



SERION ELISA *classic*

# TBE Virus IgG/IgM

## Intended use

- Qualitative and quantitative detection of human IgG and IgM antibodies in serum, plasma or cerebrospinal fluid (CSF) directed against TBE Virus
- Detection of IgM antibodies for determination of acute infections
- Detection of IgG antibodies for determination of the immune status

## Diagnostic Efficiency

The SERION ELISA *classic* TBE Virus IgG and IgM immunoassays were validated by the analysis of more than 145 serum samples from blood donors and patients with suspected TBE Virus infection in comparison with an assay from another manufacturer.

Product	Sensitivity	Specificity
SERION ELISA <i>classic</i> TBE Virus IgG	>99 %	96.1 %
SERION ELISA <i>classic</i> TBE Virus IgM	>99 %	>99 %

## Precision

### SERION ELISA *classic* TBE Virus IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.360	2.0	0.416	7.6
Serum 2	0.860	2.1	1.022	5.8
Serum 3	1.543	1.8	1.802	6.2

## SERION ELISA *classic* TBE Virus IgM

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.454	7.9	0.586	7.0
Serum 2	1.777	3.8	1.457	4.8
Serum 3	2.122	3.1	2.467	3.7

### Pathogen

TBE Viruses can be transmitted to humans by infected ticks and may cause the so called tick-borne encephalitis (TBE). They belong to the human pathogenic species among the flaviviruses. Of particular note is the highly immunogenic envelope protein E, embedded in the surface of the virus. TBE Viruses are distributed throughout Europe and Asia. Depending upon their distribution, the three TBE Virus variants are referred to as the Central European, Siberian or Far Eastern subtype.

### Disease

The majority of TBE Virus infections remain clinically asymptomatic. In 30 % of cases, a biphasic course of disease starts with the onset of flu-like symptoms following an incubation period of 7 to 14 days. After a fever-free interval of one week, 10% of patients go on to develop encephalitis or meningoencephalitis, occasionally with long-lasting neurological symptoms. The majority of patients recover fully, even when the infection takes a severe course. However, there is a morbidity rate of around 1 % for patients with

CNS involvement. A naturally acquired infection usually leads to life-long immunity. In contrast, immunization results in limited immune protection and should be refreshed at regular intervals.

### Diagnosis

Cultivation of the TBE Virus is complex, time consuming and requires special safety precautions. Direct pathogen detection by RT-PCR is possible at the onset of disease, however, a negative result does not rule out a TBE Virus infection. As a consequence, the determination of pathogen-specific antibodies by ELISA is recommended for laboratory confirmation of TBE Virus infections. The combined demonstration of IgG and IgM antibodies directed against TBE Virus, a significant increase in antibody activity by the analysis of serum pairs or the detection of intrathecally synthesized IgG or IgM antibodies serve to confirm an infection.

## Highlights

- Use of a preparation of the envelope protein E of TBE Virus
- Sensitive demonstration of IgM antibodies for the detection of acute primary infections
- IgG detection for confirmation of contact with the pathogen as well as for immune status determination and epidemiological studies
- Evaluation of IgG antibody activity referenced to the first standard serum for human IgG antibodies against TBE Viruses of the Consultant Laboratory for TBE Viruses located at the Robert Koch Institute, Berlin, Germany
- Precise quantification of the IgG and IgM antibody activity for disease stage monitoring and therapy control
- Detection of intrathecally synthesized IgG and IgM antibodies for CSF diagnostics

Product	Order No.
SERION ELISA <i>classic</i> TBE Virus IgG	ESR112G
SERION ELISA <i>classic</i> TBE Virus IgM	ESR112M

### SERION ELISA *control*

Please visit our website for more information.

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