

GENSPEED

BIOTECH



FSME IgG xPOC Antibodytest
rapid detection of specific antibodies
on site in laboratory quality



www.genspeed-biotech.com

FSME IgG xPOC test system

The GEN SPEED® FSME IgG xPOC is an in vitro diagnostic for the semi-quantitative detection of FSME (TBE, tick-borne encephalitis) specific immunoglobulin G from human capillary blood samples. The test can be performed with 20 µL of blood from the fingertip in only 20 minutes in laboratory quality.

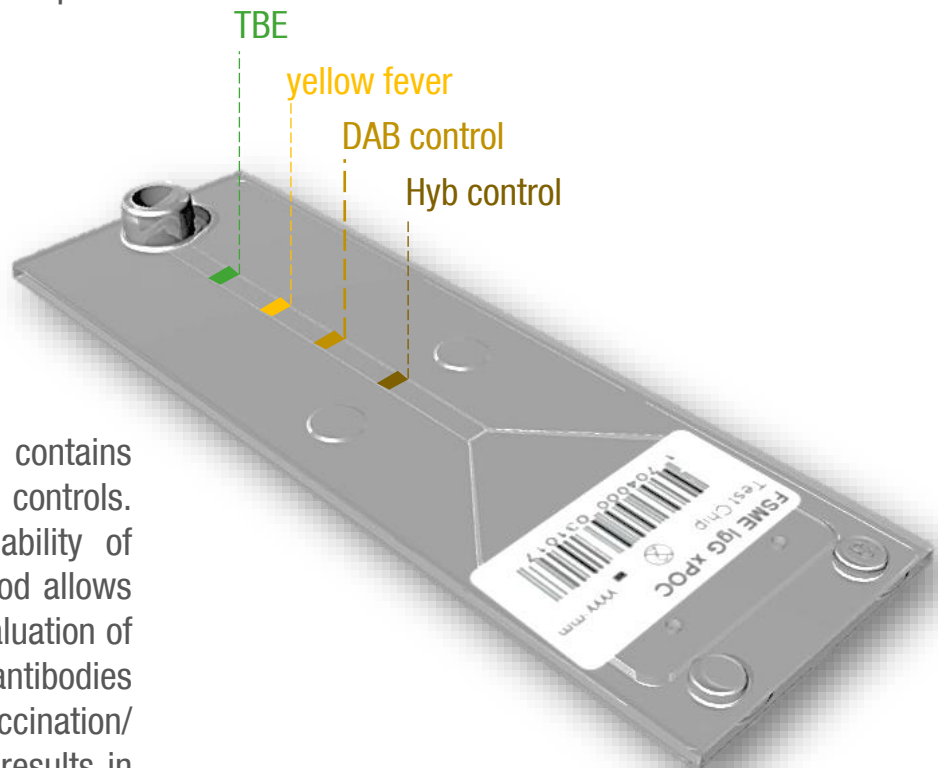
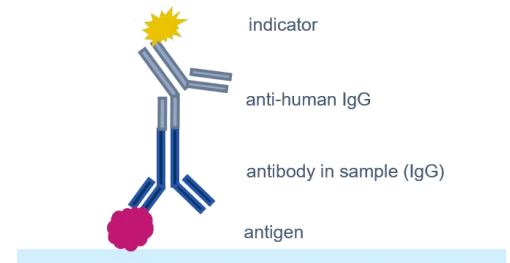
This is made possible by the patented GEN SPEED® micro-ELISA technology. The combined use of microfluidics and state-of-the-art optical readout technology reduces the test time of a standard laboratory ELISA from 2 - 4 h to only 20 minutes with comparable quality. The GEN SPEED® system is compact, fully automated and can be used practically anywhere.

The GEN SPEED® R2 Analyzer comes with a tablet (incl. keyboard), is powered via USB and the pre-installed software accounts for the intuitive operation.



FSME IgG xPOC test chip

The biochemical testing principle of the GENSPEED® FSME IgG xPOC is similar to that of a miniaturised laboratory ELISA (see top right). Immobilised specific antigens act as capture molecules. If antibodies (in this case immunoglobulin G, IgG) are present in the sample, they bind to the antigens and are subsequently labelled by a secondary detection antibody that allows optical detection.



Every FSME IgG xPOC test chip contains integrated performance controls. In order to further improve reliability of results the special detection method allows analysis and - when required - evaluation of other antibodies; especially antibodies against yellow fever (from vaccination/disease) which could cause false results in laboratories.

FSME IgG xPOC

Features and advantages

- ❑ Measurement from one drop of blood (20 µL) from the fingertip, which can be used for testing FSME as well as COVID-19
- ❑ Results within 20 minutes
- ❑ 99,3% sensitivity ¹
- ❑ 100% specificity ¹
 - The special detection method allows analysis and - when required - evaluation of other antibodies; especially antibodies against yellow fever which could cause false results in laboratories
 - No interference with antibodies against other flaviviruses
- ❑ Information on individual antibody titre
 - Semi-quantitative result with concentration ranges in the international standardized unit *Vienna Units pro Milliliter (VIEU/mL)*
 - Individual follow-up and monitoring of the immune status

Laboratory Results				
Antibody type	Concentration Range (VIEU/mL)	not detected	low	high
FSME IgG	> 1000			
Result: Neutralizing Antibodies against FSME - DETECTED				

¹ Results from the clinical comparison study with laboratory-ELISA EUROIMMUN Anti-FSME Virus ELISA "Vienna" (IgG) - CE IVD

FSME IgG xPOC procedure

The GENSPEED® FSME IgG xPOC test is very easy to perform (see quick guide below). The pre-installed GENSPEED® Immuno Report software guides the user step by step through the measurement procedure from sample collection to the result. The test result report is available electronically as a PDF file and can be sent to the patient by e-mail, or simply printed and handed over.

1

Finger prick
Use the included safety lancet [L] to prick the sterilized area of the finger tip.

2

Blood collection
Fill the included Minivette® [M] with capillary blood up to the white stopper.

3

Blood transfer
Transfer the **entire** content of the Minivette® [M] into a tube containing Solution A [A].

4

Mixing and filtration
Place the filter dropper [F] into the tube opening, mix the liquid by hand and apply 1 drop into the test chip inlet [T]. Close the drawer.

5

Incubation and measurement
Apply 1 drop of Solution B [B] into the test chip inlet [T] when the drawer re-opens. Close the drawer to start the measurement.

6

Automatic analysis and report
The assay is performed automatically by the GENSPEED R2. The results report appears in PDF format.

19. March 2022 - 10:16

Dr. Max Mustermann

Dr. Max Mustermann

GENSPEED FSME IgG

Patient:	Max Mustermann	Patient-ID:	
Address:		Insurance-Nbr.:	1111111111
Birthdate:	11. November 2011	Sex:	male

Laboratory Results

Antibody type	Concentration Range (mIU/mL)	not detected	low	high
FSME IgG	> 1000			

Result: Neutralizing Antibodies against FSME - DETECTED

FSME IgG xPOC test kit

- test in laboratory quality and CE-IVD certified
- all consumables included
- ready-to-use reagents



Product overview FSME IgG xPOC antibodytest

Art. No.	Description	
IATK216	FSME IgG xPOC test kit	25 analyses
GSHW104	GENSPEED Test System Immuno - GENSPEED R2 Analyzer - Tablet incl. GENSPEED Immuno Report Software	1 system

For more information, please visit our website www.genspeed-biotech.com

Genspeed Biotech GmbH
Gewerbepark 2
4261 Rainbach · Austria
E-mail: office@genspeed-biotech.com
Tel.: +43 7942 20910