



Inspired by Dedication

Product overview



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serion\diagnostics
Your Partner in Infectious Serology



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► Our company history

Now, after more than 45 years, Virion\Serion has evolved from a distribution company for CFT reagents – founded in 1978 – to a well-known and respected *in-vitro* diagnostics (IVD) manufacturer with one of the largest infectious disease portfolios for diagnosis of viral, bacterial, fungal and parasitic diseases worldwide.

1978

Foundation in Wuerzburg

Foundation of the Institut Virion\Serion GmbH with the product line SERION CFT in Wuerzburg (Germany).

1981

Extension of the product portfolio

Introduction of a second product line SERION ELISA *classic* for the detection of antibodies against various pathogens.

1986

Founding of SERION Immundiagnostika GmbH

Founding of SERION Immundiagnostika GmbH for the worldwide export of our *in-vitro* diagnostics.

2000

CE certification

CE certification for the development, production and sale of our *in-vitro* diagnostics to ensure our consistently high quality standards.

2003

Location China

Founding of a representative office in Beijing and simultaneous registration of the entire ToRCH panel of the SERION ELISA *classic* product line in China.

2007

SERION Immunomat

Introduction of the laboratory device SERION Immunomat for highly effective automated processing and evaluation of SERION ELISA immunoassays.



2013

Introducing SERION Immunologics

Introduction of the SERION Immunologics division for the sale of high-quality raw materials, e.g. bulk antigens, disease state sera and monoclonal antibodies, as well as the offer of various services.

2016

Foundation of Virion\Serion Biotechnology (Shenzhen) Co.Ltd.

Foundation of Virion\Serion Biotechnology (Shenzhen) Co., Ltd. to further intensify activities on the Chinese market.

2018

Introduction of SERION Diagnostics

Introduction of the SERION Diagnostics division to further focus the activities of Institut Virion\Serion GmbH in the field of *in-vitro* diagnostics.

2023

45 years of Virion\Serion

For 45 years, Virion\Serion has proven to be a reliable, competent and trustworthy partner for our customers worldwide.

Inspired by Dedication – this has always been the credo of Virion\Serion and its employees, right from the very beginning, and we want to live this claim in the future as well. For more than four decades now, Virion\Serion has proven to be a reliable, competent and trusted partner for our customers worldwide. All processes, services and products are managed in accordance with the EU directive 98/79/EC and IVD regulation (IVDR) 2017/746, under a certified quality management system according to DIN EN ISO 13485, to ensure and maintain the highest quality of our products and services. All products are manufactured in Germany (Wurzburg) and are distributed by our own field sales force in Germany and a network of distributors and partners worldwide.

Our aim is to bring value to our customers – with every product and service!

► Everything under one Roof

Over 45 years of experience and specializing in the development and manufacture of *in-vitro* diagnostics ensure the supply of high quality solutions for IVD products **made in Germany**.



► Research & Development

- Identification of the appropriate antigen by a team of specialists
- Definition of an optimal test set-up
- Internal and external performance evaluation studies

→ Guarantees a high diagnostic performance



► Antigen Production

- In house production of antigens as the core component
- More than 80 native / recombinant antigens
- State of the art antigen production techniques

→ Guarantees high quality and availability of the ELISA core component antigen

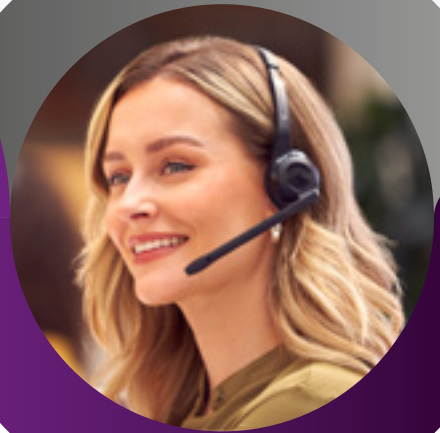


► Production Process and Quality Monitoring

- Highly automated production processes
- Large scale production capacities up to 2800 microtiter plates per lot
- According to EN ISO 13485, directive 98/79/EC and IVD Regulation (IVDR) 2017/746

→ Guarantees immunoassays of constant quality in compliance with national and international guidelines

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► Product Portfolio C€

- Comprehensive ELISA portfolio for antibody detection in serum/plasma
- A range of relevant SERION ELISA parameters validated for CSF diagnostics and avidity testing
- External controls in compliance with current quality management guidelines
- Automation solutions and user-friendly software tools

→ Guarantees assays with cost and time-efficient processing combined with precise test results

► Storage/Availability

- Huge cooled storage space for production ahead of time
- Flexible and fast reaction to increasing demands

→ Guarantees prompt supply of products right in time

► Customer Support/Sales

- Our Customer / Technical Support offers quick and competent help for product-specific and technical questions
- Scientific Product Management provides detailed product information
- Sales Managers offer customers competent on-site support

→ Guarantees fast and reliable technical and scientific support

► SERION ELISA *classic/antigen*

SERION ELISA *classic* tests are qualitative and quantitative immunoassays for the detection of human antibodies directed against specific antigens of bacteria, viruses, fungi and parasites in serum, plasma or, when indicated, cerebrospinal fluid, for the diagnosis of infectious diseases.





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Highlights:

- High diagnostic performance by the use of carefully selected antigens
- Easy handling due to standardized test procedures
- Flexible combination of all SERION ELISA *classic* immunoassays in one test run
- Easily automatable on SERION Immunomat and comparable instruments
- Fast and quantitative evaluation with a user-friendly software tool
- Precise quantification by use of the precise 4 parameter logistic function (4 PL)
- External positive controls according to current quality management guidelines
- Standardized evaluation in IU/ml with international standard preparations of the WHO, if available
- Open in use stability: 6 months
- Shelf life: Usually 22 months as of production

SERION RF Absorbent

For a precise pathogen-specific IgM antibody detection it is necessary to pretreat serum samples with rheumatoid factor (RF)-Absorbent. SERION RF Absorbent precipitates up to 15 mg IgG / ml from undiluted serum.

► SERION ELISA *classic* Special applications

CSF Diagnostics

A range of SERION ELISA *classic* immunoassays are validated for the detection of intrathecally synthesized antibodies. Antibody activities against certain infectious agents in cerebrospinal fluid (CSF)/serum samples are measured in order to calculate the resulting antibody index (AI).





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► CSF Diagnostics

Diagnostic Relevance

The diagnosis of acute or chronic neuroborreliosis is supported by the pathogen-specific demonstration of intrathecally synthesized IgG and IgM antibodies directed against *Borrelia burgdorferi*.

Combined detection of IgG antibodies directed against Masern/Measles Virus, Röteln/Rubella Virus, Varicella Zoster Virus and Herpes Simplex Virus (MRZH reaction) is a valuable addition to Multiple Sclerosis diagnostics.

Highlights:

- Detection of intrathecally synthesized antibodies and calculation of the antibody index (AI) according to the scheme of Prof. Hansotto Reiber
- SERION ELISA AI *control* for quality control in antibody index determination
- Fast and precise evaluation of AI with the evaluation software tool SERION *easyCSF*
- Same test systems for serology and CSF Diagnostics
- Different dilutions of serum and CSF samples for calculation of the AI can be selected
- Automated processing with SERION Immunomat and comparable instruments
- Exact quantification by use of the precise 4 PL function



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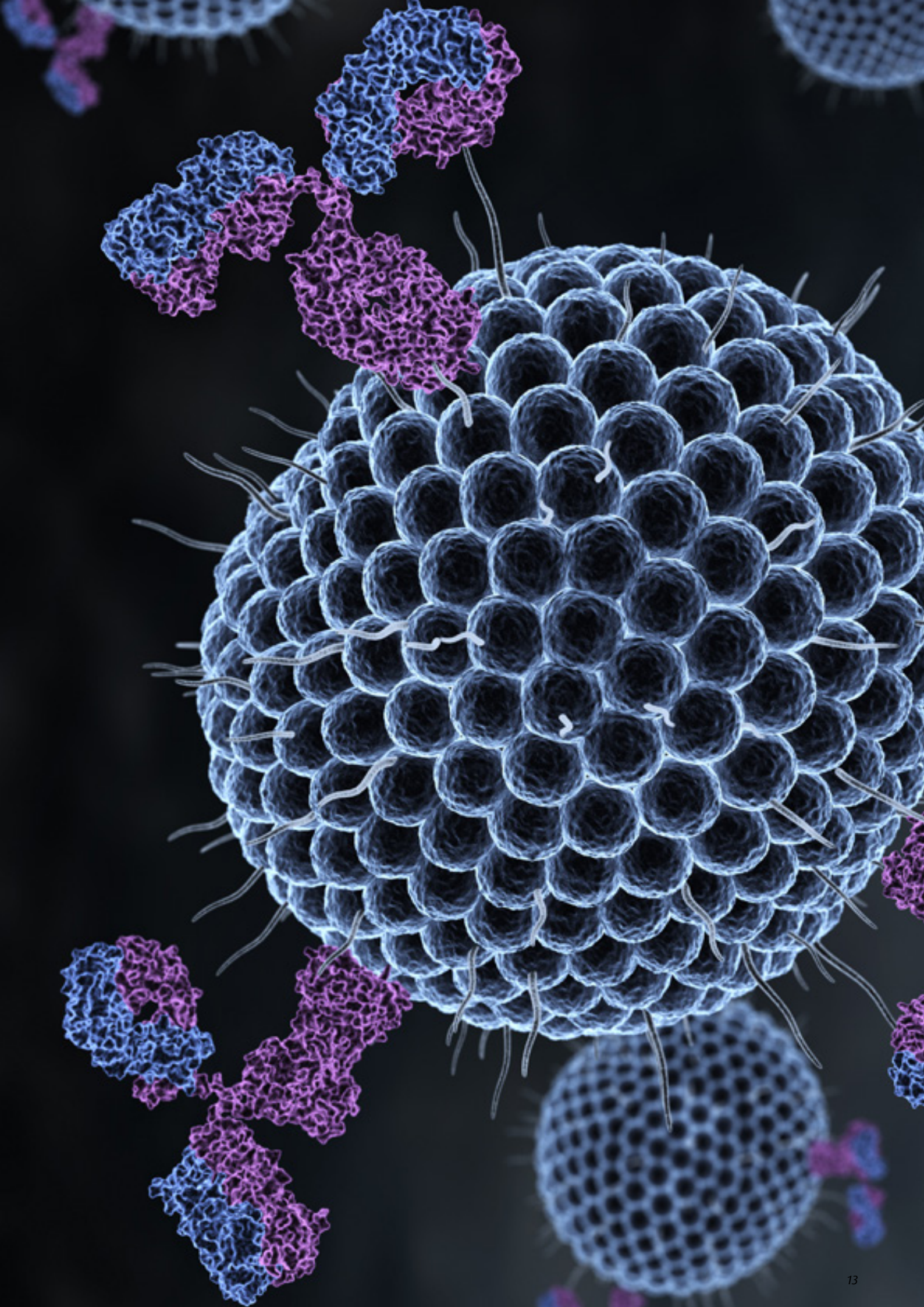
► Avidity Determination

Avidity determinations serve to support the differentiation between acute and past infections which is of particular value within the framework of prenatal serological testing. SERION Avidity Reagents are complementary components which, in combination with the corresponding SERION ELISA *classic*, enable the avidity of pathogen specific IgG antibodies to be determined.

Highlights:

- Easy handling of the avidity reagent
- Fast and precise determination of avidity indices with the software SERION *easyANALYZE*
- Differentiation between acute primary infections and previous infections





► **SERION Controls**

SERION ELISA *control*

SERION *immuno*CONTROL

SERION ELISA AI *control*

SERION ELISA Avidity Control

Certification, competitive pressure, time constraints – laboratory diagnostics faces continuously increasing requirements. An extensive range of external positive controls allow the monitoring of immunoassays to meet current quality assurance guidelines.





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► SERION ELISA *control*

SERION ELISA *control* with target values for use with SERION ELISA *classic* immunoassays.

Highlights:

- Easy handling due to predilution
- Additional quality assurance by determination of methodical precision
- Laboratory internal error limits can be determined for an optimized quality control performance



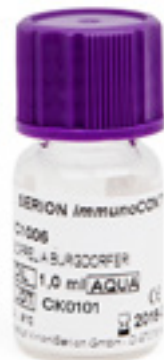
► SERION *immuno*CONTROL

Lyophilized positive control sera for qualitative antibody determination.

Highlights:

- Flexible use with SERION ELISA *classic* and other test systems*
- Convenient storage due to lyophilization
- Easy handling, analogues to patient samples
- Single and multi controls available

*after validation by the user.





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► SERION ELISA AI *control*

Human CSF/serum control sample pairs for quality control in antibody index (AI) determination.

Highlights:

- Use of native human CSF and serum conforms with modern guideline requirements for patient analogue controls
- Defined target values and validity ranges enable complete control of dilution, processing and AI calculations
- Coverage of medical decision range with pathological and non-pathological control pairs conforms with modern guidelines



► SERION ELISA Avidity Control

Lyophilized control sera for avidity determination.

Highlights:

- Low avidity controls for the usage with the SERION Avidity Reagent
- Convenient storage due to lyophilization
- Easy handling, analogous to patient samples







SERION Automation

High-efficiency automated processing and evaluation of SERION ELISA *classic* immunoassays

► SERION Immunomat

The fully automated 4-plate benchtop instrument offers a highly efficient handling and evaluation of ELISA Immunoassays due to detailed solutions and a user-friendly software.

Highlights:

- Extensive validation for antibody detection in serum, plasma or CSF and for avidity determination with SERION ELISA immunoassays
- Easy automated data transfer due to connection with laboratory information software
- Large selection and combination of preprogrammed assay protocols with different sample dilutions over a broad dilution spectrum for serological procedures and CSF diagnostics
- Stand-alone instrument with integrated pipetting system, plate transporter, ELISA washer and reader
- Combination of up to 16 different assays per plate



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SERION Software

► SERION *easyANALYZE*

SERION *easyANALYZE* allows an efficient fast and clear evaluation of SERION ELISA, test systems as well as calculation of avidity indices.



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► SERION *easyCSF*

SERION *easyCSF* combines the results of SERION ELISA tests for CSF diagnostics with clinical chemistry and thus allows the automated determination of intrathecal antibody synthesis using CSF/serum quotients, the generation of quotient diagrams according to Reiber and a pathogen-specific antibody index calculation.



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