



Human Serum and Blood Products

Biological Industries' Pre-Screened and Pre-tested human serum and blood products undergo the most stringent and rigorous Quality Control/Assurance Standards and Protocols testing all raw materials and finished products in order to meet the demands of international markets and ensure high quality and consistency.

All our human serum and blood products meet approved compliance validation and specifications prior to use and/or release of the final product to the end-user.

All our human serum and blood products undergo a methodical and comprehensive battery of physico-chemical, microbiological and biological performance testing procedures. Each batch is traceable, well-documented from source of origin through the thorough and systematic Quality Control process. All documentation and certification are available upon request.

Selecting the appropriate Human Serum Proteins depends upon at least four key factors:

- The cell line.
- The type of culture system.
- The chemical composition of the basal medium.
- The experience of the researcher.

Human Serum Albumin (HSA)

Product Name	Catalogue	Unit	Storage
	No.	Size	Temp.
Bio-Pure Human Serum Albumin (HSA Solution, 10%), Optimized for Human Embryonic, Stem Cells (hESC)	05-720-1B 05-720-1E		-20°C -20°C

HSA is a medium supplement that is a highly soluble osmolytic protein with a high molecular weight. It was specifically developed to support and maintain cell development, growth, health and productivity in most cell culture media, and especially cell membrane stability. The primary function of HSA is not only its unique demonstrative capability of binding anionic, cationic and neutral molecules, but it also has the proclivity of sequestering and stabilizing a wide array of ions and other small molecules.

HSA complies with the specifications of the manufacturer and the requirements stipulated by FDA approved tests.

All individual donations of the plasma and the corresponding plasma pool, has been tested for Hepatitis B Surface Antigen (HBsAg), Anti (Human Immunodeficiency Virus) HIV-I and II and anti-HCV and found to be negative.

Transferrin, Human, Substantially Iron-Free (APO) & Transferrin, Human, Iron-Saturated (HOLO)

Product Name	Catalogue No.	Unit Size	Storage Temp.
Transferrin, Human, Substantially Iron-Free (APO)	41-951-100 41-951-500	5	
Transferrin, Human, Iron-Saturated (HOLO)	41-952-100 41-952-500	5	

Transferrin is an important constituent in growth medium. It is a glycoprotein, but also known more specifically, as an iron-storage protein, found in mammalian serum (i.e. a blood plasma protein). Transferrin receptors, on the cell surface of actively growing cells, bind transferrin for iron transport to and from cells. In humans, it is still the most dynamically important iron pool relative to the total iron throughout the body. Nevertheless, research has shown that the majority of circulating iron-bound transferrin is transported to the bone marrow and incorporated into newly formed red blood cells or erythrocytes. The other primary storage depots for stored iron are the liver and spleen. The sum of all iron-binding sites on transferrin constitutes the total iron-binding capacity or TIBC of plasma. When iron-free, transferrin is known as apo-Transferrin and when iron saturated it is called holo-Transferrin. Traditionally, transferrin has entered the cell culture domain as a component of serum and is not a routine component of most commercially produced basal media. However, it has gained popularity and it is often added to classical basal media for the delivery of iron especially in a serum-free milieu. As a plasma-derived product, it is available for cell culture and diagnostic assays but not for therapeutic use.

Each unit of Biological Industries' transferrin is pasteurized and heated for 10 Hours $@60^{\circ}C$. It is manufactured under GMP conditions from Human Blood Plasma sub Fraction IV-1. It is important to emphasize that it is for research, laboratory or further manufacturing purposes only. It is not intended for human use. It is a USA-sourced and approved product and plasma donors undergo a rigorous selection process as per FDA requirements.

Each unit of plasma and each plasma pool has been tested to be non-reactive for Hepatitis B Surface Antigen (HBsAg), Antibody to (Human Immunodeficiency Virus) HIV-I and II, anti-HCV and Syphilis.

EZ Lympho-Sep™-Lymphocyte Separation Tubes

Ready-to-use

Alternative to the "home made" blood separation tube

Density gradient centrifugation of whole blood on a polysucrose sodium metrizoate medium is the method of choice for isolation of lymphocytes. The success of the procedure, i.e. the recovery of viable lymphocytes with the lowest proportion of contaminating granulocytes and erythrocytes, depends to a large extent on the careful layering of the blood sample onto the separation medium and the maintenance of a sharp interface between the two solutions prior to centrifugation. The EZ Lympho-SepTM system allows the blood sample to be poured directly into the centrifuge tube with no special precautions required to prevent disruption of the polysucrose - sodium metrizoate layer. Thus, a large number of samples may be handled at the same time. The mechanism also reduces the length of centrifugation time required for separation of the lymphocytes.

The heart of the EZ Lympho-Sep™ is a plastic insert that allows the blood sample to be poured directly into the tube alleviating the need for slow and careful addition of the blood. Secondly, a one-way feature of the insert allows passage of materials during the centrifugation step but prevents the flow of the separation medium during shipping. After centrifugation, the upper lymphocyte-containing fraction may be poured off without risk of contamination from the erythrocytes, which are trapped under the insert.

EZ Lympho-Sep™ are ready-to-use sterile tubes with the separation medium already in place, and the one-way valve opening during centrifugation.

We offer four different sizes:

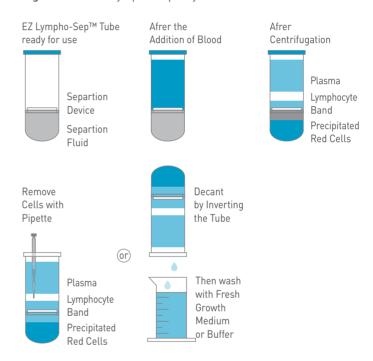
Catalogue No.	Separation Medium	Centrifuge Tube	Packaging
01-899-U02	2ml	15ml	30 Tubes/Box
01-899-U04	3ml	15ml	30 Tubes/Box
01-899-U10	10ml	50ml	18 Tubes/Box
01-899-U16	15ml	50ml	18 Tubes/Box

We can also supply empty tubes for customers who have their own media.

Features

- Ready-to-use, sterile.
- Safe method, minimum contact with biological fluids.
- Time saver, quick and easy sample filling.
- Maximum yield of viable mononuclear cells.
- A large number of samples may be handled at the same time.

Figure 1: The EZ Lympho-Sep™ system



Human Blood Products

- Tested negative or non reactive by FDA licensed tests for infectious disease markers: anti-HIV 1 & 2, HBsAG, anti-HCV, and other selected markers.
- Each product is traceable back to the donor, and additional information such as age, gender and geographic information is available upon request. (fresh units available for overnight shipments).
- Each donor is verbally and physically screened to comply with the most stringent FDA regulations. Products are obtained from volunteer and paid donors throughout the US.
- Pricing is based upon quantity ordered and information requested.
- Supply agreements and long-term contracts are available.

Human plasma

- EDTA Plasma
- Heparinized Plasma
- Fresh Frozen Plasma

Human whole Blood Products

- Off the clot
- Off the clot Male
- Off the clot Female

Processed Serum Production

The facility is solely for human production and does not process or package any animal products.

All human products are manufactured in a GMP facility FDA Regulation # 307234900.

Some of the processing capabilities include, but are not limited to:

- Defibrination
- Lipid stripping (several methods available)
- Charcoal stripping
- Diafiltration
- Large scale filtration
- Heat inactivation

Every stage of production, from receipt of raw material to the final QA review of finished product are carried out by highly trained staff according to established procedures.

Each type of plasma (or natural clot serum) used in the production of serum has its own Raw Material Specification (RMS) document on file to ensure that only the highest quality plasma is used in production. In addition to the initial inspection upon receiving, all shipments of plasma receive a 100% inspection for visual clarity and color against controlled standards. This attention to detail at the raw material stage and with control of our collections ensures lot-to-lot consistency for production of the highest quality finished product available.

For custom manufacturing contact us with your specifications or acceptance criteria for pricing and production lead time.

- Pooled Human Plasma.
- Human Serum Defibrinated Plasma.
- Delipidized Human Serum.
- Defibrinated / Delipidized Serum.
- Defibrinated / Delipidized / Charcoal Stripped.
- Charcoal Stripped Human Serum.
- Serology Negative Serum.
- Defibrinated Plasma Hepatitis Negative.
- Individual Human Serum from whole blood.
- Pooled Human Serum.

Serum Definitions

Defibrinated Serum: Serum derived from plasma by processing with chemicals.

Defibrinated, Delipidized Serum: Serum derived from plasma, processed to remove lipids. Optically clear.

Defibrinated, Delipidized, Charcoal Stripped Serum: Serum derived from plasma, processed to remove lipids and hormone proteins.

Defibrinated, Charcoal Stripped Serum: Serum derived from plasma, processed to remove hormone proteins but leaving lipids present.

Serology Negative Serum: Serum screened and found negative for serology disease state markers, screened and found negative for serology disease state markers.

Hepatitis Negative Serum: Serum derived from plasma where it is necessary for the bulk pool to be negative (non-reactive) for numerous viral markers by Elisa and PCR methodology. Suitable for negative control matrices.

Human Serum (OTC): Whole blood is collected from pre qualified human donors. Red cells are seperated by centrifuge and serum is naturally clotted. Serum is stored in plastic bottles at <=-20c

Related products

Product Name	Catalogue No.	Unit Size	Storage Temp.
EZ-DNA Genomic DNA Isolation Kit	20-600-50	50ml	AMB
EZ Blood	01-894-1B	100 ml	2-8°C
RBC Lysis Solution	01-888-1B	100ml	2-8°C
Phytohemagglutinin-M (PHA-M), Liquid	12-009-1H	5ml	-20°C
Human Fibronectin Solution, 1mg/ml	05-750-1H 05-750-1F	1ml 5ml	2-8°C 2-8°C