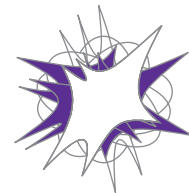


Nr. 14, 2011



virion\serion

# SERION ELISA *control*

ready - to - use  
as of Easter 2011

## Positive Controls for SERION ELISA *classic*

Dear Ladies and Gentlemen,

As an innovative and forward looking company we are constantly looking for ways to improve our products and better serve our customers. With these goals in mind we are happy to be able to inform you that, as of Easter 2011, we will be able to offer our well established **SERION ELISA *controls*** as ready-to-use reagents. These positive controls are for use when performing antibody determinations with the SERION ELISA *classic* product line. In addition to improving handling, they have been developed with the aim of facilitating accredited laboratories in the adherence to the guidelines of the German Medical Association for demonstrating compliance with the required mandatory high standards.

Institut Virion\Serion GmbH and Serion Immundiagnostica GmbH support their customers by offering **SERION ELISA *controls*** in packing units of 5 vials à 3 mL. The storage stability of the ready-to-use controls is 18 months from the date of production. Each vial is labelled with a barcode for a customer convenient and quality assured usage with Immunomat™.

The liquid **SERION ELISA *controls*** will replace the lyophilized products in the near future. Please find enclosed an overview of our, already available, ready-to-use **SERION ELISA *controls*** as well as information for usage, storage and stability and note the necessary change to the order numbers.

Do not hesitate to contact us if you have any further questions.

Kind regards  
Serion Immundiagnostica GmbH

Dr. Andreas Schmiel  
Marketing / Product Management

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# SERION ELISA *control*

## Positive Controls for use with SERION ELISA *classic*

**SERION ELISA *controls*** are positive control sera for the qualitative and quantitative antibody determination when using immunoassays of the SERION ELISA *classic* product line. The ready-to-use components are, in addition to the controls supplied with the SERION ELISA *classic* test kits, supplementary external reagents to determine validity of SERION ELISA *classic* test runs, precision and reliability of the method. **SERION ELISA *controls*** are, in accordance with the guidelines of the German Medical Association, particularly recommended as an aid for the internal quality management in accredited laboratories.

### Target Values and Validity Ranges

In comprehensive validation studies, target values and validity ranges for each test-specific **SERION ELISA *control*** are determined and documented on lot-specific certificates of analysis. These values are recommended as references for the quality management in accredited laboratories when using **SERION ELISA *controls*** in combination with SERION ELISA *classic* test kits.

**SERION ELISA *controls*** generally show positive results in test runs with SERION ELISA *classic* tests. However, a few SERION ELISA *classic* tests were evaluated to correspond to a so-called clinical threshold, e. g. in order to exclude high seroprevalences. Therefore, the evaluation of individual SERION ELISA *controls* might deliver borderline results in exceptional cases.

### Preparation

**SERION ELISA *controls*** are ready-to-use and must not be diluted any further. Rf-absorption must also not be performed.

**SERION ELISA *controls*** are recommended to be used in each SERION ELISA *classic* test run and the results recorded on a control chart. On request, our Microsoft® Excel-based evaluation tool SERION *accuracy* can be supplied.

**SERION ELISA *controls*** are recommended for use with the corresponding SERION ELISA *classic* test. The positive controls can be used with other tests only after validation by the user.

### Stability and Storage

The stability of the liquid and ready-to-use **SERION ELISA *controls*** is 18 months from the date of production when stored at 2-8 °C. The long stability guarantees high constancy and reproducibility of test results when using **SERION ELISA *controls***.



Product Overview of ready-to-use **SERION ELISA controls**

Order Nr.	SERION ELISA control
C 128 A C 128 G	Adenovirus IgA Adenovirus IgG
C 132 G C 132 M	Aspergillus fumigatus IgG Aspergillus fumigatus IgM
C 120 A C 120 G	Bordetella pertussis IgA Bordetella pertussis IgG
C 1201 G	Bordetella pertussis Toxin IgG
C 121 G	Borrelia burgdorferi IgG
C 116 G C 116 M	Brucella IgG Brucella IgM
C 139 G	Campylobacter jejuni IgG
C 117 G	Candida albicans IgG
C 137 A C 137 G	Chlamydia IgA Chlamydia IgG
C 1371 A C 1371 G C 1371 M	Chlamydia pneumoniae IgA Chlamydia pneumoniae IgG Chlamydia pneumoniae IgM
C 1372 A C 1372 G C 1372 M	Chlamydia trachomatis IgA Chlamydia trachomatis IgG Chlamydia trachomatis IgM
C 1312 G	Coxiella burnetii Phase 2 IgG
C 109 G C 109 M	Cytomegalovirus IgG Cytomegalovirus IgM
C 130 G	Diphtheria IgG
C 135 A C 135 G	Echovirus IgA Echovirus IgG
C 133 G	Enterovirus IgG
C 1361 G C 1361 M C 1362 G C 1363 G	Epstein-Barr Virus VCA IgG Epstein-Barr Virus VCA IgM Epstein-Barr Virus EBNA-1 IgG Epstein-Barr Virus EA IgG

Order Nr.	SERION ELISA control
C 118 A	Helicobacter pylori IgA
C 105 A C 105 M	Herpes Simplex Virus 1+2 IgA Herpes Simplex Virus 1+2 IgM
C 1051 G C 1051 M	Herpes Simplex Virus 1 gP IgG Herpes Simplex Virus 1 IgM
C 1052 G	Herpes Simplex Virus 2 gP IgG
C 1231 A	Influenza A Virus IgA
C 1232 A C 1232 G	Influenza B Virus IgA Influenza B Virus IgG
C 106 G	Legionella pneumophila IgG
C 102 G	Measles Virus IgG
C 103 G C 103 M	Mumps / Parotitis Virus IgG Mumps / Parotitis Virus IgM
C 127 A	Mycoplasma pneumoniae IgA
C 122 G C 122 M	Parvovirus B19 IgG Parvovirus B19 IgM
C 113 A C 113 G	Respiratory Syncytial Virus IgA Respiratory Syncytial Virus IgG
C 129 G C 129 M	Rubella Virus IgG Rubella Virus IgM
C 112 G C 112 M	TBE Virus IgG TBE Virus IgM
C 108 G	Tetanus IgG
C 110 G C 110 M	Toxoplasma gondii IgG Toxoplasma gondii IgM
C 104 G C 104 M	Varicella-Zoster Virus IgG Varicella-Zoster Virus IgM
C 138 A C 138 G	Yersinia IgA Yersinia IgG



**Analysenzertifikat**  
**Certificate of Analysis**

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**SERION ELISA control**  
**VARIZELLA-ZOSTER VIRUS IgG**

Artikelnr. / Article No.	BC104G
Chargen-Nr. / Lot No.	SMA.DR
Verfallsdatum / Expiry Date	2012-06
Zielwert / Target Value	480,5 mIU/ml
Zielwertbereich / Target Range	$\geq 240,2$ mIU/ml und / and $\leq 961,0$ mIU/ml
Versions-Nr. / Version No.	2011 / 03-1

**SERION ELISA control**

- **Ready-to-use positive Controls** for the qualitative and quantitative Antibody Determination with SERION ELISA *classic*
- **External Controls** with **Target Values and Validity Ranges**
- **Quality Management in Accordance with the Guidelines of the German Medical Association**
- **High Lot-to-Lot Consistency**
- **High Reproducibility of Results**
- **Long Storage Stability**



Please visit our website [www.virion-serion.com](http://www.virion-serion.com) for more information on our products.

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