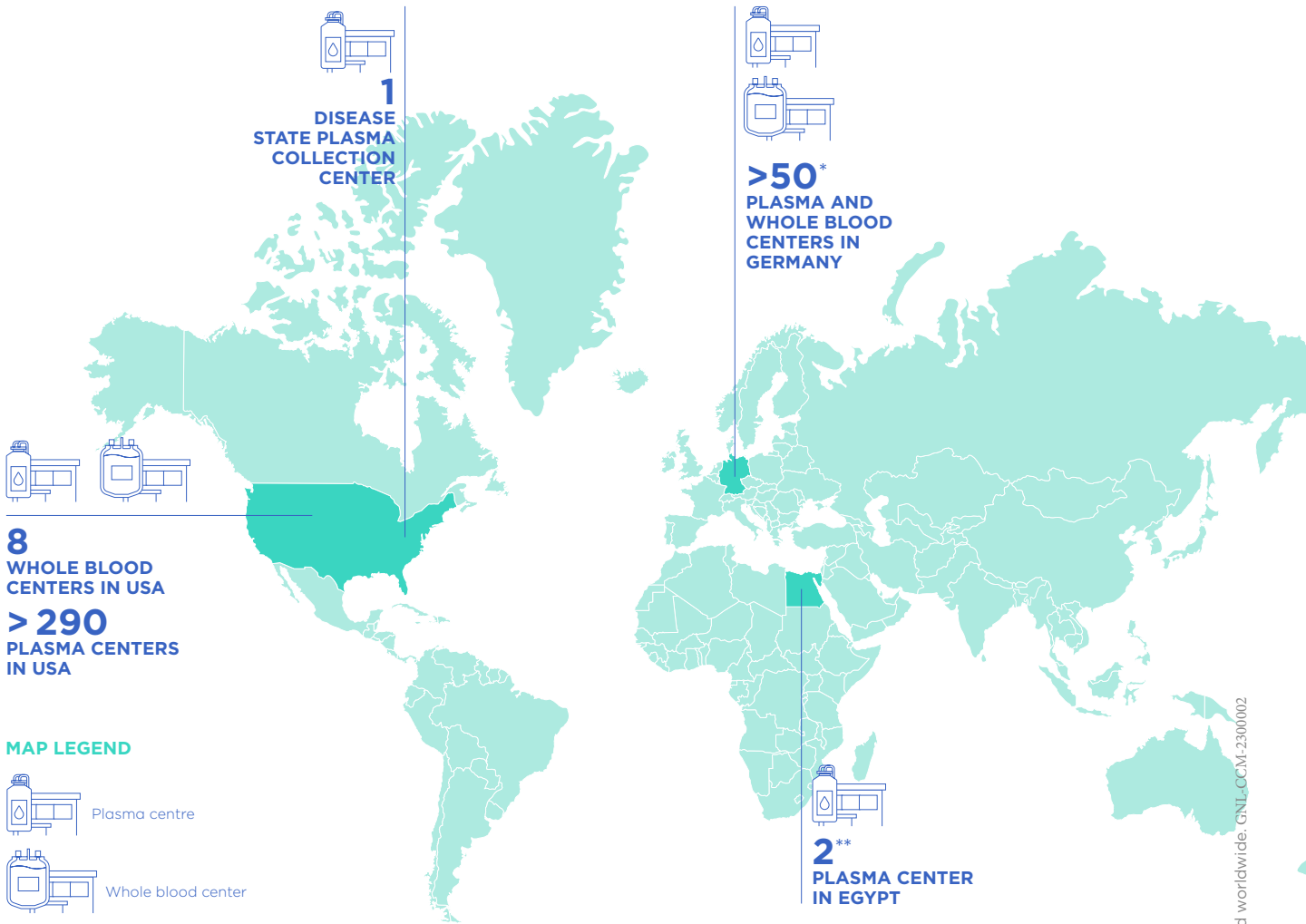
#### **APPLICATIONS**

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.**



Our manufacturing plants are located in:



Parets del Vallès (Barcelona), Spain



Clayton (NC), U.S.



Los Angeles (CA), U.S.



Grange Castle (Dublin), Ireland

\*Including Biotest

\*\*Grifols Egypt for Plasma Derivatives Joint Venture

For ordering information contact us here:

