

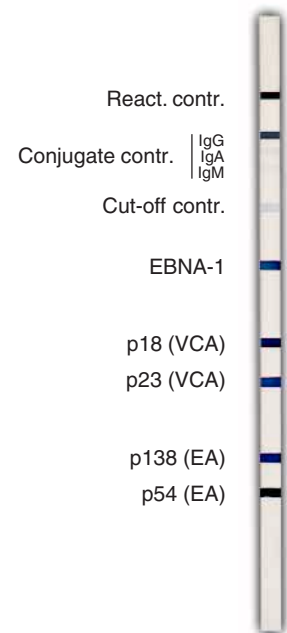
recomLine EBV IgG [Avidity] recomLine EBV IgM [IgA]

Strip-Immunoassay with antigens produced by recombinant techniques for the detection of IgG and IgM antibodies against the 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 primary infection or reactivation and their correspondence with the symptoms of other diseases, one of the main tasks in routine diagnosis is the serological detection of a primary infection, past infection or possible reactivation. For this purpose, a series of individual determinations (EIA and IFT) are generally carried out for the particular class of antigen and type of antibody.

The *recomLine* EBV, with the antigens sprayed onto the nitrocellulose, is designed as screening immunoassay. The line-assay technique allows the detection and identification of IgG and IgM antibodies directed against the different EBV antigen classes in a single approach. The application of highly specific and characteristic EBV proteins is made possible by the use of antigens produced by genetic engineering.



„The combination of p18 and EBNA-1 (in IgG detection) represents a so far unrivalled degree of certainty in the exclusion of primary infections ...“

Prof. Dr. G. Bauer, Freiburg '99

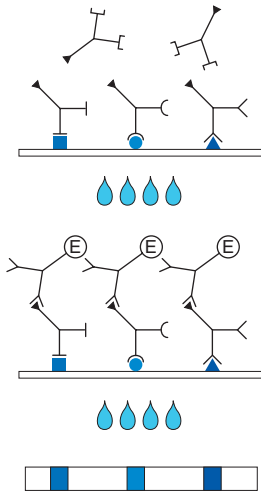
Product Advantages

- **Recombinant antigens**, therefore:
 - High sensitivity and specificity
 - Easy and clear interpretation due to easy to read bands
 - No interference with anticellular antibodies
- Easy test procedure; automation possible
- Safe evaluation due to strip specific controls (cut-off and conjugate control)
- Separate detection of IgG, IgM and IgA antibodies possible
- Easy and reliable determination of avidity possible
- Screening of different anti-EBV antibodies in a single approach
- CE label: The *recomLine* EBV tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices
- **More than 95 % of the past EBV infections are correctly identified with the *recomLine* EBV IgG strip only**

Recombinant EBV Antigens used in the Test

EBV Antigen Groups	Abbreviation	Recombinant Antigen	Size of rec. Antigens
Nuclear Antigen	EBNA-1	p 72	45 kDal
Virus capsid/structural antigens	VCA	p 23 p 18	23 kDal 18 kDal
"Early antigens"	EA	p 54 p 138	54 kDal 40 kDal

Testprinciple and Procedure



1st Incubation: A test strip loaded with EBV antigens is incubated with diluted serum or plasma in a dish for **60 min.**

wash 3 times

2nd Incubation: Peroxidase conjugated anti-human antibodies (IgG, IgM or IgA specific) are added. Incubate for **45 min.**

wash 3 times

3rd Incubation: **5 - 10 minutes** after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips occupied by antibodies.

Evaluation

In comparison to the ELISA, the *recomLine* EBV allows a more sensitive determination of the EBV status as a rule. In the following a series of different dilutions of three EBV positive sera were analysed with the *recomLine* EBV IgG as well as with commercially available EBV ELISAs. The results show, that with the *recomLine* EBV the detection of anti-EBV antibodies is usually one to two titration steps more sensitive when compared with the ELISAs. As a consequence, sera with very low anti-EBV antibody titres, that are determined false-negative with the ELISA, will be determined true-positive with the *recomLine* EBV.

Ig class contr. Cut-off contr. EBNA-1 p18 p23 p138 p54	Dilution	<i>recomLine</i> EBV IgG					ELISA cut-off index	
		EBNA-1	p18 (VCA)	p23 (VCA)	p138 (EA)	p54 (EA)	EBNA	VCA-G
	1 : 100	+++	++	++	-	-	8,36	11,60
	1 : 200	+++	++	++	-	-	8,36	9,54
	1 : 400	+++	++	++	-	-	6,23	5,76
	1 : 800	++	+	+	-	-	3,52	3,24
	1 : 1600	++	+	+	-	-	2,00	1,73
	1 : 3200	+	+	+/-	-	-	1,23	0,89
	1 : 6400	+/-	-	-	-	-	0,65	0,43
	1 : 12800	+/-	-	-	-	-	0,32	0,26
	1 : 100	+++	++	++	-	+/-	6,07	12,07
	1 : 200	++	++	++	-	-	3,84	12,07
	1 : 400	++	++	++	-	-	2,26	6,69
	1 : 800	++	+	+	-	-	1,17	3,84
	1 : 1600	+	+	+	-	-	0,65	1,97
	1 : 3200	+/-	+	+/-	-	-	0,39	1,03
	1 : 6400	+/-	-	-	-	-	0,22	0,55
	1 : 12800	-	-	-	-	-	0,15	0,29
	1 : 100	+++	+++	+++	-	-	8,83	12,07
	1 : 200	+++	+++	+++	-	-	7,15	10,62
	1 : 400	++	+++	+++	-	-	4,33	7,44
	1 : 800	++	+++	+++	-	-	2,34	4,52
	1 : 1600	+	++	++	-	-	1,42	2,64
	1 : 3200	+	++	+	-	-	0,76	1,62
	1 : 6400	+/-	+	+/-	-	-	0,41	0,86
	1 : 12800	-	+/-	+/-	-	-	0,21	0,45

The grey bars depict the serum dilution where the determination of the EBV status is still possible. The borderline ELISA results are marked with open bars.

Storage and Shelf life

At 4 °C, 18 months from the time of production

Commercial Product

Article No. 4572 ***recomLine* EBV IgG [Avidity]***
Reagents for 50 determinations

Article No. 4573 ***recomLine* EBV IgM [IgA]***
Reagents for 50 determinations

Article No. 10076 Line - anti-human IgA conjugate, 12 ml

Article No. 11010 Blot, Line - avidity reagent
Reagent for 25 avidity determinations

* [] optional available
as additional reagent

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