



# Newsletter

## CSF Diagnostics

Dear Ladies and Gentlemen,

### CSF Diagnostics SERION ELISA *classic*

The calculation of antibody indices (AI) is based on the detection of pathogen-specific immunoglobulins in serum and CSF (*cerebrospinal fluid*). Institut Virion\Serion GmbH offers a wide range of CE-certified assays that are suited for antibody detection in CSF diagnostics. For CSF application no special test systems or additional reagents are required; it can be performed with a conventional SERION ELISA *classic* tests identical to infectious-serological. The test systems enable the determination of CSF and serum samples in one test set-up. The user can select different dilutions of the CSF and different dilutions of the serum and refer to the same calibration. By taking the dilution factor into account, the determination of serum antibody activities can also be used for serology. Unified incubation conditions for all SERION ELISA *classic* tests, and for different applications (CSF diagnostics or serology) enable the combination of various SERION ELISA *classic* tests in one test run. Due to the accurate quantification based on the 4PL method which is used for SERION ELISA *classic*, antibody activities are determined in a precise way over a wide measurement range. The single-point calibration to a predefined, batch specific standard curve allows economical processing without the cost- and time-consuming generation of test-run specific standard curves with multiple calibrators.

The detection of intrathecally synthesized antibodies is based on the method of Prof. Hansotto Reiber.

The AI characterizes the antigen-specific IgG, IgM or IgA concentration in CSF synthesized in the CNS. Analogous to total antibody determination by detecting oligoclonal bands or by Reiber diagrams, it is also essential for the analysis of (pathogen)-specific antibody activities in CSF to always evaluate in relation to the antibody activity in the serum, to discriminate intrathecal antibody synthesis from antibodies of serological origin.

For CSF diagnostics the following SERION ELISA *classic* tests are validated. The CSF application for SERION ELISA *classic* Herpes Simplex Virus 1 IgG and 2 IgG is also now available.

Products	Order Nr.
SERION ELISA <i>classic</i> Adenovirus IgG	ESR 128 G
SERION ELISA <i>classic</i> Borrelia burgdorferi IgG	ESR 121 G
SERION ELISA <i>classic</i> Borrelia burgdorferi IgM	ESR 121 M
SERION ELISA <i>classic</i> Cytomegalovirus IgG	ESR 109 G
SERION ELISA <i>classic</i> Enterovirus IgG	ESR 133 G
SERION ELISA <i>classic</i> Epstein-Barr Virus VCA IgG	ESR 1361 G
SERION ELISA <i>classic</i> Epstein-Barr Virus EBNA1 IgG	ESR 1362 G
SERION ELISA <i>classic</i> FSME Virus IgG	ESR 112 G
SERION ELISA <i>classic</i> FSME Virus IgM	ESR 112 M
SERION ELISA <i>classic</i> Herpes Simplex Virus 1 IgG	ESR 1051 G
SERION ELISA <i>classic</i> Herpes Simplex Virus 2 IgG	ESR 1052 G
SERION ELISA <i>classic</i> Herpes Simplex Virus 1/2 IgA	ESR 105 A
SERION ELISA <i>classic</i> Herpes Simplex Virus 1/2 IgG	ESR 105 G
SERION ELISA <i>classic</i> Influenza A Virus IgG	ESR 1231 G
SERION ELISA <i>classic</i> Influenza B Virus IgG	ESR 1232 G
SERION ELISA <i>classic</i> Masern Virus IgG	ESR 102 G
SERION ELISA <i>classic</i> Mumps Virus IgG	ESR 103 G
SERION ELISA <i>classic</i> Röteln Virus IgG	ESR 129 G
SERION ELISA <i>classic</i> Toxoplasma gondii IgG	ESR 110 G
SERION ELISA <i>classic</i> Varicella-Zoster Virus IgA	ESR 104 A
SERION ELISA <i>classic</i> Varicella-Zoster Virus IgG	ESR 104 G

**NEW!**

## External study with SERION ELISA *classic* Borrelia Burgdorferi

The CSF diagnostics is an important factor for determination of infections with CNS involvement. For example, the diagnosis of acute or chronic Lyme neuroborreliosis is supported by the pathogen-specific demonstration of intrathecally synthesized IgG and IgM antibodies directed against *Borrelia burgdorferi*.

An external study has been performed by the Diakonessenhuis and the National Institute for Public Health and the Environment in the Netherlands demonstrating a very good diagnostic performance of SERION ELISA *classic* tests (van Gorkom et al., 2018). In total, seven different test systems have been investigated, showing varying diagnostic sensitivities (ranging from 25-100%). For SERION ELISA *classic* Borrelia burgdorferi IgG and IgM a combined sensitivity of 100 % was calculated for definite Lyme Neuroborreliosis (LNB) cases (n=12) based on CSF/serum samples for AI determination. The specificity was evaluated by analysing CSF/serum samples of other infectious diseases and non-infectious diseases and was 93% and 96%, respectively. The below table summarizes the results of SERION ELISA *classic* Borrelia burgdorferi IgG and IgM in more detail:

SERION ELISA <i>classic</i> Borrelia burgdorferi IgG and IgM	Definite LNB (n=3)	Positive LNB Controls (definite LNB cases) (n=9)	Probable LNB (n=7)	Possible LNB (n=33)	Other infectious diseases LNB (n=15)	non-infectious diseases (n=45)
Sensitivity (percentage of positives)	100 %	100 %	43 %	6 %	(7 %)	(4 %)
Specificity	-	-	-	-	93 %	96 %

The good performance of SERION ELISA *classic* Borrelia burgdorferi IgG is also demonstrated by the analysis of samples from German EQAS (Instand e.V.) for Neuroborreliosis in the time period 2009-2017. The internal evaluations showed in comparison to the target result a sensitivity of 91 % and a specificity of > 99 %.

We hope that we could convince you of the excellent performance of SERION ELISA *classic* test systems for CSF application. In this context, we would also like to mention our SERION ELISA AI *controls*, which enable a monitoring of validity and precision of the applied method and therefore serve as quality control. Please let us know if you have any questions or comments about our test systems and products.

## CSF Software

Furthermore, we would like to announce that a bi-directional LIS-connected CSF software „SERION easyCSF“ is in the final stage of development. The software serves to generate an integrated patient report for CSF diagnostics. Further details will be released soon.

**With best regards from Würzburg,  
Institut Virion\Serion GmbH**

## References:

- H. Reiber, J.B. Peter (2001): Cerebrospinal fluid analysis: disease-related data patterns and evaluation programs; J of the Neurol. Sciences 101-122[2]  
Mikrobiologisch-Infektiologische Qualitätsstandards 2016
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## Institut Virion\Serion GmbH

Friedrich-Bergius-Ring 19, 97076 Würzburg, Germany

Phone +49 931 3045 0 Fax +49 931 3045 100

Mail [info@virion-serion.de](mailto:info@virion-serion.de) Web [www.virion-serion.de](http://www.virion-serion.de)