

Borrelia ViraStripe® IgG Test Kit

Stripe-Immunoblot for the qualitative detection of **IgG** antibodies against specific **Borrelia species** antigens in human serum or cerebrospinal fluid. For using the **Borrelia ViraStripe® IgG Testkit** with cerebrospinal fluid (CSF) as sample material the corresponding, separately available instruction for use has to be considered.

The Borrelia ViraStripe® IgG Testkit is an **immunoblot** based on an enzyme-immunoassay in the line/strip format, carrying highly purified specific native antigens from *Borrelia afzelii* (Pko) and *Borrelia burgdorferi sensu stricto* as well as recombinant VIsE. The Borrelia ViraStripe® IgG Testkit is manufactured according to the guidelines **98/79/EG** and **DIN 58967-40**.

The Borrelia ViraStripe® IgG Testkit fulfils the quality standards of the microbiological-infectiological guidelines ("**MiQ**" **12/2000**), the general DIN recommendation (**DIN 58967-40**) and can be evaluated according to "**MiQ**" **12/2000** (18) and **DIN 58969-44** (5) criteria. These guidelines postulate a two-band criterion for a positive result and describe special requirements for the detection of antibodies against *Borrelia burgdorferi*.

Principle of the assay

During the serum incubation step *Borrelia* specific IgG antibodies bind to the immobilised antigens on the test strip. During the conjugate reaction, AP-conjugate binds to the antigen-antibody complex. The alkaline phosphatase converts the chromogen/substrate and thus, stains the antigen-antibody complex on the test strip purple. The washing procedures following serum, conjugate and chromogen/substrate incubation steps remove unbound antibodies and reagents.

The green separation line divides the test strip into a control section and an analytical section. The control section contains the **negative control band**, the **serum control**, **three conjugate controls** (IgG, IgA, IgM) and the **cut off control**.

The test strip code for Borrelia ViraStripe® IgG test strips is **BG**. Test strips are numbered from **01** to **50**. The analytical section contains the *Borrelia* specific antigens.

Order No.:	V-BSSGOK	Order No.:	V-BSSGDK (Deca Kit)
Kit size:	1x 50 test strips	Kit size:	10x 50 test strips
Specimen:	20 µl serum	Specimen:	20 µl serum
Time for testing:	approx. 90 minutes	Time for testing:	approx. 90 minutes

Materials provided

1x or 10x 50 test strips	Borrelia ViraStripe® Antigen Strips (IgG) Test strips including a control section and <i>Borrelia</i> specific antigens in the analytical section, ready to use	(Prod. No.: V-BSSGAS)
1x or 10x 9 ml	ViraStripe® / ViraBlot® AP-Anti-Human IgG Conjugate Concentrate , goat	(Order No.: V-UVNGKI)
1x or 10x 100 ml	ViraStripe® / ViraBlot® Diluent / Wash Buffer 10x concentrate	(Order No.: V-UVNUWP)
1x or 10x 5 g	ViraStripe® / ViraBlot® Diluent / Wash Powder	(Order No.: V-UVNUMP)
1x or 10x 90 ml	ViraStripe® / ViraBlot® Chromogen / Substrate Solution Ready to use	(Order No.: V-UVNUCS)
1 or 10 copies	Evaluation Protocol for Borrelia ViraStripe® IgG Testkit	

Additionally available

330 µl	Borrelia ViraStripe® IgG Positive Control Human, ready to use	(Order No.: V-BSSGPK)
330 µl	Borrelia ViraStripe® IgG,A,M Negative Control Human, ready to use	(Order No.: V-BSSPNK)
50 copies	Borrelia ViraStripe® IgG evaluation protocols for automated interpretation with ViraScan® software	(Order No.: V-BSSGEP)

Preparation of reagents and patient samples

Bring all reagents to room temperature (20-25°C) prior to use. Information about stability can be found on page 5.

Diluent / Wash Buffer Working Dilution: Dilute **Diluent / Wash Buffer Concentrate 1:10** with distilled or deionised water (100 ml concentrate + 900 ml water). Add Diluent / Wash Powder completely and stir well until all powder is dissolved. If needed, place onto a magnetic stirrer for 10-15 minutes. The pH value should be around pH 7.5 at 20°C.

Antigen Strips: Carefully separate the required number of test strips by use of **forceps** at the **label** and place the test strips in the prepared incubation tray (see assay procedure, step 2). Use test strips directly after removing from packing. Do not touch test strips by hand. Return unused test strips directly into the original packing, seal well and store at 2-8°C.

Patient samples: Use **20 µl patient serum** undiluted per test strip.

Controls: Use **100 µl of Positive Control** or **100 µl of Negative Control** undiluted per test strip respectively.

Conjugate Working Dilution: Prepare **Conjugate Concentrate 1:10** with Diluent / Wash Buffer Working Dilution (see table 1). Prepare freshly prior to each test run. Do not store for further use.

Chromogen / Substrate Solution: Ready to use.

Borrelia ViraStripe® IgG Test Kit

- 2 -

Preparation of Conjugate Working Dilution IgG

Number of strips	Diluent / Wash Buffer Working Dilution	Conjugate Concentrate	Final volume	Number of strips	Diluent / Wash Buffer Working Dilution	Conjugate Concentrate	Final volume		
1	1.35 ml	+	0.15 ml	1.5 ml	26	35.10 ml	+	3.90 ml	39.0 ml
2	2.70 ml	+	0.30 ml	3.0 ml	27	36.45 ml	+	4.05 ml	40.5 ml
3	4.05 ml	+	0.45 ml	4.5 ml	28	37.80 ml	+	4.20 ml	42.0 ml
4	5.40 ml	+	0.60 ml	6.0 ml	29	39.15 ml	+	4.35 ml	43.5 ml
5	6.75 ml	+	0.75 ml	7.5 ml	30	40.50 ml	+	4.50 ml	45.0 ml
6	8.10 ml	+	0.90 ml	9.0 ml	31	41.85 ml	+	4.65 ml	46.5 ml
7	9.45 ml	+	1.05 ml	10.5 ml	32	43.20 ml	+	4.80 ml	48.0 ml
8	10.80 ml	+	1.20 ml	12.0 ml	33	44.55 ml	+	4.95 ml	49.5 ml
9	12.15 ml	+	1.35 ml	13.5 ml	34	45.90 ml	+	5.10 ml	51.0 ml
10	13.50 ml	+	1.50 ml	15.0 ml	35	47.25 ml	+	5.25 ml	52.5 ml
11	14.85 ml	+	1.65 ml	16.5 ml	36	48.60 ml	+	5.40 ml	54.0 ml
12	16.20 ml	+	1.80 ml	18.0 ml	37	49.95 ml	+	5.55 ml	55.5 ml
13	17.55 ml	+	1.95 ml	19.5 ml	38	51.30 ml	+	5.70 ml	57.0 ml
14	18.90 ml	+	2.10 ml	21.0 ml	39	52.65 ml	+	5.85 ml	58.5 ml
15	20.25 ml	+	2.25 ml	22.5 ml	40	54.00 ml	+	6.00 ml	60.0 ml
16	21.60 ml	+	2.40 ml	24.0 ml	41	55.35 ml	+	6.15 ml	61.5 ml
17	22.95 ml	+	2.55 ml	25.5 ml	42	56.70 ml	+	6.30 ml	63.0 ml
18	24.30 ml	+	2.70 ml	27.0 ml	43	58.05 ml	+	6.45 ml	64.5 ml
19	25.65 ml	+	2.85 ml	28.5 ml	44	59.40 ml	+	6.60 ml	66.0 ml
20	27.00 ml	+	3.00 ml	30.0 ml	45	60.75 ml	+	6.75 ml	67.5 ml
21	28.35 ml	+	3.15 ml	31.5 ml	46	62.10 ml	+	6.90 ml	69.0 ml
22	29.70 ml	+	3.30 ml	33.0 ml	47	63.45 ml	+	7.05 ml	70.5 ml
23	31.05 ml	+	3.45 ml	34.5 ml	48	64.80 ml	+	7.20 ml	72.0 ml
24	32.40 ml	+	3.60 ml	36.0 ml	49	66.15 ml	+	7.35 ml	73.5 ml
25	33.75 ml	+	3.75 ml	37.5 ml	50	67.50 ml	+	7.50 ml	75.0 ml

Table 1: 1:10 dilution of conjugate concentrate with Diluent / Wash Buffer Working Dilution

Assay procedure

- Rinse incubation tray channels once with 1.5 ml Diluent / Wash Buffer Working Dilution, decant the liquid**
Mark the trays with water-resistant pen. Rinsing removes dust particles.
- Place the needed amount of test strips into the incubation tray - one test strip per channel**
For each patient serum and each control, carefully separate one test strip by use of forceps at the label and place them into the incubation tray channels. **The side showing the green separation line and the label must face up.**
- Add 1.5 ml Diluent / Wash Buffer Working Dilution and incubate by rocking for 5 minutes at room temperature (RT)**
Make sure the test strips are completely covered with liquid. Use a 2D rocker with a rocking frequency of approx. 40/min. Avoid spilling of liquid. **Do not decant the liquid after incubation.**
- Add 20 µl of each patient serum or 100 µl of each control**
Add patient sera and controls directly onto the labelled end of the test strips while the 2D rocker is running or make sure to tilt the incubation tray after adding each serum.
- Incubate by rocking for 30 minutes at RT**
Make sure the test strips are completely covered with liquid. Use a 2D rocker with a rocking frequency of approx. 40/min.
- Decant the liquid**
Carefully tap the incubation tray on absorbent paper to remove the remaining liquid. **Test strips adhere to the incubation tray when liquid is decanted.**
- 3 x washing:**
- add 1.5 ml Diluent / Wash Buffer Working Dilution
- incubate by rocking for 5 minutes at RT
- decant the liquid
Wash on the 2D rocker. Carefully tap the incubation tray on absorbent paper to remove the remaining liquid.
- Add 1.5 ml fresh Conjugate Working Dilution**
Make sure the test strips are completely covered with Conjugate Working Dilution
- Incubate by rocking for 15 minutes at RT**
Make sure the test strips are completely covered with liquid. Use a 2D rocker with a rocking frequency of approx. 40/min.
- Decant the liquid**
Carefully tap the incubation tray on absorbent paper.
- 3 x washing as in step 7**
Wash on the 2D rocker.
- Add 1.5 ml distilled or deionised water and incubate by rocking for 1 minute at RT**
Make sure the test strips are completely covered with liquid. Use a 2D rocker with a rocking frequency of approx. 40/min.
- Decant the liquid**
Carefully tap the incubation tray on absorbent paper.
- Add 1.5 ml Chromogen / Substrate Solution**
Make sure the test strips are completely covered with liquid.
- Incubate by rocking at RT**
Stop the reaction as soon as the cut off control becomes visible. **The Cut off control is located in the test strip control section. Caution:** Prolonged incubation causes background staining.
- Stop the reaction by decanting the liquid**
Carefully tap the incubation tray on absorbent paper.
- Wash 3 x with 1.5 ml distilled or deionised water**
Wash without incubation time.
- Dry test strips for interpretation**
Carefully tap the incubation tray on absorbent paper to remove the remaining liquid. Place wet test strips with forceps on unbleached absorbent paper and allow to air dry before interpretation.

Assay interpretation

1. Evaluation protocol: Record data on the evaluation protocol. Glue the test strips on the evaluation protocol. Place the green separation line of the test strips exactly onto the separation line printed on the evaluation protocol.
2. Validity of test strips: A test strip is considered as valid if the following bands are visible:
 - The **serum control**.
 - The **conjugate control** of the conjugate class being used. If more than one of the three conjugate controls becomes visible, the strongest band must indicate the appropriate conjugate class.
 - The **cut off control**.

and if the following band is **not** visible:

 - The **negative control band**.

Do not assess invalid test strips!
3. Assignment of antigen bands: The green separation line of the test strips indicates position and orientation for the assignment of bands with the bandlocator on the evaluation protocol. Assign bands and record results according to 4.
4. Assessment of bands: According to quality laboratory guidelines, the use of a cut off control for each run is recommended (16). **The cut off control of the Borrelia ViraStripe® IgG is located in the control section on each test strip.** The intensity of the cut off control indicates the threshold of which bands are being assessed:
 A band is considered as **distinct** if its intensity is **equal** to or **higher** than the intensity of the cut off control. Mark bands with **X** in the evaluation protocol appropriately.
 A band is not assessed if it is **not present** or if its intensity is **lower** than the intensity of the cut off control.
5. Interpretation of patient bands: Patient bands have to be considered as symptoms of the disease. A final clinical diagnosis should always be made considering anamnesis, clinical manifestations and laboratory data (24).
 “If the pattern of reactive bands meets the specific conditions, the result is positive, i.e. the positive result of an EIA or another test of the first step is confirmed. If, despite the presence of specific diagnostic bands, the criteria for a positive result are not fulfilled, the result is considered equivocal. In such a case a follow-up control may be recommended.” (18)
 Bands of the following antigens are considered as **highly specific** for Borrelia species:
p83, p58, p43, p39, p30, OspC, p21, Osp17/DbpA, p14 and VlsE.

IgG Interpretation criteria

General note: Distinct bands must have a minimum intensity (\geq cut off), which has to be determined by the cut off control. The cut off control is located in the control section of each test strip.

Identified bands	Result	Interpretation
At least two distinct bands out of: p83, p58, p43, p39, p30, OspC, p21, Osp17 or DbpA, p14, VlsE	Positive	Specific antibodies against Borrelia species detectable. An infection with Borrelia species is probable.
One distinct VlsE band	Equivocal	Specific antibodies against VlsE detectable. An infection with Borrelia species is possible. If a recent infection is suspected, check additionally for IgM antibodies. If possible test a second sample for IgM and IgG specific antibodies after 2-3 weeks.
One or no distinct bands (Exception: singular VlsE band)	Negative	No specific antibodies against Borrelia species detectable. If an infection is suspected, check a second sample for IgM and IgG specific antibodies after 2-3 weeks.

IgG test strip

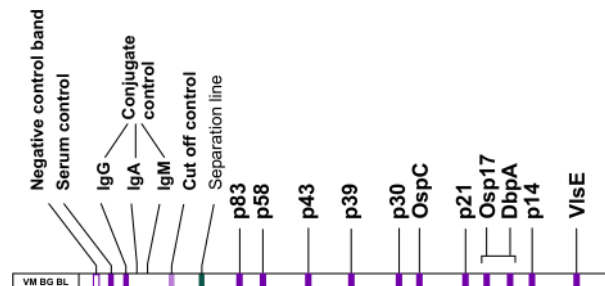


Figure 1: Schematic drawing of a Borrelia ViraStripe® IgG test strip in full scale.

Nomenclature and description of Borrelia species bands from literature

Band nomenclature:	Antigen:	Comments:
VisE	Specific VisE (Variable major protein (VMP) like sequence Expressed)	Antibodies against VisE are described as specific. IgG antibodies are already being developed at an early stage and remain until the late stage of the disease (9).
p83/100	Highly specific protein of membrane vesicles on the cell surface	Generally these antibodies appear 6-12 weeks after infection. They are typical for stage III, but might also appear in stages I and II (1,4,14,15).
p58	Specific	Protein not well characterised, separated from 60 kD (Hsp60), appears often in stage III (6).
p43	Specific	Still little characterised. Mainly described for stage III.
p39	Highly specific BmpA (Borrelia membrane protein A)	In many patients antibodies against p39 are already detectable in the early stage of the disease (1,15).
p30	Specific	At present protein not well characterised (6).
OspC	Highly specific OspC (Outer surface protein C)	At least 13 different immuno-distinct types of OspC are known (1,8,12,13,21,22).
p21	Specific	Still little characterised (3).
Osp17 / DbpA	Specific Osp17 (Outer surface protein 17) / DbpA (Decorin binding protein A)	Binding to decorin on the host cell. Antibodies against Osp17/DbpA are described as specific. The presence of IgG antibodies is associated among others with Arthritis and Neuroborreliosis. Species specific (9,10,19).
p14	Specific	Protein from Borrelia afzelii is characterised as specifically immunogenic (7).

Diagnostic significance of antibodies against Borrelia species

- IgG antibodies** are produced for the first time several weeks to months after infection and are often not detectable in early stages of infection (22). In suspicion of a recent infection, IgM antibodies should be checked and a second sample should be analysed later. Patients in the 2nd or 3rd stage of the disease are usually positive for IgG antibodies. Antibody titers decrease gradually during convalescence (22).
- IgM antibodies** usually appear 2-3 weeks after onset of the disease for the first time (22). Antibody titers often decline several weeks to months after convalescence. But they may also persist up to several years (7,11,20).
- IgA antibodies** are detectable at an early stage of borreliosis in many patients, in some cases earlier than IgM antibodies.
- The immune response and consequently the band pattern differs from patient to patient. As a general rule: The number of

- antibody types and therefore the number of specific bands is increasing with progression of the disease (1).
- An early antibiotic therapy can suppress the development of antibodies (17).
- Medication and immunoglobulin therapy can cause unspecific antibody reactions (24).
- Cross reactivities to Borrelia antigens are described for infections with Treponema, Leptospira and other bacteria with flagella (2,15,22). An acute EBV infection can cause a polyclonal stimulation of Borrelia antibodies (22). If IgM antibodies against OspC or p41 are detected without clinical symptoms for borreliosis an EBV infection needs to be tested for. Cross reactivities in cases of autoimmune diseases, MS, ALS, Influenza and Syphilis are described as well.

IgG performance data

Sensitivity:

156 sera from patients with the Lyme borreliosis manifestations Erythema migrans, Erythema chronicum migrans, multiple Erythemata migrantia, Acrodermatitis chronica atrophicans, Lyme arthritis and neuroborreliosis were assessed to determine the sensitivity of the Borrelia ViraStripe® IgG Testkit.

Stage of Lyme borreliosis	Borrelia ViraStripe® IgG, % (n)	Borrelia ViraStripe® IgG / IgM, % (n)
Erythema migrans (n= 29)	48% (14)	79% (23)
Multiple Erythemata migrantia (n= 13)	85% (11)	85% (11)
Erythema chronicum migrans (n= 27)	89% (24)	96% (26)
Neuroborreliosis (n= 24)	92% (22)	96% (23)
Acrodermatitis chronica atrophicans (n= 34)	97% (33)	97% (33)
Lyme arthritis (n= 29)	100% (29)	100% (29)

Specificity:

To determine the specificity of the Borrelia ViraStripe® IgG Testkit 129 sera from blood donors showing a negative result with a reference test (Borrelia „MiQ“ + VlsE ViraBlot® IgM and IgG Testkit) were assessed.

Collective	Borrelia ViraStripe® IgG, % (n)	Borrelia ViraStripe® IgG / IgM, % (n)
Blood donors (n= 129)	99% (128)	97% (125)

Warnings and precautions

1. All human serum components were tested for HCV, HIV1,2 antibodies and HBs antigens and found to be negative. Nevertheless, all human kit components as well as the patient samples should be considered as potentially infectious and handled according to safety precautions. While working with potentially infectious/hazardous materials, all national and international rules, regulations, guidelines and laws must be taken into account. This also applies to storage and disposal of chemicals and reagents being used.

2. While working with hazardous or toxic substances/ biological agents precautions have to be applied following national biosafety regulations. In general, biological and chemical agents should be handled according to „Good Laboratory Practice (GLP)“ guidelines. Precautions among others are:

- Do not pipette by mouth.
- Wear disposable gloves and safety glasses while working.
- Do not eat, drink or smoke in the working area.

Storage and stability of reagents

1. **Test strips:** In closed bags stable until the expiration date if stored at 2-8°C.

2. **Conjugate Concentrate:** Stable until the expiration date if stored at 2-8°C.

3. **Conjugate Working Dilution:** Prepare freshly prior to each run. Do not store for further use.

4. **Diluent / Wash Buffer Concentrate, 10x:** Stable until the expiration date if stored at 2-8°C.

3. The chromogen/substrate solution contains BCIP and NBT. Avoid contact with skin and mucous membranes. In case of contact with skin and eyes wash immediately with large quantities of water.

4. Samples and all potentially contaminated materials must be decontaminated using validated laboratory techniques, e.g. by autoclaving 20 minutes at 121°C under humid conditions. Liquid disposals can be mixed with sodium hypochlorite to a final concentration of 1% sodium hypochlorite. Incubate 30 min for complete disinfection.

5. Please refer to material safety data sheets for detailed information on potential risks, first aid guidelines, accidental release measures, handling and storage recommendations, personal protective equipment, directions for disposal and indications to toxicology.

5. **Diluent / Wash Buffer Working Dilution:** Stable for 2 weeks if stored at 2-8°C. For longer storage, aliquot and freeze at -20°C.

6. **Diluent / Wash Powder:** Stable until the expiration date if stored at 2-8°C.

7. **Chromogen / Substrate Solution:** Stable until the expiration date if stored at 2-8°C. Avoid exposure to light!

Specimen indications

1. The **Borrelia ViraStripe® IgG Testkit** must be used with human serum or cerebrospinal fluid.

2. Only clear, non-hemolysed, non-microbially contaminated specimens must be used.

3. Using icteric, lipemic, hemolytic and/or heat-inactivated serum may lead to false results.

4. Normally, human serum can be stored up to 5 days at 2-8°C. Specimens may be stored at -20°C (or below) for long term storage.

5. Prior test processing, specimens should have reached room temperature. Mix specimens carefully after thawing. Precipitates in specimens can be removed by centrifugation.

6. Avoid multiple freeze and thaw cycles.

Borrelia ViraStripe® IgG Testkit

- 6 -



















Limitation of the procedure

1. To ensure reliable results, follow carefully the Instruction for Use and "Good Laboratory Practice".
2. A positive result is based on elevated specific antibody titers and should be considered as a symptom. The correlation to a disease is only conditionally possible.
3. A negative result does not exclude a contact with the pathogen or the presence of a disease.
4. Adequately trained personnel only should perform the assay procedure.
5. The detection of specific antibodies can vary within different assays from different manufacturers and can lead to different results due to different sensitivity, specificity and assay methodologies.
6. Test strips showing a high background level should not be interpreted, especially if band intensities are lighter than the background level.
7. *In vitro* diagnostics must not be used beyond expiration date as reliable results may not be possible.
8. Efficient washing after each incubation step is essential for consistent results; insufficient washing may lead to false results.

Literature

1. AGUERO-ROSENFELD, M.: J. Clin. Microbiol. 3090-3095 (1993)
2. ALFEN, I. et al.: Lab. med. 12-19 (1994)
3. CDC/ASTPHLD: Lyme disease Workgroup Recommendations, Dearborn (1994)
4. DITTON H.J.: FEMS Microbiol. 217-230 (1992)
5. DIN 58969-44: Medical microbiology – Diagnostics of infectious diseases in serology and molecular biology, Part 44: Immunoblot (IB); Special requirements for the detection of antibodies against *Borrelia burgdorferi* (2005)
6. DRESSLER F.: J. Infect. Dis. 392-400 (1993)
7. HAUSER, U. et al.: Interpretation Criteria for Standardized Western Blots for Three European Species of *Borrelia burgdorferi* Sensu Lato, J. Clin. Microbiol. 1433-1444 (1997)
8. FINGERLE, V. et al.: J. Clin. Microbiol. 1861-1869 (1995)
9. SCHULTE-SPECHTEL, U. et al.: Significant Improvement of the Recombinant *Borrelia*-specific Immunoglobulin G Immunoblot test by addition of VisE and a DbpA homologue derived from *Borrelia garinii* for Diagnosis of Early Neuroborreliosis. J. Clin. Microbiol. (41): 1299-1303 (2003)
10. HEIKKILÄ, T. et al.: Species-Specific Serodiagnosis of Lyme Arthritis and Neuroborreliosis due to *Borrelia sensu stricto*, *B. afzelii*, and *B. garinii* by using Decorin Binding Protein A. J. Clin. Microbiol. (40): 453-460 (2002)
11. HAMMERS-BERGGREN, S.: J. Clin. Microbiol. 1519-1525 (1994)
12. JAURIS-HEIPKE, S. et al.: J. Clin. Microbiol. 1860-1866 (1995)
13. JAURIS-HEIPKE, S.: Int. Conference of Lyme Borreliosis. (1994)
14. LAM, T.: Infection and Immunity, 290-298 (1994)
15. MA, B.: J. Clin. Microbiol. 370-376 (1992)
16. RILI-BÁK: Bák-Richtlinie zur Qualitätssicherung quantitativer laboratoriumsmedizinischer Untersuchungen, (2008), www.bundesaeztekammer.de
17. PREAC-MURISIC, V.: Infect. 355-359 (1989)
18. WILSKE, B. et al.: MiQ: Qualitätsstandards in der mikrobiologisch-infektiologischen Diagnostik 12-2000: Lyme - Borreliose, URBAN&FISCHER, (2000)
19. JAURIS-HEIPKE, S. et al.: Osp 17, a novel immunodominant outer surface protein of *Borrelia afzelii*: Recombinant expression in *Escherichia coli* as its use as a diagnostic antigen for serodiagnosis of Lyme borreliosis. Med. Microbiol. Immunol. (Berl), 187 (4): 213-219 (1999)
20. HAUSER, U. et al.: J. Clin. Microbiol. 2241-2247 (1999)
21. WILSKE, B. et al.: Phenotypic Analysis of Outer Surface Protein C (OspC) of *Borrelia burgdorferi* Sensu Lato by Monoclonal Antibodies: Relationship to Genospecies and OspA Serotype; J. Clin. Microbiol. 103-109 (1995)
22. WILSKE, B.: Diagnose und Labor, (1990)
23. ZÖLLER, L.: J. Clin. Microbiol. 174-182 (1991)
24. THOMAS, L.: Labor und Diagnose, Med. Verlagsgesellschaft Marburg (2008)

Symbols used

	Manufacturer		Order Number
	Refer to Instructions for Use		Use by / Expiration Date
	<i>In-Vitro</i> Diagnostic Medical Device		Temperature Limitation (Storage)
	Lot Number		Positive Serum Control
	Sufficient for 50 Tests		Negative Serum Control
	Room Temperature in °C		Control
	Person in Charge		Date
	Serum Number		Chromogen/Substrate Incubation Time in Minutes
	Evaluation Protocol		Protocol Number