



SERION ELISA AI *control* CSF Diagnostics

SERION ELISA AI *control* are human CSF/serum control sample pairs for quality control in the determination of the antibody index (AI) with immunoassays of the SERION ELISA *classic* product line. Together with the controls contained within the SERION ELISA *classic* test kit, they are an additional, external reagent for checking the validity of the sample preparation and the test run that has been carried out. SERION ELISA AI *control* can be used especially for quality assurance in accredited test laboratories in accordance with the requirements of the guidelines of German Medical Association (RiLiBÄK). The components consist of natural human origin and correspond to the patient material for testing in routine diagnostics.

Antibody determination in CSF diagnostics

The analysis of cerebrospinal fluid is used to detect or rule out inflammatory responses involving the CNS, autoimmune responses or other diseases. The determination of intrathecally synthesized pathogen-specific antibodies is part of special analyses in CSF diagnostics. The marker used here is the antibody index (AI), which is determined from the ratio of the quotients of the pathogen-specific antibody activity in CSF and serum ($Q_{\text{spec.IgX}}$) to the corresponding quotient of the total immunoglobulin content in CSF and serum (Q_{IgX} & $Q_{\text{lim.IgX}}$). Because of the high level of precision required in CSF diagnostics adherence to strict quality standards is essential. SERION ELISA AI *control* serve as external

controls to establish validity and precision in the determination of pathogen-specific antibody activity within the framework of quality assurance.

SERION ELISA AI *control*

SERION ELISA AI *control* are lyophilized CSF/serum control sample pairs prepared from human serum and spinal fluid. Because of their similarity to the patient samples they meet the requirements of the guidelines of German Medical Association (RiLiBÄK) and the recommendations of the German Society of CSF Diagnostics and Clinical Neurochemistry (DGLN). The controls are to be treated like patient samples and have target values and validity ranges that are in ranges relevant for decision-making. If SERION ELISA *classic* is used, SERION ELISA AI *control* 1 show a non-pathological antibody index around 1.0 and SERION ELISA AI *control* 2 show an antibody index >1.5 . Through determination of the pathogen-specific antibody activities in CSF and serum, and taking into account the dilutions used, the pathogen-specific antibody quotient $Q_{\text{spec.IgX}}$ is calculated. The antibody index (AI) is obtained by determining the quotient from $Q_{\text{spec.IgX}}$ and the quotient of the total immunoglobulin content Q_{IgX} stated on the certificate of analysis. SERION ELISA AI *control* contain two serum samples (250 μl) and two CSF samples (each 500 μl), which are diluted in accordance with the recommendations of the DGLN.

Highlights of SERION ELISA AI *control* for CSF diagnostics

- CSF/serum control sample pairs for the determination of antibody indices (AI) with SERION ELISA *classic* immunoassays in accordance with the requirements of the guidelines of German Medical Association (RiLiBÄK)
- External control samples prepared from human serum and human CSF with indications of target values and validity ranges
- SERION ELISA AI *control* 1 with antibody indices in the non-pathological range around 1.0
- SERION ELISA AI *control* 2 with antibody indices in the pathological range > 1.5

Order Information

SERION ELISA AI *control* 1 (non-pathological AI target values around 1.0)

Product Description	Order No.
SERION ELISA AI <i>control</i> 1 Borrelia burgdorferi IgG	CLS 121 G1
SERION ELISA AI <i>control</i> 1 Borrelia burgdorferi IgM	CLS 121 M1
SERION ELISA AI <i>control</i> 1 Measles Virus IgG	CLS 102 G1
SERION ELISA AI <i>control</i> 1 Rubella Virus IgG	CLS 129 G1
SERION ELISA AI <i>control</i> 1 Varicella-Zoster Virus IgG	CLS 104 G1
SERION ELISA AI <i>control</i> 1 Herpes Simplex Virus 1/2 IgG	CLS 105 G1

SERION ELISA AI *control* 2 (pathological AI target values > 1.5)

Product Description	Order No.
SERION ELISA AI <i>control</i> 2 Borrelia burgdorferi IgG	CLS 121 G2
SERION ELISA AI <i>control</i> 2 Borrelia burgdorferi IgM	CLS 121 M2
SERION ELISA AI <i>control</i> 2 Measles Virus IgG	CLS 102 G2
SERION ELISA AI <i>control</i> 2 Rubella Virus IgG	CLS 129 G2
SERION ELISA AI <i>control</i> 2 Varicella-Zoster Virus IgG	CLS 104 G2
SERION ELISA AI <i>control</i> 2 Herpes Simplex Virus 1/2 IgG	CLS 105 G2