

recomWell FSME / TBE Virus IgG

recomWell FSME / TBE Virus IgM

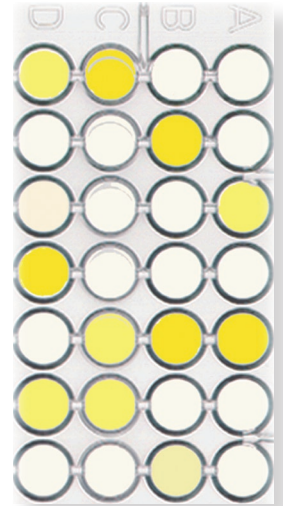
Enzyme immunoassay for the detection of IgG and IgM antibodies against tick-borne encephalitis (TBE) virus in human serum, plasma or CSF

TBE virus is a member of the Flaviviridae family. The virus is transmitted to humans by hard ticks, with *Ixodes ricinus* as the most important species in Europe. Transmission by virus infected milk from goat, sheep or cow is only rarely observed.

The major part of all TBE virus infections is without any clinical symptoms. The incubation time is 4 - 6 days. About 30 % of infected persons show a mono- or biphasal course of the disease: typical symptoms of the first viremia phase are flu like symptoms (mild fever, headache and vomitus). After an afebrile period of about one week about 10% of infected persons are showing an isolated Meningitis or Menigoencephalitis accompanied by high fever and vomitus. Lethality in Europe varies between 0,5 % and 2 %.

Active vaccination is the most effective form of prophylaxis against TBE infection. At least four different vaccines are currently available which are all made from purified and formaldehyde-inactivated virus. In Germany, cases in which the virus is detected either directly or indirectly are notifiable according to § 7, para 1 IfSG.

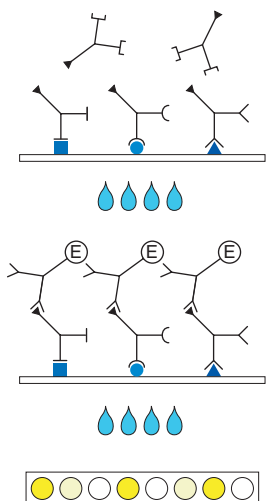
Enzyme immunoassays like the *recomWell FSME / TBE Virus* are mainly used for serological testing in routine labs.



Product Advantages

- *recomWell FSME / TBE Virus* and *recomWell Borrelia*, the diagnosis of tick-borne diseases from a single source
- Test procedure and reagents identical in all MIKROGEN ELISA - reagents exchangeable
- Standardised CSF serum analysis available - CE certified instruction for use
- Software for the calculation of the antibody index
- Easy to quantify
- Break-a-part: single sample examination possible
- Easy test procedure; automation possible
- CE label: The *recomWell FSME /TBE Virus* tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

Test Principle and Procedure



Indirect sandwich ELISA.

Microtitre plates are coated with inactivated TBE virus antigen.

1st Incubation Add patient samples diluted 1:101 (sample: 10 µl of serum or plasma), incubate for **1 h at 37 °C**.

wash 4 times

2nd Incubation Add peroxidase conjugated anti-human IgG or IgM antibodies (conjugate), incubate for **30 min at 37 °C**.

wash 4 times

Color reaction Add ready-to-use TMB solution and incubate for **30 min at room temperature**. Stop the substrate reaction with H_3PO_4 and measure the extinction at 450 nm.

Evaluation

Diagnostic sensitivity and specificity

	<i>recomWell</i> FSME / TBE Virus	
	IgG	IgM
Diagnostic sensitivity ¹	100 % (155/155)	100 % (133/133)
Diagnostic specificity ²	100 % (124/124)	100 % (196/196)

¹Clinically defined samples consistently tested reactive (i.e. positive or borderline) by 5 commercially available comparative tests (ELISA), Origin: Landesamt für Gesundheit und Lebensmittelsicherheit, Oberschleißheim.

²Consistently tested negative by 2 commercially available comparative tests (ELISA), Origin: Bavarian Red Cross, Wiesentheid.

Relative agreement

	<i>recomWell</i> FSME / TBE Virus	
	IgG	IgM
Positive agreement ¹	96,6 % (225/233 ²)	96,8 % (149/154 ²)
Negative agreement ¹	97,9 % (139/142)	94,1 % (208/221)

¹Positive and negative agreement was determined using a legally marketed ELISA.

²Samples with a „borderline“ test result were regarded as positive.

Seroprevalence

	<i>recomWell</i> FSME / TBE Virus IgG		<i>recomWell</i> FSME / TBE Virus IgM	
	Seropositive	Seronegative	Seropositive	Seronegative
Blood donors	33,0 % (66/200)	67,0 % (134/200)	0,0 % (0/200)	100,0 % (200/200)

Seroprevalence for FSME / TBE Virus in the examined blood donors was determined by two commercially available comparative tests (ELISA) for IgG with 32,5% and 36,5% and for IgM with 1,0% and 1,5% respectively. Origin of the samples: Bavarian Red Cross, Wiesentheid. Seroprevalence is strongly dependent on the origin of the samples. For IgG it may also depend on vaccination titre.

Article No.

6504 ***recomWell* FSME / TBE IgG**
Reagents for 96 determinations

6505 ***recomWell* FSME / TBE IgM**
Reagents for 96 determinations

Storage and Shelf Life

At 4 °C 12 months from the date of production