



Inspired by Dedication

Product overview 2022/2023

serion\diagnostics
Your Partner in Infectious Serology

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Your Contact Person:



Inspired by Dedication

The history of Institut Virion\Serion GmbH
is a story of challenge and success

Now, after more than 40 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.

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 cus-

tomers worldwide. All processes, services and products are managed in accordance with the EU directive 98/79/EG, 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 we offer!

• 1978	Foundation of Institut Virion\Serion GmbH with market launch of the product line SERION CFT reagents	• 1981	Market launch of the product line SERION ELISA classic	• 1986	Foundation of the product line SERION ELISA classic	• 2000	CE Certification	• 2003	Relocation and expansion to new headquarters	• 2004	Relocation and expansion to new headquarters	• 2007	Market launch of the Immunomat

Our Company History

• 2008	Development Multianalyt	• 2011	Expansion of antigen production department	• 2013	Launch of SERION Immunologics	• 2015	Implementation of regular plasma screening process	• 2016	Foundation of Virion\Serion Biotechnology (Shenzhen) Co., Ltd.	• 2018	Launch of SERION Diagnostics	• 2020	Market launch of the product line SERION ELISA agile
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Everything under one Roof

Over 40 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 and 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 an optimal test set-up to ensure high diagnostic performance**

Antigen Production

- In house production of antigens as the core component
- More than 100 native / recombinant antigens
- State of the art antigen production techniques

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

Customer Support/Sales

- Distribution partners all over the world to cover customers' requests
- On-the-spot support by SERION Diagnostics sales managers
- Scientific and technical support from the head office in Wurzburg

→ **Guarantees fast and reliable technical and scientific support**

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**

Production Process and Quality Monitoring

- Highly automated production processes
- Large scale production capacities up to 3000 microtiter plates per lot
- In accordance with EN ISO 13485 and Directive 98/79/EC

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

Product Portfolio

- Comprehensive ELISA portfolio for antibody detection in serum/plasma
- A range of relevant SERION ELISA parameters validated for CSF diagnostics and avidity testing
- New product line SERION ELISA *agile* for the detection of antibodies against SARS-CoV-2
- 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**



SERION ELISA classic

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.

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 selected software tools
- Precise quantification by use of the precise 4 parameter logistic function (4 PL)
- External positive SERION ELISA control 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 24 months as of production



Pathogen	Ig	Order No.	Pathogen	Ig	Order No.
Adenovirus	IgA/IgG/IgM	ESR128	Francisella tularensis	IgG/IgM	ESR142
Aspergillus fumigatus	IgA/IgG/IgM	ESR132	FSME/TBE Virus	IgG/IgM	ESR112
Bordetella pertussis	IgA/IgG/IgM	ESR120	Helicobacter pylori	IgA/IgG/IgM	ESR118
Bordetella pertussis Toxin	IgA/IgG	ESR1201	Herpes Simplex Virus 1/2	IgA/IgG/IgM	ESR105
Borrelia burgdorferi	IgG/IgM	ESR121	Herpes Simplex Virus 1	IgG/IgM	ESR1051
Bruceella	IgA/IgG/IgM	ESR116	Herpes Simplex Virus 2	IgG/IgM	ESR1052
Campylobacter jejuni	IgA/IgG/IgM	ESR139	Influenza A Virus	IgA/IgG/IgM	ESR1231
Candida albicans	IgA/IgG/IgM	ESR117	Influenza B Virus	IgA/IgG/IgM	ESR1232
Chikungunya Virus	IgG/IgM	ESR148	Legionella pneumophila 1-7	IgG/IgM	ESR106
Chlamydia	IgA/IgG	ESR137	Leishmania	IgG	ESR147
Chlamydia pneumoniae	IgA/IgG/IgM	ESR1371	Leptospira	IgG/IgM	ESR125
Chlamydia trachomatis	IgA/IgG/IgM	ESR1372	Masern/Measles Virus	IgG/IgM	ESR102
Coxiella burnetii Phase 1	IgA/IgG	ESR1311	Mumps Virus	IgG/IgM	ESR103
Coxiella burnetii Phase 2	IgG/IgM	ESR1312	Mycoplasma pneumoniae	IgA/IgG/IgM	ESR127
Coxsackievirus	IgA/IgG/IgM	ESR134	Parainfluenza Virus	IgA/IgG	ESR126
Cytomegalovirus	IgG/IgM	ESR109	Parvovirus B19	IgG/IgM	ESR122
Dengue Virus	IgG/IgM	ESR114	Respiratory Syncytial Virus	IgA/IgG/IgM	ESR113
Dengue Virus superior	IgM	ESR1141	Röteln/Rubella Virus	IgG/IgM	ESR129
Diphtheria	IgG	ESR130	Tetanus	IgG	ESR108
Echinococcus	IgG	ESR107	Toxoplasma gondii	IgG/IgM	ESR110
Echovirus	IgA/IgG/IgM	ESR135	Varicella zoster Virus	IgA/IgG/IgM	ESR104
Enterovirus	IgA/IgG/IgM	ESR133	West Nile Virus	IgG/IgM	ESR141
Epstein-Barr Virus VCA	IgG/IgM	ESR1361	Yersinia	IgA/IgG/IgM	ESR138
Epstein-Barr Virus EBNA1	IgG	ESR1362	Zika Virus	IgA/IgG	ESR149
Epstein-Barr Virus EA	IgG	ESR1363	Candida Antigen		ESR200

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.

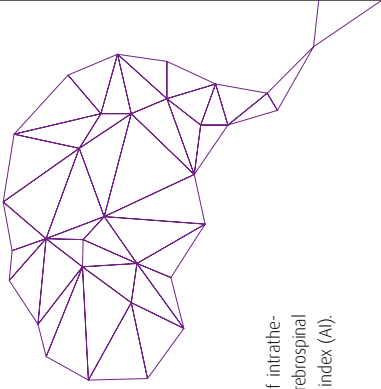
Product

SERION RF Absorbent

Order Nr.

Z200

SERION ELISA classic Special applications



1. CSF Diagnostics

A range of SERION ELISA classic immunossays 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).

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 Maserin/Measles Virus, Röteln/Rubella Virus, Varicella Zoster Virus and Herpes Simplex Virus (MRZH reaction) is a valuable addition to Multiple Sklerosis diagnostics.

List of all validated parameters

Pathogen	Ig	Order No.
Adenovirus	IgG	ESRT28
Borrelia burgdorferi	IgG/IgM	ESRT21
Cytomegalovirus	IgG	ESRT09
Enterovirus	IgG	ESRT33
Epstein-Barr Virus EBNA 1	IgG	ESRT362
Epstein-Barr Virus VCA	IgG	ESRT361
FSME/TBE Virus	IgG/IgM	ESRT12
Herpes Simplex Virus 1/2	IgA/IgG	ESRT05
Herpes Simplex Virus 1	IgG	ESRT051
Herpes Simplex Virus 2	IgG	ESRT052
Influenza A Virus	IgG	ESRT231
Influenza B Virus	IgG	ESRT232
Masern/Measles Virus	IgG	ESRT02
Mumps Virus	IgG	ESRT03
Röteln/Rubella Virus	IgG	ESRT29
SARS-CoV-2	IgG	ESR400
Toxoplasma gondii	IgG	ESRT10
Varicella Zoster Virus	IgA/IgG	ESRT04

Highlights:

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

2. 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.

Product	Ig	Order No.
Cytomegalovirus	IgG	BT09AVID
Rubella Virus	IgG	BT29AVID
Toxoplasma gondii	IgG	BT10AVID

Highlights:

- Easy handling of the avidity reagent
- Precise determination of avidity indices with low coefficient of variation (CV)
- Differentiation between acute primary infections and previous infections



Fully automatable Anti-SARS-CoV-2 ELISAs
based on high quality antigens

SERION ELISA *agile*

Sometimes we are confronted with extreme situations that require extraordinary solutions.

SERION ELISA *agile* is optimized for a higher test throughput while maintaining the same critical performance and evaluation levels as our renowned product line SERION ELISA *classic*.

Highlights:

- New reagent setup that efficiently provides excellent results
- Streamlined workflow for maximum flexibility in both manual and automated processing
- New clear and concise design



Highlights SERION ELISA *agile* SARS-CoV-2 IgA/IgG/IgM:

- The utilization of the whole spike protein ensures an early and sensitive detection of SARS-CoV-2 IgG
- Quantitative IgG test allows monitoring of immune response after infection of vaccination
- Expression of SARS-CoV-2 IgG antibody activity in standardized BAU/ml possible
- Detection of intrathecally synthesized IgG antibodies for CSF diagnostics
- Excellent correlation of the IgG test with neutralization assays
- Sensitive IgA and IgM antibody detection with high specificity ideal for determination of acute infections as complement to direct pathogen detection
- Quantitative evaluation of IgA antibody activities
- In house produced antigens guarantee reliable and reproducible results

Product	Ig	Order No.
SARS-CoV-2	IgA	ESR400A
SARS-CoV-2	IgG	ESR400G
SARS-CoV-2	IgM	ESR400M

SERION controls

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.



1. SERION ELISA control

SERION ELISA control for use with SERION ELISA classic and SERION ELISA agile test kits with target values

Pathogen	Ig	Order No.	Pathogen	Ig	Order No.
Adenovirus	IgA/IgG	BC128	Herpes Simplex Virus 1/2	IgA/IgG/IgM	BC105
Aspergillus fumigatus	IgA/IgG/IgM	BC132	Herpes Simplex Virus 1	IgG/IgM	BC1051
Bordetella pertussis	IgA/IgG	BC120	Herpes Simplex Virus 2	IgG/IgM	BC1052
Bordetella pertussis Toxin	IgA/IgG	BC1201	Influenza A Virus	IgA/IgG/IgM	BC1231
Borrelia burgdorferi	IgG/IgM	BC121	Influenza B Virus	IgA/IgG/IgM	BC1232
Brucella	IgA/IgG/IgM	BC116	Legionella pneumophila 1-7	IgG/IgM	BC106
Campylobacter jejuni	IgA/IgG/IgM	BC139	Leishmania	IgG	BC107
Candida albicans	IgA/IgG/IgM	BC117	Leptospira	IgG/IgM	BC125
Chikungunya Virus	IgG/IgM	BC148	Masern/Measles Virus	IgG/IgM	BC102
Chlamydia pneumoniae	IgA/IgG/IgM	BC1371	Mumps Virus	IgG/IgM	BC103
Chlamydia trachomatis	IgA/IgG/IgM	BC1372	Mycoplasma pneumoniae	IgA/IgG/IgM	BC127
Coxiella burnetii Phase 2	IgG/IgM	BC1312	Parainfluenza Virus	IgA/IgG	BC126
Coxsackievirus	IgA/IgG/IgM	BC134	Parvovirus B19	IgG/IgM	BC122
Cytomegalovirus	IgG/IgM	BC109	Respiratory Syncytial Virus	IgA/IgG	BC113
Dengue Virus	IgG/IgM	BC114	Röteln/Rubella Virus	IgG/IgM	BC129
Dengue Virus superior	IgM	BC141	SARS-coV-2	IgA/IgG/IgM	BC400
Diphtheria	IgG	BC130	Tetanus	IgG	BC108
Echinococcus	IgG	BC107	Toxoplasma gondii	IgG/IgM	BC110
Echovirus	IgA/IgG/IgM	BC135	Varicella Zoster Virus	IgA/IgG/IgM	BC104
Enterovirus	IgA/IgG/IgM	BC133	West Nile Virus	IgG/IgM	BC141
Epstein-Barr Virus (VCA)	IgG/IgM	BC1361	Yersinia	IgA/IgG/IgM	BC138
Epstein-Barr Virus (EBNA1)	IgG	BC1362	Zika Virus	IgA/IgG	BC149
Epstein-Barr Virus (EA)	IgG	BC1363	Candida Antigen		BC200
FSME/TBE Virus	IgG/IgM	BC112			
Helicobacter pylori	IgA/IgG/IgM	BC118			

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

2. SERION immunoCONTROL

Lyophilized positive control sera for qualitative antibody determination.

Single-controls

Pathogen	Ig	Order No.	Pathogen	Ig	Order No.
Borrelia burgdorferi	IgG	IC1006	Herpes Simplex Virus 1/2	IgM	IC2028
Borrelia burgdorferi	IgM	IC2006	Masern/Measles Virus	IgG	IC1036
Chlamydia pneumoniae	IgG	IC1011	Masern/Measles Virus	IgM	IC2036
Chlamydia trachomatis	IgG	IC1012	Mumps Virus	IgG	IC1037
Cytomegalovirus	IgM	IC2016	Mumps Virus	IgM	IC2037
Epstein-Barr Virus VCA	IgG	IC1022	Mycoplasma pneumoniae	IgG	IC1038
Epstein-Barr Virus VCA	IgM	IC2022	Mycoplasma pneumoniae	IgM	IC2038
Epstein-Barr Virus EBNA1	IgG	IC1023	Parvovirus B19	IgG	IC1040
Helicobacter pylori	IgG	IC1027	Parvovirus B19	IgM	IC2040
			Röteln/Rubella Virus	IgM	IC2042
			Varicella Zoster Virus	IgG	IC1046
			Varicella Zoster Virus	IgM	IC2046



Multi-controls

Pathogen	Ig	Order No.
Masern/Measles Virus + Mumps Virus	IgG	IC1301
Parvovirus B19 + Varicella Zoster Virus	IgG	IC1302
TbRCH 1/2	IgG	IC1701

Highlights:

- Use of native human serum
- Flexible use with SERION ELISA classic and other test systems*
- Convenient storage due to lyophilization
- Easy handling, analogues to patient samples on automates
- Single and multi controls available

*after validation by the user.

3. SERION ELISA AI control

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



Controls with target values in the non-pathologic AI-range (1.0)

Pathogen	Ig	Order No.
Borrelia burgdorferi	IgG	CLS121G1
Borrelia burgdorferi	IgM	CLS121M1
Herpes Simplex Virus 1/2	IgG	CLS105G1
Masern/Measles Virus	IgG	CLS102G1
Röteln/Rubella Virus	IgG	CLS129G1
Varicella Zoster Virus	IgG	CLS104G1

Controls with target values in the pathologic AI-range (>1.5)

Pathogen	Ig	Order No.
Borrelia burgdorferi	IgG	CLS121G2
Borrelia burgdorferi	IgM	CLS121M2
Herpes Simplex Virus 1/2	IgG	CLS105G2
Masern/Measles Virus	IgG	CLS102G2
Röteln/Rubella Virus	IgG	CLS129G2
Varicella Zoster Virus	IgG	CLS104G2

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 validation of dilution, processing and calculations
- Coverage of medical decision range with pathological and non-pathological control pairs conforms with modern guidelines



4. SERION ELISA Avidity Control

Lyophilized control sera for avidity determination.

Pathogen	Ig	Order No.
Toxoplasma gondii	IgG	BRT10AVID
Rubella Virus	IgG	BRT29AVID
Cytomegalovirus	IgG	BRT09AVID

Highlights:

- Low avidity controls for the usage with 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* and SERION ELISA *agile* 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

SERION Software Solutions and Evaluation Tools

1. SERION easyANALYZE

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

2. 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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