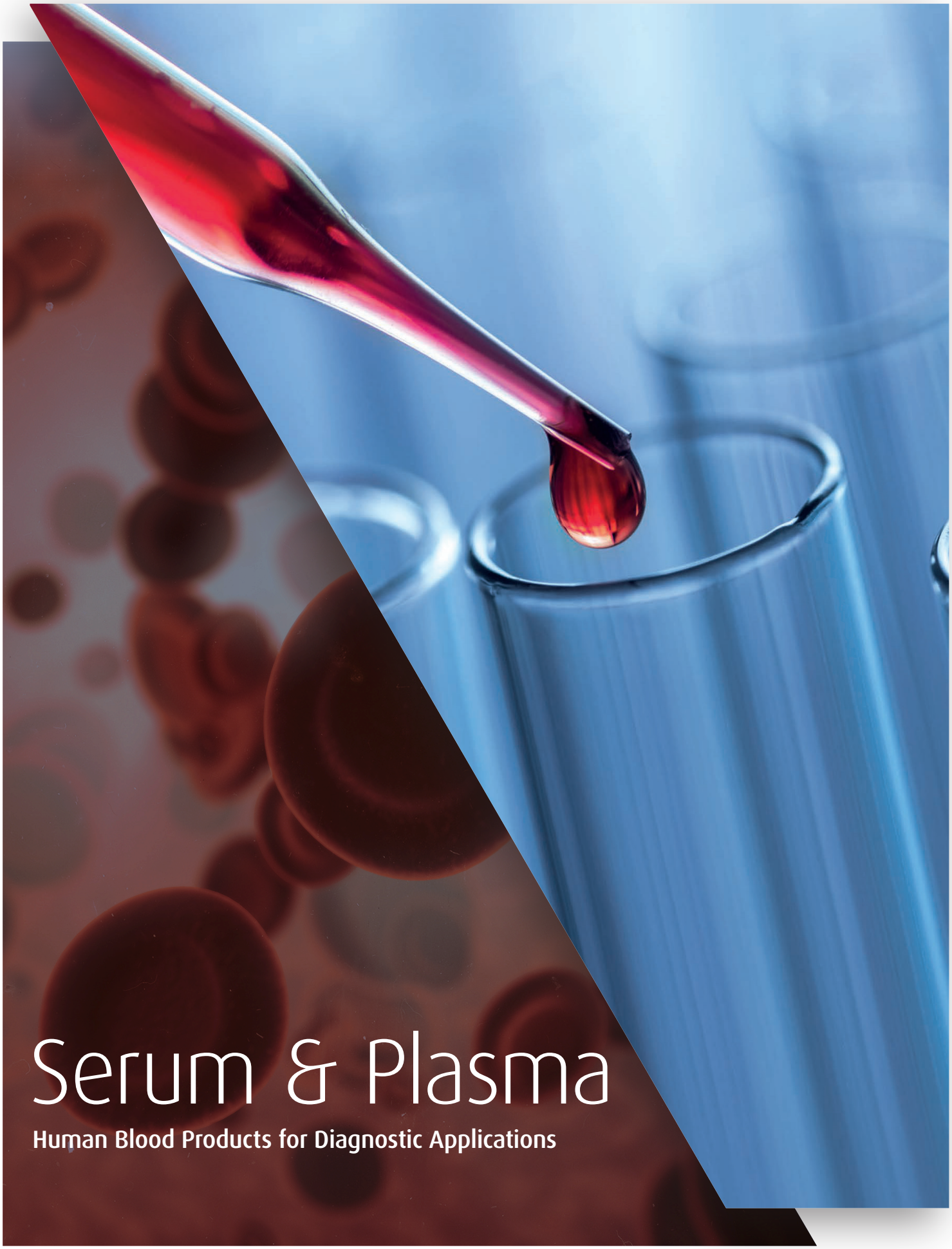


Serum & Plasma

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

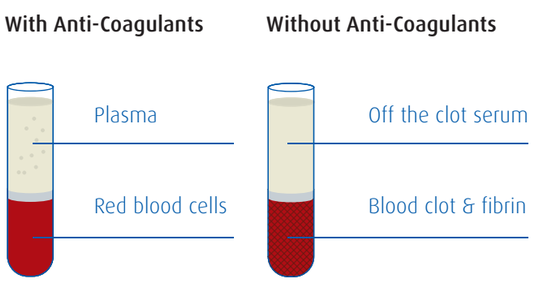
Blood Clotting

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

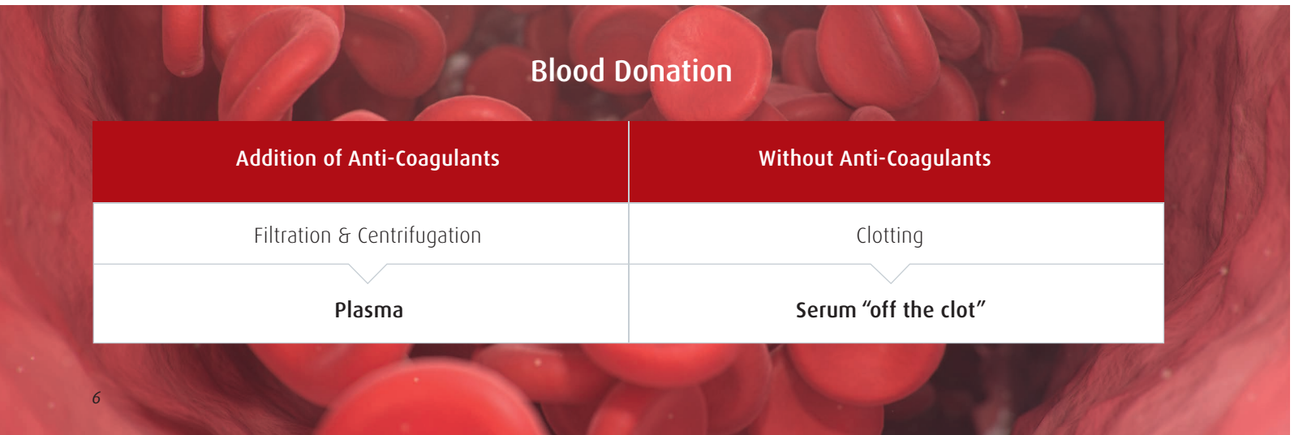
The surface of a collecting tube or bag would start the clotting cascade. Therefore, anticoagulants are usually added to prevent the formation of a clot during blood donation. These anti-coagulants are mostly based on citrate binding the calcium ions which are essential for most reactions in the clotting 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 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. All material is tested and certified in compliance with regulatory requirements (e.g. donor traceability through the blood bank, virus testing, etc.).

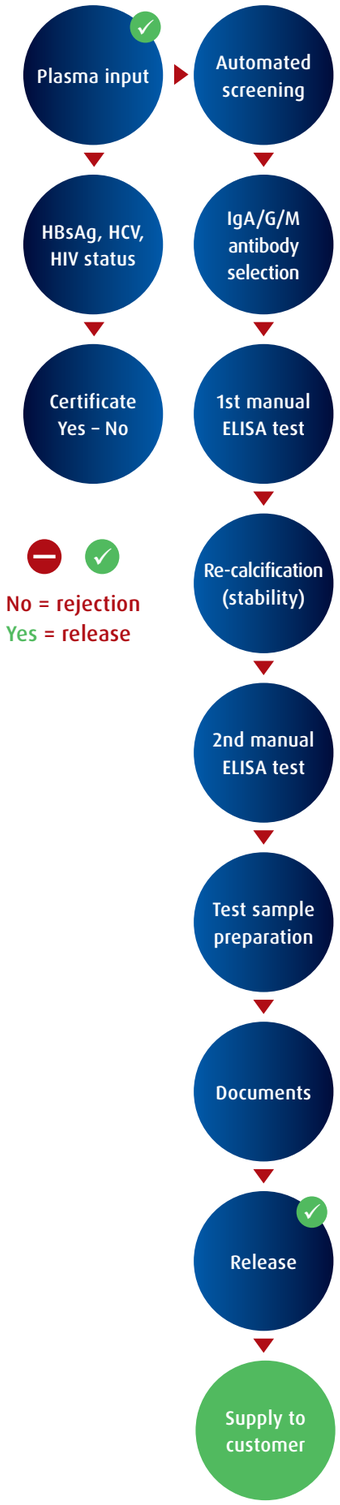
Packaging & Test Samples

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

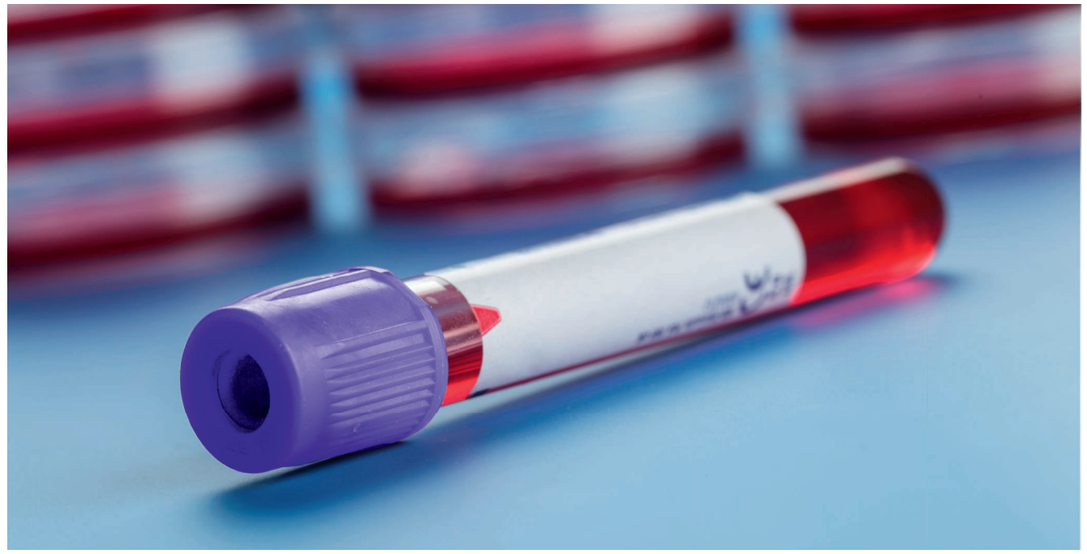
Human serum and plasma are highly complex biological materials. Their biological activity depends on many factors, which include correct handling during storage, freezing and thawing. To minimize damage of critical serum or plasma components, all sera are frozen rapidly after production.

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).

SERION immunologics
Product Overview

Explore Our Products
Scan to Download the Latest Product Overview (PDF)

VIEW PDF

SERION autoimmune

Recombinant Antigens	Order No.
b2GP1 (protein, expressed in insect cells. Molecular weight: 38 kDa)	BA505R01
GBM (protein, expressed in insect cells. Molecular weight: 32 kDa)	BA504R01
Jo-1 (protein, expressed in *E. coli*. Molecular weight: 59 kDa)	BA503R01
La/SSB (protein, expressed in *E. coli*. Molecular weight: 48 kDa)	BA501R01
PR3 (protein, expressed in insect cells. Molecular weight: 26 kDa)	BA502R01
tTG (protein, expressed in yeast. Molecular weight: 78 kDa)	BA506R01

SERION antigens

Native Antigens	Order No.
Adenovirus Type 2 Hexon	BA128VS
Aspergillus fumigatus	BA132F01
Bordetella pertussis Filamentous Hemagglutinin (FHA)	BA120VS3
Bordetella pertussis Toxin	BA120VS4
Bordetella pertussis whole-cell Antigen	BA120VS8
Borrelia afzelii	BA121VS
Borrelia garinii	BA121GVS
Brucella abortus	BA116VS
Campylobacter jejuni	BA139VS
Candida albicans	BA117VS
Chlamydia pneumoniae	BA1371VSER
Chlamydia pneumoniae - Premium	BA1371VS
Chlamydia trachomatis	BA1372VSER
Cytomegalovirus (CMV)	BA109VS
Diphtheria Toxoid	BA130VS
Echinococcus granulosus	BA107VS
Helicobacter pylori	BA118VS
Herpes Simplex Virus 1 (HSV-1)	BA1051VS
Herpes Simplex Virus 2 (HSV-2)	BA1052VS
Legionella pneumophila	BA106VS
Leptospira biflexa	BA125VS
Measles Virus - Premium	BA102VS-S
Mumps Virus	BA103VS
Mycoplasma pneumoniae	BA127VS
Parainfluenza Virus Type 1	BA1261VS
Parainfluenza Virus Type 2	BA1262VS
Parainfluenza Virus Type 3	BA1263VS
Respiratory Syncytial Virus (RSV)	BA113VS
Tetanus Toxoid	BA108VS
Tick-borne encephalitis (TBE) Virus - Premium	BA112VS
Toxoplasma gondii	BA110VS
Varicella Zoster Virus (VZV)	BA104VS
Varicella Zoster Virus (VZV) Glycoprotein	BA104VSG
Yersinia enterocolitica O:3 YOP	BA138VS
Yersinia enterocolitica O:8 YOP	BA13808VS
Yersinia enterocolitica O:9 YOP	BA13809VS

Recombinant Antigens	Order No.
Borrelia afzelii Pko DbpA	BA121R01
Borrelia afzelii Pko OspC	BA121R02
Chlamydia trachomatis MOMP	BA1372VSR2
Chlamydia trachomatis MOMP Fragment	BA1372VSR1
Coxsackievirus	BA134VS01
Cytomegalovirus (CMV) pp52 (UL44)	BA109R01
Cytomegalovirus (CMV) gB (UL55)	BA109R02
Cytomegalovirus (CMV) pp150 (UL32)	BA109R03
Cytomegalovirus (CMV) pp130 (UL57)	BA109R04
Cytomegalovirus (CMV) pp28 (UL99)	BA109R05
Cytomegalovirus (CMV) pp65 (UL83)	BA109R06
Cytomegalovirus (CMV) IE1 (UL123)	BA109R07
Dengue Virus type 2 Envelope protein E	BA114R01
Echovirus	BA135VS01
Enterovirus	BA133VS01
Epstein-Barr Virus (EBV) Capsid Antigen P18	BA1361VSR22
Epstein-Barr Virus (EBV) Capsid Antigen P23	BA1361VSR21
Epstein-Barr Virus (EBV) Early Antigen P138	BA1363VSR6
Epstein-Barr Virus (EBV) Early Antigen P54	BA1363P54VS
Epstein-Barr Virus (EBV) Nuclear Antigen EBNA1, P72 (stabilized)	BA1362R01
Herpes Simplex Virus 1 (HSV-1) Glycoprotein G	BA1051RVS-G
Herpes Simplex Virus 2 (HSV-2) Glycoprotein G	BA1052RVS-G
Human Parvovirus B19, VP2 VLP	BA122R01
Measles Virus Nucleoprotein	BA102R01
Mumps Virus Nucleoprotein	BA103R01
Mycoplasma pneumoniae P1	BA127VSP1
Parvovirus VP1	BA122VSVP1
Rubella Spike Ectodomain (E1-E2)	BA129R01
Rubella VLP	BA129R02
TBEV Envelope protein E	BA112R01
TBEV Envelope Protein E (optimized)	BA112R02
Varizella Zoster Virus (VZV) Envelope Glycoprotein B	BA104R03
Varicella Zoster Virus (VZV) Envelope Glycoprotein E	BA104R02
West Nile 6His-4xED3	BA141VSR14
West Nile Virus Envelope protein E	BA141R01
Zika Virus NS1	BA149R01

All Antigens are routinely packaged in units of **1 mg. 5 mg and 10 mg** packaging sizes are also available. Upon request, bulk quantities can be filled individually.

All native antigens are verified to be pathogen inactivated and certified as non-infectious.

SERION beads

SERION beads	Functionalization	Size Range	Packaging	Order No.
MagSERION amine beads	Carboxy groups	2,8-3,2 µm	100 mg	031MP-C
MagSERION amine beads	Amine groups	2,8-3,2 µm	100 mg	031MPSS

SERION Rheumatoid Factor Absorbent

Product	Packaging	Order No.
SERION Rheumatoid Factor Absorbent	1000mL	RF00R

Bovine Serum Albumin

Bovine Serum Albumin	Packaging	Order No.
Standard Grade, U.S. origin	10 g	BSA-0010SG
Standard Grade, U.S. origin	100 g	BSA-0100SG
Standard Grade, U.S. origin	1000 g	BSA-1000SG
Protease Free, U.S. origin	10 g	BSA-0010PF
Protease Free, U.S. origin	100 g	BSA-0100PF
Protease Free, U.S. origin	1000 g	BSA-1000PF
Fatty Acid Free, U.S. origin	10 g	BSA-0010FF
Fatty Acid Free, U.S. origin	100 g	BSA-0100FF
Fatty Acid Free, U.S. origin	1000 g	BSA-1000FF
Sulfhydryl Blocked, U.S. origin	10 g	BSA-0010SH
Sulfhydryl Blocked, U.S. origin	100 g	BSA-0100SH
Sulfhydryl Blocked, U.S. origin	1000 g	BSA-1000SH

SERION plasma

Specific Antibody **Positive**	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
Diphteria	-	PLS130G	-
Echinococcus granulosus	-	PLS107G	-
Enterovirus	PLS133A	PLS133G	PLS133M
Epstein-Barr Virus (EBV) VCA	-	PLS1361G	PLS1361M
Francisella tularensis	-	PLS142G	PLS142M
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	PLS126A	PLS126G	-
Parvovirus B19	-	PLS122G	PLS122M
Respiratory Syncytial Virus (RSV)	PLS113A	PLS113G	-
Rubella Virus	-	PLS129G	PLS129M
Tetanus	-	PLS108G	-
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	Order No.
Borrelia burgdorferi IgG negative	PLS121GN
Candida albicans IgA/IgG/IgM negative	PLS117N
Candida albicans IgG negative	PLS117GN
Diphteria IgG negative	PLS130GN
Helicobacter pylori IgG negative	PLS118GN
Cytomegalovirus (CMV) IgG negative	PLS109GN
Epstein-Barr Virus (EBV) 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
Tetanus IgG negative	PLS108GN
Tick-borne encephalitis (TBE) Virus IgG negative	PLS112GN
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

SERION antibodies

SERION antibodies in cell culture supernatant	Clone	Order No.
Anti-Chlamydia pneumoniae IgM	G12B2	MAB1371.001
Anti-Cytomegalovirus (CMV) IgM	Z3A3B8	MAB109.002
Anti-Herpes Simplex Virus 1/2 (HSV-1/2) IgM	K11A12D11	MAB105.001
Anti-Measles Virus IgM	P5H6	MAB102.001
Anti-Mumps Virus IgM	F11E4A7	MAB103.001
Anti-Mycoplasma pneumoniae IgM	NA15F4A12	MAB127.001
Anti-Rubella Virus IgM	B16B11F8	MAB129.001
Anti-Toxoplasma gondii IgM	A13H1E4	MAB110.001
Anti-Varicella Zoster Virus (VZV) IgM	D30B3D1	MAB104.001

SERION antibodies in human matrix	Clone	Order No.
Anti-Chlamydia pneumoniae IgM	G12B2	MAB1371.001H
Anti-Cytomegalovirus (CMV) IgM	Z3A3B8	MAB109.002H
Anti-Herpes Simplex Virus 1/2 (HSV-1/2) IgM	K11A12D11	MAB105.001H
Anti-Measles Virus IgM	P5H6	MAB102.001H
Anti-Mumps Virus IgM	F11E4A7	MAB103.001H
Anti-Mycoplasma pneumoniae IgM	NA15F4A12	MAB127.001H
Anti-Rubella Virus IgM	B16B11F8	MAB129.001H
Anti-Toxoplasma gondii IgM	A13H1E4	MAB110.001H
Anti-Varicella Zoster Virus (VZV) IgM	D30B3D1	MAB104.001H

Contact

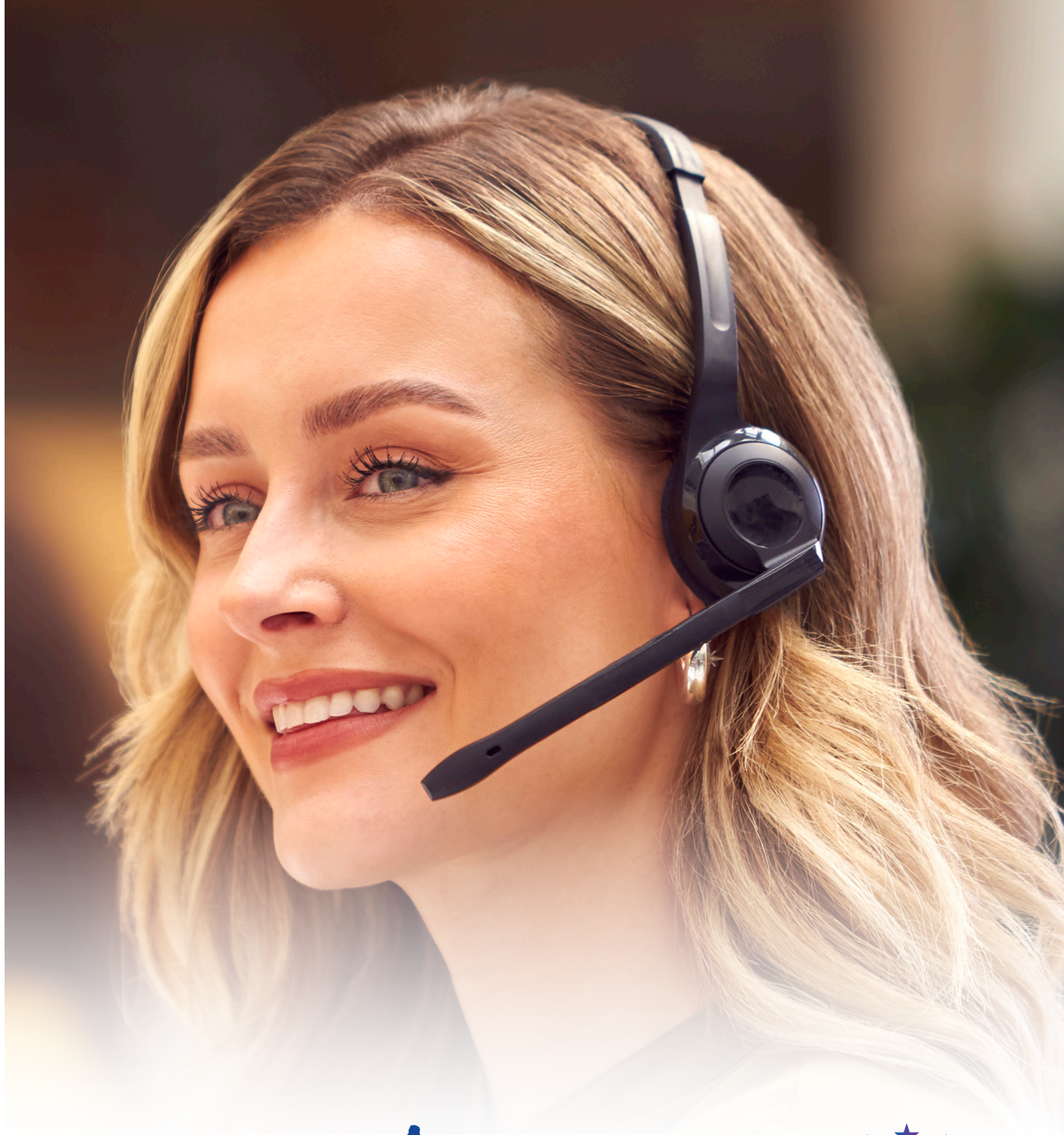
For more information about our products and services, please write to us at **immunologics@virion-serion.de** or contact one of our colleagues directly. We are looking forward to your message!

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