MIKROGEN DIAGNOSTIK

Automated Strip Interpretation recomScan

*recom*Line Parvovirus B19 IgG [Avidity]
*recom*Line Parvovirus B19 IgM

Strip-Immunoassay with antigens produced by recombinant techniques for the detection of IgG and IgM antibodies against human Parvovirus B19

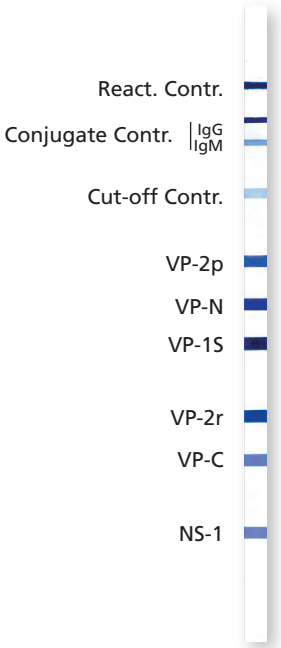
Human Parvovirus B19 occurs endemically world-wide. At intervals of several years, it causes epidemics in small areas from late fall to early summer, affecting kindergartens and schools in particular.

Its surface is formed by a protein envelope which consists of two polypeptides (VP-1 and VP-2). VP-1 differs from VP-2 only by an additional N-terminal fragment. Furthermore, a non-structural protein (NS-1) is synthesized, which is required for virus replication.

Clinical spectrum of a Parvovirus B19 infection:

- Fifth disease (erythema infectiosum): It progresses in 20% of cases without symptoms or with flu-like symptoms. Apart from the exanthema, polyarthralgia and a generalized swelling of the lymph nodes can occur occasionally.
- Aplastic crisis in patients suffering from hemolytic anemias.
- Spontaneous abortion/hydrops fetalis after infection during pregnancy.
- Persistent infection in immunosuppressed persons with chronic anemia and bone marrow depression.

By the kind of antigen pattern and the avidity determination of IgG antibodies the *recom*Line Parvovirus B19 provides an indication of the time of infection. The determination of antibodies against the NS-1 antigen can be helpful in the clarification of persistent Parvovirus B19 infections. With the use of VP-2 particles the presentation of conformational epitopes in addition to the linear epitopes is achieved.



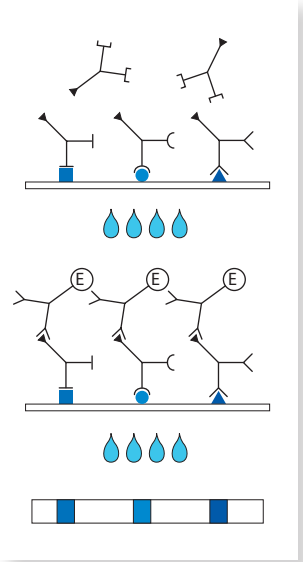
Product advantages

- Recombinant antigens
  - ➢ High sensitivity and specificity
  - ➢ Easy and clear interpretation due to easy to read bands
- Easy test procedure; automation possible
- Easy and objective strip interpretation and documentation with *recom*Scan software
- Test procedure and reagents identical in all MIKROGEN strip tests - reagents exchangeable
- Safe evaluation due to strip specific controls (cut-off and conjugate control)
- Separate detection of IgG and IgM antibodies possible
- Easy and reliable determination of avidity possible
- CE label: The *recom*Line Parvovirus B19 tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices
- **Antigen reaction pattern provides accurate determination of infection status**

Related recombinant Parvovirus B19 antigens

Parvovirus antigen	Recombinant antigen	Size [kDa]
Main capsid antigen (conformational epitopes)	VP-2p	56
N-terminal parts of structure proteins VP-1 and VP-2	VP-N	60
VP-1 specific segment (differentiation to VP-2)	VP-1S	31
Main capsid antigen (linear epitopes)	VP-2r	56
C-terminal part of structure proteins VP-1 and VP-2	VP-C	42
None structural protein NS-1	NS-1	75

Test Principle and Procedure



1st Incubation — A test strip loaded with Parvovirus B19 antigens is incubated with diluted serum or plasma in a dish for **1 hour**.

wash 3 times

2nd Incubation — Peroxidase conjugated anti-human antibodies (IgG or IgM specific) are added. Incubate for **45 minutes**.

wash 3 times

Color reaction — **8 minutes** after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips occupied by antibodies.

Examples

date	day after symptoms	*recom*Well Parvovirus B19 IgG	*recom*Well Parvovirus B19 IgM	*recom*Line Parvovirus B19	strip result	interpretation
1	2	164 U/ml positive	102 U/ml positive	IgG: ++ + - + -	positive	acute infection
				avidity: n n	low avidity	
				IgM: ++ ++ +/- ++ -	positive	
2	17	251 U/ml positive	84 U/ml positive	IgG: ++ +++ ++ +++ ++	positive	acute infection
				avidity: i n	low avidity	
				IgM: ++ ++ +/- ++ -	positive	
3	59	296 U/ml positive	33 U/ml positive	IgG: ++ +++ +++ ++ +	positive	status after infection
				avidity: h h	high avidity	
				IgM: + + - - -	positive	
4	144	219 U/ml positive	21 U/ml indeterm.	IgG: ++ +++ +++ ++ -	positive	past infection
				avidity: h h	high avidity	
				IgM: +/- - - - -	negative	
blood donor 1		positive	negative	IgG: +++ +++ +++ +/- -	positive	past infection
				avidity: h h	high avidity	
blood donor 2		positive	negative	IgG: ++ - - - -	positive	past infection
				avidity	no conclusion	

Typical Parvovirus B19 course of infection and two examples of healthy blood donors with past infections
The course of infection covers a period of approx. 21 weeks after appearance of symptoms. IgM reactivity decreased significantly between sample 2 and 3. The decrease of the VP-C IgG reactivity, the high avidity and the appearance of NS-1 IgG antibodies indicate a status after infection (sample 3). High avidity appears earliest 4 weeks after infection. NS-1 antibodies titers appear only six to eight weeks after infection, but not in all patients. In a study samples from blood donors were tested, 66% were IgG positive. Many samples presented this typical antigens pattern in past infections as shown. In Germany the infection rate in adults is about 60% and in children between 15-30%.

Article-No

4472	***recom*Line Parvovirus B19 IgG [Avidity]*** Reagents for 20 determinations
4473	***recom*Line Parvovirus B19 IgM** Reagents for 20 determinations
11010	**Avidity reagent** Reagent for 25 avidity determinations

*[] optional available as additional reagent

Storage

At +2°C - +8°C

MIKROGEN GmbH | Floriansbogen 2-4 | 82061 Neuried | Germany | Tel.: +49 89 54801-0 | Fax: +49 89 54801-100
www.mikrogen.de | mikrogen@mikrogen.de