Serum & Plasma

Human Blood Products for Diagnostic Applications

serion\immunologics

Your Partner in Raw Material Sourcing

Institut Virion\Serion GmbH

Institut Virion\Serion GmbH is one of the leading manufacturers of infection serology ELISA diagnostics and has developed more than 120 highly specific and sensitive test systems for serological detection of infectious diseases. With a joint venture organization in China and a global network of distributors the company is selling their products consistently and successfully in more than 100 countries worldwide.

With Virion's business unit SERION Immunologics the company also offers different raw materials such as highly purified antigens, antibody positive sera, monoclonal antibodies or magnetic beads for manufacturing of diagnostics.

Besides high quality bulk antigens, also human serum and further blood products are required by the diagnostic industry. To source human serum or plasma of highest quality and safety standards, SERION Immunologics is cooperating with reliable partners in the U.S. and Europe.

Benefit from our extensive in-house screening program for a large number of different disease state parameter. These are tested with Virion' s highly specific and sensitive ELISA assays to be used as reference standards in diagnostic applications.

Human Blood Products

Blood, often described as liquid tissue, is essential for almost all functions of the human body. Five [5] to six [6] liters blood of an adult supply all organs with oxygen and enable transportation of nutrients, removal of metabolic waste.

Another essential function is the defense against pathogens, adjustment of temperature and control of the fluid level. Some of these important tasks are carried out by blood cells, namely oxygen carrying erythrocytes, leukocytes which belong to the immune system and thrombocytes playing a key role in blood clotting.

Since blood plays such a vital role, the loss of already one liter can be life-threatening. Therefore, several million liters of blood are donated worldwide to save the lives of a multitude of patients. Not only blood loss can be treated with the help of these donations, also products to medicate severe diseases like hemophilia are based on donated blood. All in all, the usage of blood and blood products can be divided into three categories described in the following.

Research

Human serum, plasma or albumin is widely used in different fields of research. For the cultivation of human cells, human serum serves as a growth supplement to work within a homologous human system. In addition to cell expansion, blood cells are also used as a test system for the development and optimization in advanced therapies. Furthermore, human blood products are also used as blocking reagent, control or as a calibration standard.

Diagnostics

Blood products are not only used for the direct treatment of diseases or injuries. Human plasma, serum and albumin are also key products for the diagnostic industry. They are an integral part of most diagnostic test kits, used as negative or positive controls, calibration standards, blocking reagents or diluents.
SERION Immunologics offers a wide range of infectious disease state products, based on human plasma or serum, exclusively intended for diagnostic use only.

Therapeutics

The partition of blood into plasma or single cell types enables the optimum usage of every blood donation. Patients lacking thrombocytes can be for example treated with a concentrate consisting of these cells. On the other hand an erythrocyte concentrate gained from the same blood donation, may be given to patients suffering from great blood loss. Finally, the residual plasma can be used to fractionate proteins, e.g. coagulation factors which are essential for the treatment of bleeding disorders.

Plasma & Serum

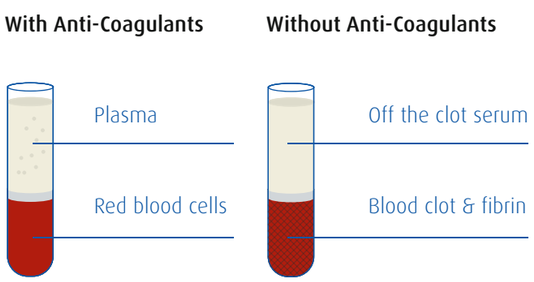
Blood Clotting

To prevent blood loss after injuries, the coagulation cascade is activated by wounds or through contact to foreign surfaces. At the end of a complex series of reactions, the activation of thrombin results in the cleavage of fibrinogen to fibrin. Fibrin forms fibers and together with attracted thrombocytes they clot to close the wound.

Human Plasma

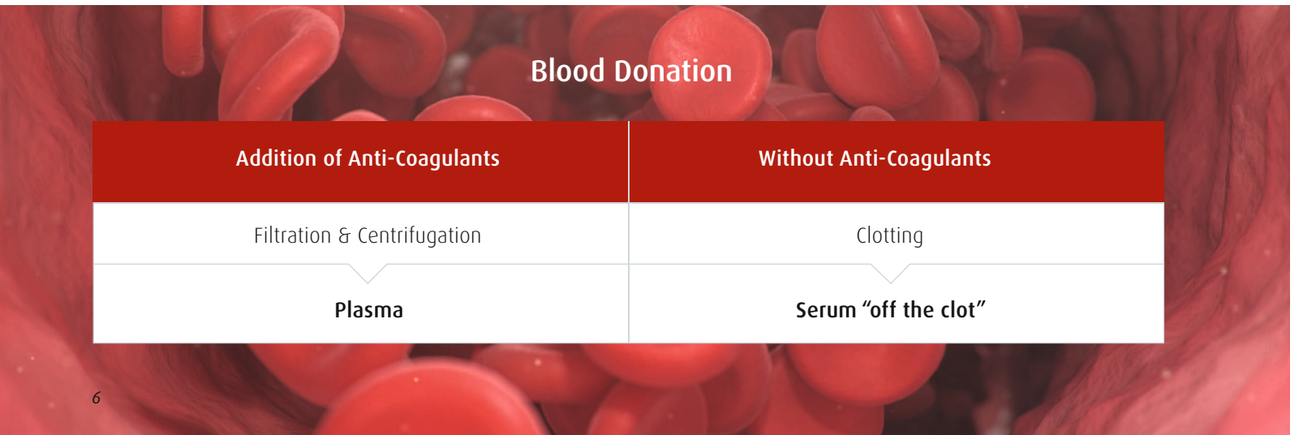
The surface of a collecting tube or bag would start the clotting cascade. Therefore, anticoagulants are usually added to prevent the formation of a clot during blood donation. These anti-coagulants are mostly based on citrate binding the calcium ions which are essential for most reactions in the clotting cascade. After separation of blood cells the remaining soluble part is called plasma.

Figure 1:
Difference of serum and plasma



Human Serum

If anti-coagulants are not added the clotting cascade will be activated and a blood clot forms shortly after donation. The clot consists of cells, fibrin and sediments at the bottom. Due to the fact that the soluble fraction of this material is then taken off the clot, the resulting product is named as „off the clot" serum.
In summary, the main difference between plasma and serum is the presence of coagulation factors and anticoagulants in plasma (see figure 1).



Blood Donation

Blood Products Demand

Due to the growing world population and the improved health care situation in many countries the consequence is a constantly increasing demand for blood products. About 60 million liters blood or plasma are being donated per year. Unfortunately, donations capacity can often not keep up with the rapid development which then quickly leads to a situation of shortage.

Donor Selection

To ensure maximum safety for a patient, the selection of single donors underlies strict regulations. Therefore the donor's age, minimum weight and health status are monitored. Reasons for exclusion can be factors such as a pregnancy, recent residence in certain countries or the intake of drugs. Some of these reasons lead to a permanent, others only to a temporary rejection.

Donation Centers

Not only the selection of donors but also the reliability of the donation centers has great influence on the quality and safety aspects of a final product. Blood donation regulations are analogous in the United States and Europe.

- **Traceability**
  Donation centers must keep records over all donations for at least 30 years.

- **Look back system**
  An unfailing system need to be established to track down the donor for any blood donation in the shortest time.

- **Quality assurance (QA)**
  All plasma material is collected from qualified and registered donors by FDA approved blood centers in the USA or European blood centers following the EU directive 2002/98/EC. All material is tested and certified to comply with ethical and regulatory requirements.

- **Qualified personal**
  The leading physician of a donation center has to be a specialist for transfusion medicine. It is absolutely mandatory that a physician is present when the donation takes place.

Blood Donation & Testing

Blood Donation vs. Plasmapheresis

There are different possibilities to donate blood or blood fractions. On the one hand there is the classical whole blood donation in which up to 500 mL are given. Usually it takes several weeks for the body to replace the blood cells. Thus a minimum of 8 weeks must lie between two donations. In contrast to that it is possible to leave the blood cells with the donor and only take the soluble part, the plasma. During this so-called plasmapheresis, the cellular components are separated from the liquid part outside the body. The cells are then transfused back to the donor. The advantage of this process is that a donation can be done every two days with up to 880 ml at a time. Especially the pharmaceutical industry greatly depends on plasma donated this way.

Restrictive Testing

Part of the strict controls, which every accredited donation center performs, is a thorough testing of every donation. Besides basic blood values, to detect a potential disease and determination of the blood group, extensive viral tests are carried out. With these tests a past or present infection with HIV 1 or 2, Hepatitis B or C and Syphilis can be detected (see Viral testing). Additional measures such as the follow-up of the donor make sure that no blood products with latent infections below the detection limit are released.

Viral Testing

- ✓ Detection of Ab's against HIV 1 or 2
- ✓ Detection of Ab' s against Hepatitis C
- ✓ Detection of Ab' s against Syphilis
- ✓ Detection of Hepatitis B antigens
- ✓ Nucleic acid test for Hepatitis C
- ✓ Nucleic acid test for HIV 1 genome

SERION Immunologics only sources raw material, which is found to be negative for all mandatory virus and bacteria tests, carried out with validated test kits.

All test kits must be accredited and released by the respective national agencies (FDA approval or CE marked test systems). SERION Immunologics only works together with fully accredited blood donation centers.

Recovered vs. Source Plasma

If plasma is taken from whole blood donations it is called recovered plasma. Whereas plasma donated separately, using plasmapheresis is called source plasma.

Please note: Because no test method can guarantee the 100% complete absence of infective agents these products should therefore always handled with appropriate precautions!

Disease State Diagnostics
We Take Care Of Your Health

Disease State Serum & Plasma

Infectious disease state plasma and sera are used as reference standards or as positive and negative controls in diagnostic test systems. Plasma is collected from single donors within a wide collection network. In order to assure product stability and performance human plasma is converted into defibrinated plasma (serum) by a well-established re-calcification procedure.

Continuous in-house screening of always new donor samples ensures consistent serum and plasma availability and access even to rare pathogens.

Quality

All plasma material is obtained from qualified and registered donors by approved blood centers in the U.S. and in Europe. All material is tested and certified in compliance with regulatory requirements (e.g. donor traceability through the blood bank, virus testing, etc.).

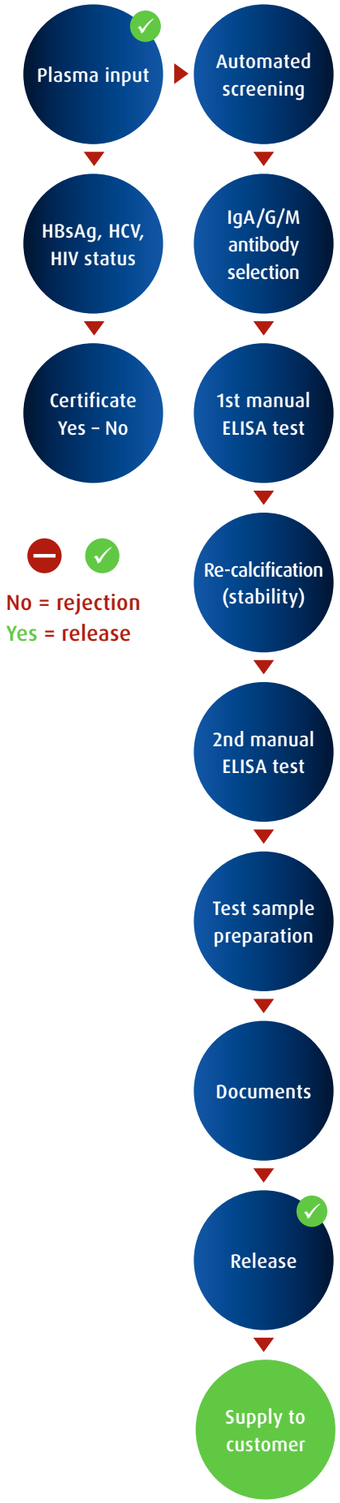
Packaging & Test Samples

Standard volumes are available in 10 mL, 50 mL and bulk volumes larger than 100 mL. Test samples are available in 1 mL sizes.

Negative Controls

Selected IgG negative sera are available for e.g. EBV, H. pylori, Measles, Mumps & VZV. We offer even multiple IgG negative sera, e.g. negative for all four ToRCH parameters.

Screening Flow Chart



Plasma Screening

Automated Screening

To guarantee customers consistent plasma & serum availability we perform a screening for high titer antibody positive plasma in-house. The screening program starts with a fast automated pre-screening. In this screening, all plasma samples tested automatically for possible IgG, IgM or IgA reactive antibodies.

Manual ELISA Testing

Plasmas, that show positive results, are selected in a second step for a manual re-testing with Virion\Serion's corresponding highly specific and sensitive ELISA kits.

Re-calcification

To guarantee best product stability, plasma is converted into defibrinated plasma through an established re-calcification procedure.

2nd Manual ELISA Control

To ensure that there is no impairment of the final product, all re-calcified plasmas are subjected to a second manual ELISA test.

Product Release

After preparation of test samples and finalization of all documents, the finished products are released for sampling and for sale to our customers.

Practical Tips

General Information

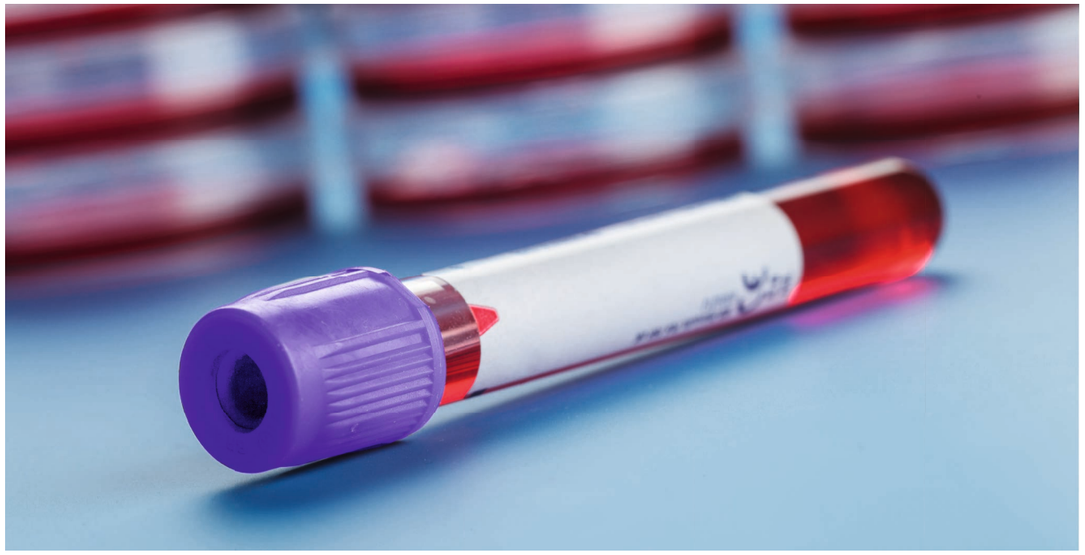
Human serum and plasma are highly complex biological materials. Their biological activity depends on many factors, which include correct handling during storage, freezing and thawing. To minimize damage of critical serum or plasma components, all sera are frozen rapidly after production.

Delivery & Storage

Serum and plasma is supplied to our customers deep frozen in HDPE bottles on dry ice. Any serum which you do not use straight away should be stored protected from light at -18 °C or below. Repeated freeze-thaw cycles should generally be avoided. Thawed products can be stored at 2-8 °C up to one week. If only small quantities of serum are required at a time, we would recommend freezing small aliquots which can be thawn and used as required.

Thawing

Thawing of the products should proceed as quickly as possible, in order to minimize the time of exposition in elevated salt concentrations in the thawed liquid. The serum must not be exposed to higher temperatures during thawing as sensitive molecules could be denatured. Bottles that are taken from a freezer should be allowed to acclimatize for approximately 10 minutes at room temperature, or as an alternative overnight in a refrigerator. The products can then be thawed in a water bath at 37 °C. We recommend frequent swirling of the bottles, in order to achieve a homogeneous distribution of proteins and salts in the liquid. At the same time this avoids that the product is exposed to elevated temperatures for a longer time.
To ensure homogeneity of its ingredients serum or plasma should also be shaken occasionally while working at room temperature.



Service

Our aim is not only to manufacture high quality products, but also to support our customers with advice and practical assistance in their daily scientific work. Should you need further information relating to serum, plasma or any other SERION Immunologics products, please give us a call or send us your request via email (immunologics@virion-serion.de).

Order Information

We routinely screen for the following parameters. Please contact us to check current availabilities.

Specific Antibody Positive

Pathogen Specificity	Order No. IgA	Order No. IgG	Order No. IgM
Adenovirus	PLS128A	PLS128G	PLS128M
Aspergillus fumigatus	PLS132A	PLS132G	PLS132M
Bordetella pertussis	PLS120A	PLS120G	PLS120M
Bordetella pertussis Toxin	PLS1201A	PLS1201G	
Borrelia burgdorferi		PLS121G	PLS121M
Brucella abortus	PLS116A	PLS116G	PLS116M
Campylobacter jejuni	PLS139A	PLS139G	PLS139M
Candida albicans	PLS117A	PLS117G	PLS117M
Chlamydia pneumoniae	PLS1371A	PLS1371G	PLS1371M
Chlamydia trachomatis	PLS1372A	PLS1372G	PLS1372M
Cytomegalovirus (CMV)		PLS109G	PLS109M
Dengue Virus		PLS114G	PLS114M
Echinococcus granulosus		PLS107G	
Enterovirus	PLS133A	PLS133G	PLS133M
Epstein-Barr Virus (EBV) VCA		PLS1361G	PLS1361M
Francisella tularensis		PLS142G	PLS142M
Hantavirus Puumala		PLS145G	PLS145M
Helicobacter pylori	PLS118A	PLS118G	PLS118M
Herpes Simplex Virus 1 (HSV-1)		PLS1051G	PLS1051M
Herpes Simplex Virus 1/2 (HSV-1/2)	PLS105A	PLS105G	PLS105M
Herpes Simplex Virus 2 (HSV-2)		PLS1052G	PLS1052M
Influenza A Virus		PLS1231G	PLS1231M
Influenza B Virus		PLS1232G	PLS1232M
Legionella pneumophila		PLS106G	PLS106M
Leishmania		PLS147G	
Leptospira biflexa		PLS125G	PLS125M
Measles Virus		PLS102G	PLS102M
Mumps Virus		PLS103G	PLS103M
Mycoplasma pneumoniae	PLS127A	PLS127G	PLS127M
Parainfluenza Virus 1/2/3		PLS126G	PLS126M
Parvovirus B19		PLS122G	PLS122M
Respiratory Syncytial Virus (RSV)	PLS113A	PLS113G	
Rheumatoid Factor (RF)			PLS000RF
Rubella Virus		PLS129G	PLS129M
SARS-CoV-2	PLS400A	PLS400G	PLS400M
Tick-borne encephalitis (TBE) Virus		PLS112G	PLS112M
Toxoplasma gondii	PLS110A	PLS110G	PLS110M
Varicella Zoster Virus (VZV)	PLS104A	PLS104G	PLS104M
West Nile Virus		PLS141G	PLS141M
Yersinia enterocolitica	PLS138A	PLS138G	PLS138M

Specific Antibody Negative

Pathogen Specificity	Order No. IgG
Borrelia burgdorferi IgG negative	PLS121GN
Cytomegalovirus (CMV) IgG negative	PLS109GN
Epstein-Barr Virus (EBV) VCA and EBNA1 IgG negative	PLS136GN
Herpes Simplex Virus 1/2 (HSV-1/2) IgG negative	PLS105GN
Measles Virus IgG negative	PLS102GN
Mumps Virus IgG negative	PLS103GN
Measles/ Mumps/ Rubella/ VZV IgG negative	PLS_MMRZ_GN
Measles/ Mumps/ VZV/ EBV IgG & IgM negative	PLS_MMZE_N
Respiratory Parameter IgA, IgG & IgM negative Adenovirus/ Chlamydia pneumoniae/ Mycoplasma pneumoniae/ Parainfluenza Virus 1/2/3/ Parvovirus B19/ Respiratory Syncytial Virus (RSV)	PLS_RESP_N
Rubella Virus IgG negative	PLS129GN
Toxoplasma gondii IgG negative	PLS110GN
Toxoplasma/ Rubella/ CMV/ HSV-1/2 IgG & IgM negative	PLS_ToRCH_N
Vaccine Parameter IgG negative Measles/ Mumps/ Rubella/ VZV/ Diphtheria/ Tetanus/ Tick-borne encephalitis (TBE)	PLS_VAC_GN
Varicella Zoster Virus (VZV) IgG negative	PLS104GN

Notice:
The sera listed are not clinical samples that can be offered with the corresponding clinical data (findings). All serums/plasmas offered by SERION Immunologics are usually single donor bulk samples which are used for the preparation of controls or calibrators. For further availabilities of human specimen samples, please also refer to Central BioHub (www.centralbiohub.com).

Contact

Stefan Papadileris
International Sales Manager

Phone: +49 931 30 45 561
Mobile: +49 172 67 05 053
Fax: +49 931 30 45 556
s.papadileris@virion-serion.de

Gledys Natacha Ortiz-Michel
Sales Administration and Order Management

Phone: +49 931 30 45 216
Fax: +49 931 3045 556
g.ortiz-michel@virion-serion.de

Dr. Claudia Dollack
Scientific Product Manager

Phone: +49 931 30 45 449
Mobile: +49 162 43 63 846
Fax: +49 931 30 45 556
c.dollack@virion-serion.de

Dr. Thomas Schumacher
CSO

Phone: +49 931 30 45 560
Mobile: +49 172 65 58 749
Fax: +49 931 30 45 556
t.schumacher@virion-serion.de

virion\serion

Institut Virion\Serion GmbH

Friedrich-Bergius-Ring 19
97076 Würzburg, Germany
Phone +49 931 30 45 0
Fax +49 931 30 45 100
info@virion-serion.de
www.virion-serion.de

2021|09