



# Inspired by Dedication

Product catalogue 2018/2019

serion\immunologics  
*Your Partner in Raw Material Sourcing*

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# Your Partner in Raw Material Sourcing

Based on 40 years of experience and success in infectious disease diagnostics, the division SERION Immunologics was created in 2013 to focus on the raw material business of Virion\Serion.

The company was founded in 1978 in Germany and is an expert in manufacture and worldwide distribution of *in vitro* diagnostics (IVD) for infectious diseases. Especially in the field of ELISA systems, Virion\Serion enjoys a particularly high reputation. With subsidiaries in China and Brazil as well as a global network of distributors, Virion\Serion's diagnostic products are sold in over 100 countries worldwide. All IVD products are represented by the division SERION Diagnostics.

The core of SERION Immunologics business is the product line SERION antigens, representing the in-house antigen production of Virion\Serion and including native as well as recombinant antigens. Current antigen production processes cover everything from conventional cell culture for virus propagation, cultivation of bacterial pathogens, such as *B.*

*pertussis*, to advanced recombinant antigen production in *E. coli*, yeast and insect cells expression systems (Baculovirus and S2 insect cells).

In order to address the needs of IVD manufacturers, SERION plasma and SERION antibodies are additional important parts of SERION Immunologics' product portfolio. These two product groups allow a quick and customer-specific choice of controls, calibrators and standards. Additionally, SERION customized also offers the possibility of special services such as ELISA plate coating and customized antigen or antibody development. The choice of a variety of bovine serum albumin (BSA) products as part of the product line SERION reagents completes the extensive product selection.

## Products

SERION Immunologics manufactures and provides a wide range of diagnostic raw materials and services, which are categorized in the following product groups:

### Raw Materials

- SERION antigens
- SERION plasma
- SERION antibodies
- SERION reagents – BSA

### SERION customized

- Antigen and antibody development
- ELISA plate coating
- Buffer production
- Lyophilization

High flexibility, experienced employees and competent customer support makes SERION Immunologics a strong and respected partner in the field of IVD related raw materials and components.



# Quality is our standard

Institut Virion\Serion GmbH is a certified IVD manufacturer according to European IVD directive 98/79/EC. All diagnostic medical devices are CE marked. The quality management system is certified according to DIN EN ISO 13485.



# Our Company History

<b>2018</b>	Foundation of SERION Diagnostics
<b>2017</b>	Market launch of SERION antibodies
<b>2016</b>	Foundation of Virion\Serion Biotechnology (Shenzhen) Co., Ltd.
<b>2015</b>	Implementation of regular plasma screening process
<b>2013</b>	Foundation of SERION Immunologics
<b>2011</b>	Expansion of antigen production department
<b>2010</b>	Establishment of SERION Brasil in Curitiba (Brazil)
<b>2007</b>	Market launch of the Immunomat
<b>2004</b>	Relocation and expansion to new headquarters
<b>2003</b>	Base in China (Beijing)
<b>2000</b>	CE Certification
<b>1981</b>	Market launch of the product line SERION ELISA <i>classic</i>
<b>1978</b>	Foundation of Institut Virion\Serion GmbH

# SERION antigens

Critical raw materials, such as antigens, are key factors for establishing reproducible and robust immunodiagnostic test systems. SERION Immunologics produces a variety of high-class infectious disease antigens for ELISA, lateral flow diagnostics (LFD) and bead based IVD and non-IVD applications.

Currently, SERION Immunologics has the capacity to produce antigens such as VZV, CMV or *Toxoplasma* in a multi-gram scale. The antigen production facilities are certified up to biosafety level 3 (BSL3) and are DIN EN ISO 13485 controlled, ensuring highest quality standards. This guarantees that industrial requirements can be fulfilled at any time. The product portfolio includes antigens isolated from pathogen cultivation, e.g. Measles, Mumps, B. pertussis (native antigens), or recombinant antigens (e.g. HSV, Parvovirus), altogether covering a range of more than 80 individual antigens that are produced on a routine basis. All antigens are purified

using a range of techniques to ensure optimal performance in diagnostic applications. This includes extraction, ultra-centrifugation, filtration and different types of state of the art chromatography processes. Native antigens are known for their high sensitivity in diagnostics applications, especially in IgM detection, and recombinant antigens are well known for their specificity, especially in IgG assays. SERION antigens covers a broad range of infectious diseases including viral, bacteria, fungal or parasitic diseases such as toxoplasmosis and are an ideal basis for the development and production of infectious disease kits and reagents.

## Features and benefits:

- Proven track record in antigen development and manufacturing
- DIN EN ISO 13485 quality management system
- Large scale production capacities
- Biosafety level 3 (BSL3) production environment
- Full flexibility for customized antigen projects

## Native Antigens

Antigen	Packaging	Order No.
Adenovirus Type 2 Hexon	1 mg	BA128VS
Bordetella pertussis Filamentous Hemagglutinin (FHA)	1 mg	BA120VS3
Bordetella pertussis Toxin	1 mg	BA120VS4
Bordetella pertussis whole-cell Antigen	1 mg	BA120VS8
Borrelia afzelii	1 mg	BA121VS
Borrelia garinii	1 mg	BA121GVS
Brucella abortus	1 mg	BA116VS
Campylobacter jejuni	1 mg	BA139VS

Antigen	Packaging	Order No.
Candida albicans	1 mg	BA117VS
Chlamydia abortus	1 mg	BA1373VSER
Chlamydia pneumoniae	1 mg	BA1371VSER
Chlamydia pneumoniae - Premium	1 mg	BA1371VS
Chlamydia trachomatis	1 mg	BA1372VSER
Cytomegalovirus (CMV)	1 mg	BA109VS
Echinococcus granulosus	1 mg	BA107VS
Helicobacter pylori	1 mg	BA118VS
Herpes Simplex Virus 1 (HSV-1)	1 mg	BA1051VS
Herpes Simplex Virus 2 (HSV-2)	1 mg	BA1052VS
Legionella pneumophila	1 mg	BA106VS
Leptospira biflexa	1 mg	BA125VS
Measles Virus	1 mg	BA102VS
Measles Virus - Premium	1 mg	BA102VS-S
Mumps Virus	1 mg	BA103VS
Mycoplasma pneumoniae	1 mg	BA127VS
Parainfluenza Virus Type 1	1 mg	BA1261VS
Parainfluenza Virus Type 2	1 mg	BA1262VS
Parainfluenza Virus Type 3	1 mg	BA1263VS
Respiratory Syncytial Virus (RSV)	1 mg	BA113VS
Rotavirus	1 mg	BA1193VS
Rubella Virus	1 mg	BA129G2VS
Tick-borne encephalitis (TBE) Virus	1 mg	BA112VSL
Tick-borne encephalitis (TBE) Virus - Premium	1 mg	BA112VS
Toxoplasma gondii	1 mg	BA110VS
Varicella Zoster Virus (VZV)	1 mg	BA104VS
Varicella Zoster Virus (VZV) Glycoprotein	1 mg	BA104VSG
Yersinia enterocolitica O:3 YOP	1 mg	BA138VS
Yersinia enterocolitica O:8 YOP	1 mg	BA13808VS
Yersinia enterocolitica O:9 YOP	1 mg	BA13809VS

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

Please let us know if you are interested in 0.25 mg test samples.

However, 5 mg and 10 mg portions are just as possible as customer-specific package sizes.

## Recombinant Antigens

Antigen	Packaging	Order No.
Borrelia afzelii Pko DbpA	1 mg	BA121R01
Borrelia afzelii Pko OspC	1 mg	BA121R02
Chikungunya Glycoprotein E1	1 mg	BA148R2
Chikungunya Glycoprotein E1 (A226V)	1 mg	BA148R3
Chikungunya Glycoprotein E2	1 mg	BA148R1
Chlamydia trachomatis MOMP	1 mg	BA1372VSR2
Coxsackievirus	1 mg	BA134VS01
Echovirus	1 mg	BA135VS01
Enterovirus	1 mg	BA133VS01
Epstein-Barr Virus (EBV) Capsid Antigen P18	1 mg	BA1361VSR22
Epstein-Barr Virus (EBV) Capsid Antigen P23	1 mg	BA1361VSR21
Epstein-Barr Virus (EBV) Early Antigen P138	1 mg	BA1363VSR6
Epstein-Barr Virus (EBV) Early Antigen P54	1 mg	BA1363P54VS
Epstein-Barr Virus (EBV) Nuclear Antigen EBNA1, P72	1 mg	BA1362VS
Herpes Simplex Virus 1 (HSV-1) Glycoprotein G	1 mg	BA1051RVS-G
Herpes Simplex Virus 2 (HSV-2) Glycoprotein G	1 mg	BA1052RVS-G
Mycoplasma pneumoniae P1	1 mg	BA127VSP1
Parvovirus NS1	1 mg	BA122VSNS1
Parvovirus PepA (VP1 unique)	1 mg	BA122VSP1A
Parvovirus PepB (VP2 C-term.)	1 mg	BA122VSP1B
Parvovirus PepC (VP1 N-term.)	1 mg	BA122VSP1C
Parvovirus PepD (VP1 C-term.)	1 mg	BA122VSP1D
Parvovirus VP1	1 mg	BA122VSP1
Parvovirus VP2	1 mg	BA122VSP1E
Parvovirus VP2 VLP	1 mg	BA122VSP2

Please let us know if you are interested in 0.25 mg test samples.

However, 5 mg and 10 mg portions are just as possible as customer-specific package sizes.

For antigen orders in the U.S., please contact our local sales partner The Binding Site Inc.:

**Immunologicals**

**Binding Site**  
THE BINDING SITE

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# SERION plasma

Human sera and plasma are essential reagents in serological diagnostic tests. Infectious disease state plasma/sera are used as manufacturing standards or as positive and negative controls or calibrators in most diagnostic test systems. SERION Immunologics offers numerous disease state sera, which are collected following applicable ethical guidelines.

Plasma is collected from single donors within a wide collection network. Based on continuous routine screening capacities, SERION Immunologics ensures constant plasma availability, even of rare disease state sera.

All plasma materials are obtained from qualified and registered donors by approved blood centers in the U. S. or Europe. All materials are tested and certified to comply with regulatory requirements (e.g. donor traceability through the blood bank, virus testing, etc.). The materials are offered as plasma or converted plasma (serum) depending on the user needs. The conversion of plasma into serum is performed by a well-established conversion process (re-calcification) to optimize stability and performance of the plasma materials. Since the pathogen specificity for plasma and serum articles is almost identical, only the serum articles are listed below.

Please contact us if you are explicitly interested in plasma articles or further specificities not listed below.

## Features and benefits:

- Constant availability
- Broad portfolio
- Improved stability by plasma conversion
- Customized screening



## Products

Pathogen Specificity	Order No.
Adenovirus IgA	PLS128A
Adenovirus IgG	PLS128G
Adenovirus IgM	PLS128M
Aspergillus fumigatus IgA	PLS132A
Aspergillus fumigatus IgG	PLS132G
Aspergillus fumigatus IgM	PLS132M
Bordetella pertussis IgA	PLS120A
Bordetella pertussis IgG	PLS120G
Bordetella pertussis IgM	PLS120M
Bordetella pertussis Toxin IgA	PLS1201A
Bordetella pertussis Toxin IgG	PLS1201G
Borrelia burgdorferi IgG	PLS121G
Borrelia burgdorferi IgM	PLS121M
Brucella abortus IgA	PLS116A
Brucella abortus IgG	PLS116G
Brucella abortus IgM	PLS116M
Campylobacter jejuni IgA	PLS139A
Campylobacter jejuni IgG	PLS139G
Campylobacter jejuni IgM	PLS139M
Candida albicans IgA	PLS117A
Candida albicans IgG	PLS117G
Candida albicans IgM	PLS117M
Chlamydia pneumoniae IgA	PLS1371A
Chlamydia pneumoniae IgG	PLS1371G
Chlamydia pneumoniae IgM	PLS1371M
Chlamydia trachomatis IgA	PLS1372A
Chlamydia trachomatis IgG	PLS1372G
Chlamydia trachomatis IgM	PLS1372M
Cytomegalovirus (CMV) IgG	PLS109G
Cytomegalovirus (CMV) IgM	PLS109M
Dengue Virus IgG	PLS114G
Dengue Virus IgM	PLS114M
Echinococcus granulosus IgG	PLS107G
Enterovirus IgA	PLS133A
Enterovirus IgG	PLS133G
Enterovirus IgM	PLS133M

SERION Immunologics routinely performs screenings on the following parameters. Selected IgG negative sera (e.g. Cytomegalovirus, Herpes Simplex Virus, Measles Virus etc.) are also available upon request. Please contact us to check current availabilities.

Pathogen Specificity	Order No.
Epstein-Barr Virus (EBV) VCA IgG	PLS1361G
Epstein-Barr Virus (EBV) VCA IgM	PLS1361M
Francisella tularensis IgG	PLS142G
Francisella tularensis IgM	PLS142M
Hantavirus Puumala IgG	PLS145G
Hantavirus Puumala IgM	PLS145M
Helicobacter pylori IgA	PLS118A
Helicobacter pylori IgG	PLS118G
Helicobacter pylori IgM	PLS118M
Herpes Simplex Virus 1 (HSV-1) IgG	PLS1051G
Herpes Simplex Virus 1 (HSV-1) IgM	PLS1051M
Herpes Simplex Virus 1/2 (HSV-1/2) IgA	PLS105A
Herpes Simplex Virus 1/2 (HSV-1/2) IgG	PLS105G
Herpes Simplex Virus 1/2 (HSV-1/2) IgM	PLS105M
Herpes Simplex Virus 2 (HSV-2) IgG	PLS1052G
Herpes Simplex Virus 2 (HSV-2) IgM	PLS1052M
Influenza A Virus IgG	PLS1231G
Influenza A Virus IgM	PLS1231M
Influenza B Virus IgG	PLS1232G
Influenza B Virus IgM	PLS1232M
Legionella pneumophila IgG	PLS106G
Legionella pneumophila IgM	PLS106M
Leishmania IgG	PLS147G
Leptospira biflexa IgG	PLS125G
Leptospira biflexa IgM	PLS125M
Measles Virus IgG	PLS102G
Measles Virus IgM	PLS102M
Mumps Virus IgG	PLS103G
Mumps Virus IgM	PLS103M
Mycoplasma pneumoniae IgA	PLS127A
Mycoplasma pneumoniae IgG	PLS127G
Mycoplasma pneumoniae IgM	PLS127M
Parainfluenza Virus 1/2/3 IgG	PLS126G
Parainfluenza Virus 1/2/3 IgM	PLS126M
Parvovirus B19 IgG	PLS122G
Parvovirus B19 IgM	PLS122M
Respiratory Syncytial Virus (RSV) IgA	PLS113A
Respiratory Syncytial Virus (RSV) IgG	PLS113G

Pathogen Specificity	Order No.
RF positive	PLS000RF
Rubella Virus IgG	PLS129G
Rubella Virus IgM	PLS129M
Tick-borne encephalitis (TBE) Virus IgG	PLS112G
Tick-borne encephalitis (TBE) Virus IgM	PLS112M
Toxoplasma gondii IgA	PLS110A
Toxoplasma gondii IgG	PLS110G
Toxoplasma gondii IgM	PLS110M
Varicella Zoster Virus (VZV) IgA	PLS104A
Varicella Zoster Virus (VZV) IgG	PLS104G
Varicella Zoster Virus (VZV) IgM	PLS104M
West Nile Virus IgG	PLS141G
West Nile Virus IgM	PLS141M
Yersinia enterocolitica IgA	PLS138A
Yersinia enterocolitica IgG	PLS138G
Yersinia enterocolitica IgM	PLS138M

1 mL test samples can be offered free of charge at any time.

For plasma and serum orders in Germany, Austria and Switzerland, please contact our local sales partner The Binding Site Germany:

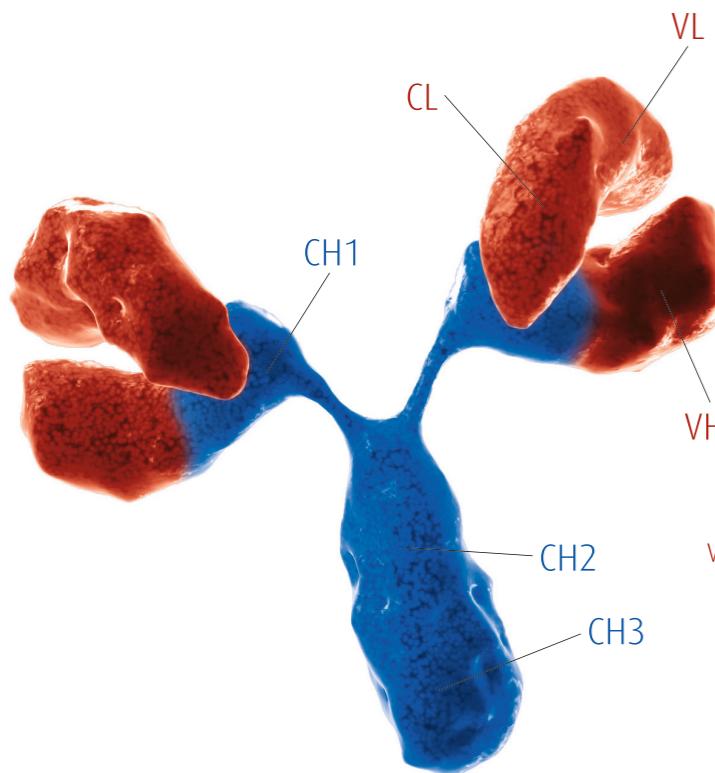
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# SERION antibodies

As a highly reliable and readily available alternative to human serum, SERION Immunologics also offers humanized monoclonal antibodies.



**Figure 1:**  
VL = Mouse variable region of light chain  
VH/CL = Mouse constant and variable regions of heavy and light chain  
CH1/CH2/CH3 = Human region of heavy chain

The performance of these monoclonal antibodies, in comparison to human disease state sera, has been tested extensively, showing that the antibodies behave similar to sera. Therefore, they can be optimally and alternatively used for preparation of calibrators, controls and standards.

SERION antibodies are produced in transgenic mice by replacing the mouse sequence of the heavy chain constant

region (IgM, IgG or IgA loci) by the corresponding human sequence. After immunization with the antigen of interest, generated antibody clones are cultivated by standard hybridoma techniques. These consist of the human constant region of the heavy chain, mouse variable region of the heavy chain and mouse light chain. The human constant region of the heavy chain can be directly recognized by the anti-human conjugate, which is used in numerous *in vitro* diagnostic assays.

## Features and benefits:

- High affinity
- High specificity
- Industrial batch sizes
- Constant availability
- Constant quality and performance

Pathogen Specificity	Antibody Class	Clone	Order No.
Anti-Chlamydia pneumoniae	IgM	G12B2	MAB1371.001
Anti-Cytomegalovirus (CMV)	IgM	Z11E4F7	MAB109.001
Anti-Cytomegalovirus (CMV)	IgM	Z3A3B8	MAB109.002
Anti-Dengue Virus	IgM	V11F8H3	MAB114.001
Anti-Epstein-Barr Virus (EBV) VCA P18	IgM	A12F10	MAB1361.001
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-Mumps Virus	IgM	F19B9A5	MAB103.002
Anti-Mycoplasma pneumoniae	IgM	NA15F4A12	MAB127.001
Anti-Rubella Virus	IgM	B16B11F8	MAB129.001
Anti-Rubella Virus	IgM	A7A11H3	MAB129.002
Anti-Toxoplasma gondii	IgM	A13H1E4	MAB110.001
Anti-Varicella Zoster Virus (VZV)	IgM	D30B3D1	MAB104.001
Anti-Varicella Zoster Virus (VZV)	IgM	D20F3C7	MAB104.002
Anti-Zika Virus	IgM	JA10E10	MAB149.001

0.5 mL test samples can be offered free of charge at any time.

Further antibodies, e.g. *Borrelia burgdorferi* IgM and *Toxoplasma gondii* IgG, are under development. If you need another monoclonal antibody, please contact us. Customer-specific development is possible at any time.

A cooperation with



# SERION reagents – Bovine Serum Albumin

To support our customers in the challenging IVD environment, SERION Immunologics opted to create a line for selected reagents and components such as different BSA formulations. Further products will be added in future and we are always open for the development of customized reagents for various applications.

Bovine serum albumin (BSA) is a globular serum protein of approx. 66.5 kDa. Due to its high stability and its lack of interference in many biological reactions, BSA is widely used in diagnostics test systems. Typical applications include the use as protein calibrator, stabilizer or as a blocking reagent.

BSA is often referred to as „Fraction V“, based on the original fractionation of human plasma developed by Edwin Cohn. Primarily developed for human albumin production, the process was later adapted to bovine serum albumin. In modern manufacturing processes, Cohn fractionation is now replaced by a modified, more effective heat shock method, resulting in a BSA of significantly higher degree of purity (> 98%).

SERION Immunologics offers a variety of BSA products especially selected to cover the needs of the diagnostic industry.

All bovine products are sourced from controlled abattoirs and are manufactured in the U.S. All animals receive ante- and post-mortem inspections in order to meet regulatory requirements and are classified as „free from infectious diseases and parasites“.

## Products

Product Description	Packaging	Order No.
Bovine Serum Albumin, Standard Grade, U.S. origin	10 g	BSA-0010SG
Bovine Serum Albumin, Standard Grade, U.S. origin	100 g	BSA-0100SG
Bovine Serum Albumin, Standard Grade, U.S. origin	1000 g	BSA-1000SG 1000 g
Bovine Serum Albumin, Protease Free, U.S. origin	10 g	BSA-0010PF 10 g
Bovine Serum Albumin, Protease Free, U.S. origin	100 g	BSA-0100PF 100 g
Bovine Serum Albumin, Protease Free, U.S. origin	1000 g	BSA-1000PF 1000 g
Bovine Serum Albumin, Fatty Acid Free, U.S. origin	10 g	BSA-0010FF 10 g
Bovine Serum Albumin, Fatty Acid Free, U.S. origin	100 g	BSA-0100FF 100 g
Bovine Serum Albumin, Fatty Acid Free, U.S. origin	1000 g	BSA-1000FF 1000 g
Bovine Serum Albumin, Sulfhydryl Blocked, U.S. origin	10 g	BSA-0010SH 10 g
Bovine Serum Albumin, Sulfhydryl Blocked, U.S. origin	100 g	BSA-0100SH 100 g
Bovine Serum Albumin, Sulfhydryl Blocked, U.S. origin	1000 g	BSA-1000SH 1000 g
Bovine Serum Albumin, 30 % Solution, with 0.1 % Sodium Azide, U.S. origin	1 L	BSA-001SL 1 L
Bovine Serum Albumin, 30 % Solution, with 0.1 % Sodium Azide, U.S. origin	10 L	BSA-010SL 10 L



# SERION customized

SERION Immunologics offers a range of customized services including antigen development and production, manufacturing of coated ELISA plates as well as buffer preparation and lyophilization. In addition, together with our partner ArkAb (Limoges, France), SERION Immunologics now offers custom development and manufacturing of monoclonal antibodies, especially for IgM. If you have any project in mind, please contact us to discuss feasibility and the best possible production procedure.

## **Antigens and antibodies:**

Due to the long-term experience of Virion\Serion as a developer and manufacturer of high performing and recognized IVD infectious disease antigens, SERION Immunologics is capable to developing and manufacturing a wide range of antigens. Based on the additional expertise of our cooperation partner ArkAb (Limoges, France), we are also the right partner for the development of new monoclonal antibodies.

## **ELISA Plate Coating:**

SERION Immunologics offers a fully automated production line for ELISA coating, incubation and vacuum packaging. A modular system enables processing of up to four different lots with individual requirements in one production flow. Embedded in a DIN EN ISO 13485 certified production environment the state-of-the-art coating system is ready for your batch production.

## **Buffer production:**

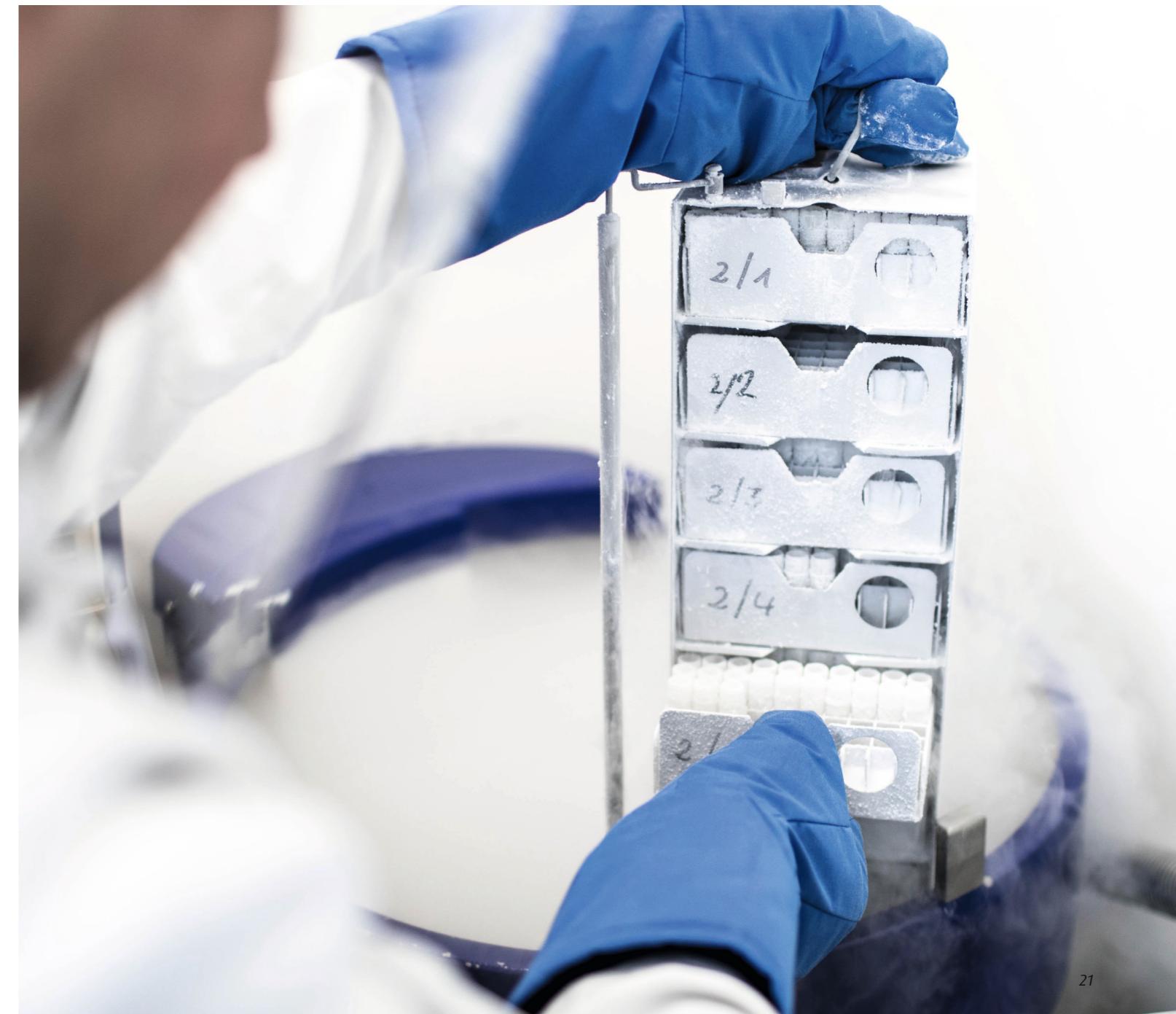
SERION customized also comprises the production of tailor-made reagents or buffer formulations, beginning from a simple bottling up to the production of complex buffer solutions. Based on Institut Virion\Serion GmbH's certification for the production of in vitro diagnostics according to DIN EN ISO 13485, all products are manufactured to the highest standards.

## **Lyophilization:**

Freeze drying often increases the shelf-life of sensitive biological substances, such as antigens or antibodies, significantly. Therefore, this method is widely used in the manufacture of diagnostic reagents and components, such as CFT reagents or conjugates. Lyophilized products can be easily reconstituted with water or a suitable buffer and the reagent can be instantly used in a diagnostic test. Therefore, lyophilization is often the method of choice if a sensitive biological substance needs to be preserved for long-term storage or to remove the need for shipping of cooled or frozen reagents. Currently batch sizes of up to several thousand vials per lyophilization run can be freeze-dried under continuous quality conditions according to DIN EN ISO 13485.

## **Features and benefits – SERION customized**

- Maximum flexibility
- Proven track record
- Technical customer support
- DIN EN ISO 13485 quality management system



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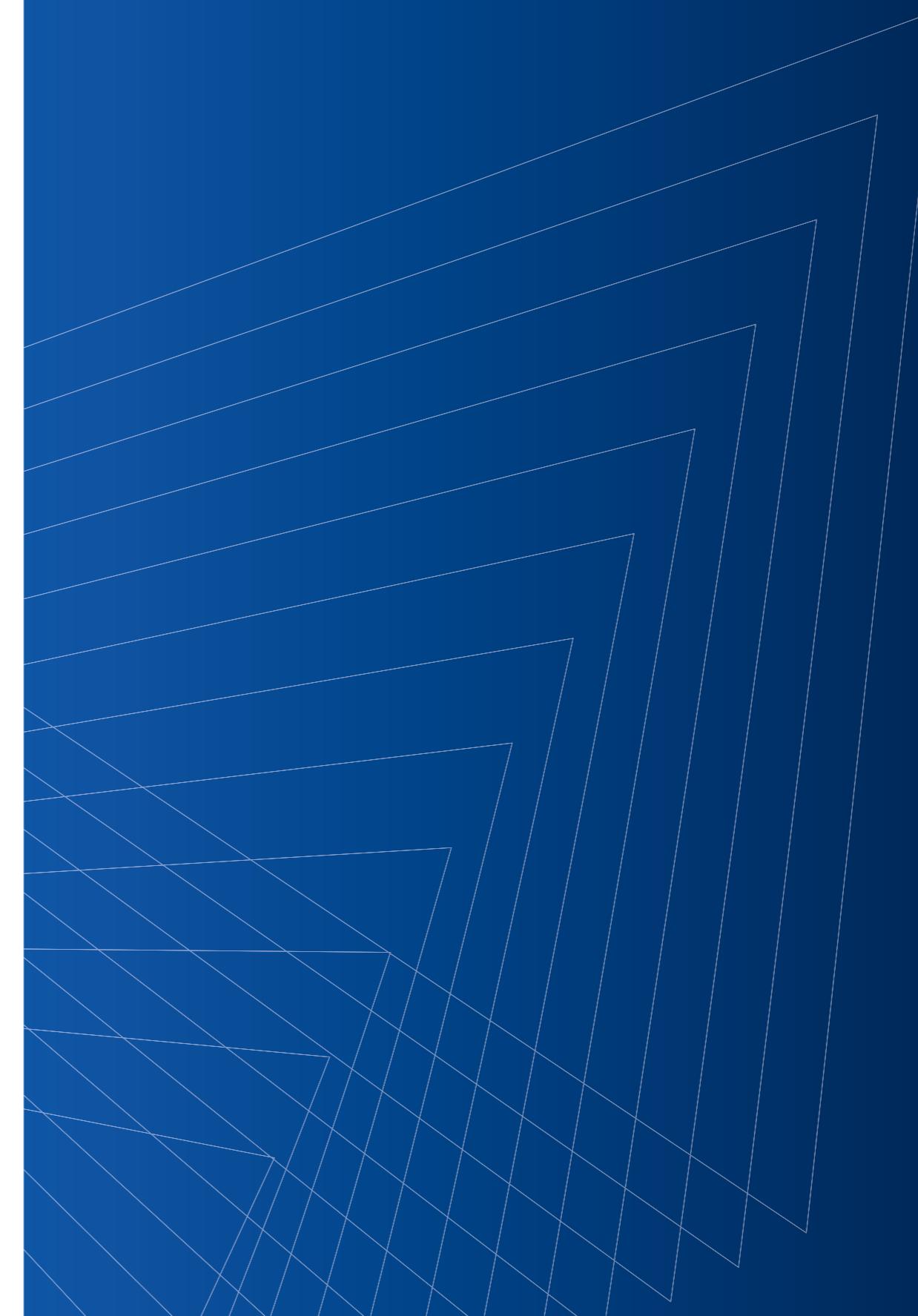
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virion\serion

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