

Instruction For Use Borrelia Vet. Hund/Dog IgM-Set

REF: DC122K80

Accessory to VIROTECH Borrelia Vet. Hund/Dog-Pferd/Horse IgG ELISA

REF: DC122.00

FOR IN VITRO DIAGNOSTICS ONLY
For professional use only

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1. Intended purpose

Detection / Measurement	For use with Borrelia Vet. Hund/Dog-Pferd/Horse IgG ELISA product from Virotech Diagnostics
Function	aid to diagnosis
Classification	n/a
Automation	n/a
Type	qualitative
Specimen	serum of a dog
Testing population	dogs
Intended user	specialised personnel in laboratories

Accessory to:

VIROTECH Borrelia Vet. Hund/Dog-Pferd/Horse IgG ELISA, species B. burgdorferi sensu stricto (DC122.00)

2. Package Contents

1. **IgM Konjugat/Conjugate (anti-Hund/Dog) ELISA, 11ml**, Goat horseradish peroxidase conjugate, contains preservative
2. **Borrelia Vet. Hund/Dog IgM ELISA Cut off Ctrl., 1300µl**, with protein stabilisers and preservative
3. Quality Control Certificate
4. Labversion of IFU
5. Hazard information
6. Test Procedure Scheme

The SDS is available at: www.virotechdiagnostics.com

3. Storage and stability of the components

Store the IgM-conjugate and the control at 2-8°C.

The ready-to-use conjugate is light-sensitive and should be stored in the dark.

4. Warnings and precautions

1. The preservative may be irritating to the skin, eyes and mucous membranes. In case of contact, wash the affected parts of the body immediately under running water and consult a doctor.
2. All specimens, diluted specimens and the conjugate should be considered as potentially infectious material and handled with care. The respective guidelines for laboratory work apply.

5. Test Procedure

For the detection of IgM dog antibodies against Borrelia, the Borrelia Vet. Hund/Dog-Pferd/Horse IgG ELISA product from Virotech Diagnostics is required (**REF**: DC122.00).

The test procedure is performed with dog serum as described in the instruction for use of the ELISA. The only difference is that the anti-dog IgM conjugate and the IgM cut-off control are used instead of the anti-dog IgG conjugate and the IgG cut-off control.

The working dilution of the dog serum is: 1:400; e.g., pre-dilution: mix 10µl serum + 90µl dilution buffer (1:10); further dilution: take 10µl of this mixture and pipette 390µl dilution buffer to it (1:40). This corresponds to a 1:400 dilution.

The ready-to-use IgM cut-off control may only be used on the corresponding parameter-specific and lot-specific plate lot. This is stated on the Quality Control Certificate.

6. Results

Virotech units (VE)

The Virotech units (VE) of the cut-off controls are defined as 10 VE

Calculation of the Virotech Units (VE)

The concentration of the result is given in Virotech units = VE.

The absorbance of the blank (450/620nm) must be subtracted from all absorbances.

$$\text{VE (dog serum)} = \frac{\text{OD (dog serum)}}{\text{OD (cut-off control)} \times 2} \times 10$$

The OD value of the IgM cut-off control must be >0.220 OD. If this requirement is not met, the test must be repeated.

7. Interpretation of results

result (VE)	evaluation
< 8.0	negative
8.0 – 12.0	borderline
> 12.0	positive

1. If the measured VE of the sample is above 12 VE, the sample is considered positive.
2. If the measured VE are within the indicated grey range, there is no significantly high antibody concentration; the samples are considered borderline.

For the reliable detection of an infection, it is necessary to determine the antibody content of two serum samples: one serum sample should be tested immediately after the onset of infection, a second sample two weeks later. The antibody concentration of both samples must be determined in parallel, i.e., in one test set. A correct diagnosis based on the evaluation of a single serum sample is not possible.

3. If the measured values are below the defined grey range, no measurable antigen-specific IgM antibodies are present in the sample. The samples are considered negative.

8. Limits of the assay

1. Hyperlipaemic, haemolytic and/or microbially contaminated samples may cause false positive or false negative results.
2. The interpretation of serological results should always consider the clinical picture, epidemiological data and possibly other available laboratory findings.
3. The relevance of IgM borreliosis serology in dogs has not yet been conclusively clarified.

9. Disposal considerations









Reagent

Chemicals and preparations, as well as their containers, are generally hazardous waste. Their disposal is subject to national waste legislation and regulations. The competent authority provides information on the disposal of hazardous waste.

Information on Packaging Materials

 PAP 22	 Plastics HDPE 2	 PP 5	 LDPE 4	 Glass GL 72
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10. Symbol key

	Manufacturer
	In vitro diagnostics
	Production lot number
	Usable until
	Temperature limit
	CE marking
	Article number
 Hinweis auf eIFU	Follow the Instruction for Use http://ifudownload.virotechdiagnostics.com