Epstein-Barr Virus

MIKROGEN DIAGNOSTIK

NEW

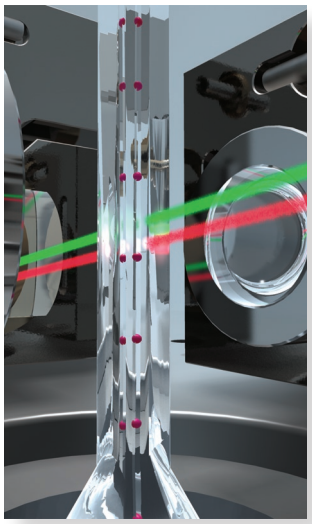
*recom*Bead EBV IgG
*recom*Bead EBV IgM

Fluorescence based particle immunoassay using recombinant antigens for the detection of IgG or IgM antibodies against Epstein-Barr Virus (EBV)

The Epstein-Barr virus, an ubiquitously occurring herpes virus, can cause the symptoms of infectious mononucleosis (Pfeiffer´s disease) on primary infection. Moreover, as a result of the lifelong persistence of this pathogen, reactivations can occur, especially in immuno-incompetent persons.

Due to the diversity of symptoms caused by EBV infection and their correspondence with the symptoms of other diseases, a secure EBV diagnosis is of great relevance for differential diagnostics. One of the main tasks in routine diagnosis is therefore the serological differentiation of a primary infection from a past infection and the exclusion of an EBV infection.

The modern Luminex® multiplex technology integrates the advantages from ELISA and strip assays: Quantitative detection of antibodies against individual antigens. Highly specific and characteristic EBV proteins are used for the multiplex *recom*Bead EBV test systems. A classification of the different stages of infection (primary infection, past infection) is possible due to the consecutive appearance of antibodies against the different EBV antigens.



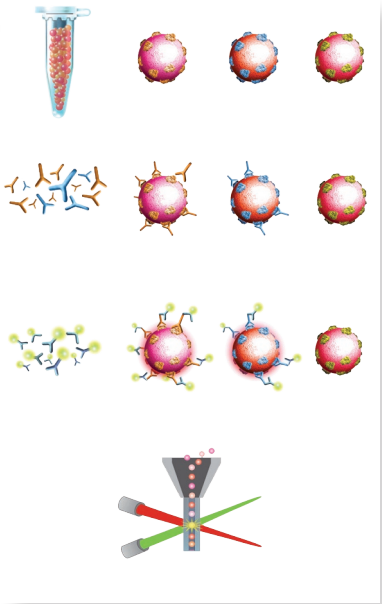
Product Advantages

- Reliable EBV screening due to recombinant antigens
  - ➢ Safe detection of past infections due to the very high specificity with the diagnostic EBV key antigen EBNA-1
  - ➢ Safe detection of acute EBV infections already in the early phase due to the optimized antigen combination in the *recom*Bead EBV IgG and *recom*Bead EBV IgM test systems
- Automated interpretation with feasible connection with LIMS
- Integration of advantages from ELISA and confirmation assay: Quantitative detection of antibodies against individual antigens
- Ideal screening or confirmation assay for high sample throughput
- Very high measuring accuracy and very good reproducibility of test results, therefore reliable testing of follow-up samples
- Integrated controls - no additional control samples necessary
- Small sample volume (10 µl)
- Combination of all Mikrogen *recom*Bead test systems on one plate due to unified processing and exchangeable reagents
- CE label: The *recom*Bead EBV test systems meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

Relevant EBV antigens and recombinant analogs

EBV antigen groups	Abbreviation	Recombinant antigen	Usage
Nuclear antigen	EBNA-1	p72	IgG
Virus capsid / structural antigen	VCA	p23 p18	IgG IgG, IgM
„Immediate Early Antigen“	IEA	BZLF1	IgG, IgM
„Early Antigen“	EA	p54 p138	IgG, IgM

Test Principle and Procedure



1st Incubation — Microspheres coated with EBV specific antigens are incubated with diluted serum or plasma for **60 min**.

wash 3 times

2nd Incubation — Phycoerythrin marked anti-human antibodies (IgG or IgM specific) are added. Incubate for **30 min**.

Aspirate and add system fluid

Measurement — Either with Luminex® 100™ or Luminex® 200™ system

Evaluation

Diagnostic Sensitivity

	*recom*Bead EBV IgG				*recom*Bead EBV IgM
	EBNA-1	VCA		EA + IEA	
	Past infection* (n=499)	Acute infection (n=112)	Past infection (n=575)	Acute infection (n=112)	Acute infection (n=92)**
negative	0	71	1	5	0
positive	499	41	574	107	92
Sensitivity	100 %	36,6 %	99,8 %	95,5 %	100 %

* Patients with past EBV infection and anti-EBNA-1 IgG antibodies
** Patients with acute EBV infection and anti-EBV IgM antibodies

Diagnostic Specificity

	*recom*Bead EBV IgG				*recom*Bead EBV IgM
	EBNA-1		VCA	EA + IEA	
	EBV sero negative (n=142)	Acute infection (n=112)	EBV sero negative (n=142)	EBV sero negative (n=142)	EBV sero negative (n=142)
negative	142	112	142	142	142
positive	0	0	0	0	0
Specificity	100 %	100 %	100 %	100 %	100 %

Article-No

4552 — ***recom*Bead EBV IgG**
Reagents for 96 determinations

4553 — ***recom*Bead EBV IgM**
Reagents for 96 determinations

Storage and Shelf Life

At +2°C - +8°C
6 months from the date of production

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