研究用試薬

Anti-Borrelia EUROLINE-RN-AT-adv (IgM)
Test instruction

ORDER NO.	ANTIBODIES AGAINST	IG CLASS	SUBSTRATE	FORMAT
DN 2131-3201-2 M DN 2131-5001-2 M DN 2131-24001-2 M	Borrelia antigens	IgM	Ag-coated immunoblot strips	32 x 01 (32) 50 x 01 (50) 240 x 01 (240)

Indications: The EUROLINE test kit provides qualitative in vitro determination of human antibodies of the immunoglobulin class IgM to the Borrelia antigens in serum or plasma to support the diagnosis of infections with Borrelia and associated diseases: erythema chronicum migrans, lymphadenosis cutis benigna, acrodermatitis chronica atrophicans, arthritis, carditis, lymphocytic meningoradiculitis, neuroborreliosis.

Principles of the test: The test kit contains test strips coated with purified recombinant antigens. In the first reaction step, the immunoblot strips are incubated with diluted patient samples. In the case of positive samples, the specific IgM antibodies (also IgA and IgG) will bind to the corresponding antigenic site. To detect the bound antibodies, a second incubation is carried out using an enzyme-labelled anti-human IgM (enzyme conjugate) catalysing a colour reaction.
The format DN 2131-5001-2 M belongs to the Immunoblot-PreQ system. The test strips are already placed into the incubation trays (EUROTrays).

Contents of the test kit (DN 2131-####-2 M):

Component	3201	24001	5001	Symbol
1. Test strips coated with antigens OspC-adv Bsp, OspC-adv Bg, OspC-adv Bb, OspC-adv Ba, p39, p41 and VlsE Bb	2 x 16 strips	15 x 16 strips	5 x 10 strips in EUROTrays	STRIPS
2. Positive control (IgM, human), 50x concentrate	2 x 0.04 ml	5 x 0.04 ml	3 x 0.1 ml	POS CONTROL 50x
3. Enzyme conjugate Alkaline phosphatase-labelled anti-human-IgM (goat), 10x concentrate	2 x 3 ml	16 x 3 ml	---	CONJUGATE 10x
4. Enzyme conjugate Alkaline phosphatase-labelled anti-human-IgM (goat), ready for use	---	---	3 x 30 ml	CONJUGATE
5. Universal buffer 10x concentrate	1 x 100 ml	8 x 100 ml	1 x 100 ml	BUFFER 10x
6. Substrate solution Nitroblue tetrazolium chloride/5-Bromo-4-chloro-3-indolylphosphate (NBT/BCIP), ready for use	2 x 30 ml	8 x 50 ml	3 x 30 ml	SUBSTRATE
7. Test instruction	1 booklet	1 booklet	1 booklet	---

LOT Lot description
IVD In vitro diagnostic medical device
CE
Storage temperature
Unopened usable until

The following components are not provided in the test kits but can be ordered at EUROIMMUN under the respective order numbers.
Performance of the test requires an **incubation tray**:
ZD 9895-20030-1 Incubation tray with 30 channels (200 trays)
ZD 9898-3044-1 Incubation tray with 44 channels (black, for the EUROBlotOne and EUROBlotCamera system, 30 trays).

If using Immunoblot-PreQ (EUROIMMUN order no. DN 2131-5001-2 M), no additional incubation tray is needed.

For evaluation of the incubated test strips, the current version of the EUROLineScan software provided by EUROIMMUN is recommended.

Updates with respect to the previous version are marked in grey.

For the creation of work protocols and the evaluation of incubated test strips using **EUROLineScan** green paper and adhesive foil are required:
ZD 9880-0101 Green paper (1 sheet)
ZD 9885-0116 Adhesive foil for approx. 16 test strips
ZD 9885-0130 Adhesive foil for approx. 30 test strips.
If a visual evaluation is to be performed in individual cases, the required evaluation protocol can be ordered under:
ZD 2131-0101-2 M Visual evaluation protocol Anti-Borrelia EUROLINE-RN-AT-adv IgM

If using Immunoblot-PreQ (EUROIMMUN order no. DN 2131-5001-2 M), the strips should stay in the EUROTrays during evaluation. For the evaluation we generally recommend using a EUROIMMUN camera system connected to EUROLineScan software. Strips need to be dry before starting the evaluation.

Preparation and stability of the reagents

Note: This test kit may only be used by trained personnel. Test strips and incubation trays are intended for single use ⊗. All reagents must be brought to room temperature (+18°C to +25°C) approx. 30 minutes before use. Unopened, reagents are stable until the indicated expiry date when stored at +2°C to +8°C. After initial opening, reagents are stable for 12 months or until the expiry date, unless stated otherwise in the instructions. Opened reagents must also be stored at +2°C to +8°C and protected from contamination.

- **Coated test strips:** Ready for use. Open the package with the test strips only when the strips have reached room temperature (+18°C to +25°C) to prevent condensation on the strips. After removal of the strips/Immunoblot-PreQ, the package should be sealed tightly and stored at +2°C to +8°C.
- **Positive control:** The control is a 50x concentrate. For the preparation of the working-strength control the amount required should be removed from the bottle using a clean pipette tip and diluted 1:51 with working-strength universal buffer. Example: add 30 µl of control to 1.5 ml of working-strength diluted universal buffer and mix thoroughly. The working-strength control should be used at the same working day.
- **Enzyme conjugate:** The enzyme conjugate is supplied as a 10x concentrate. For the preparation of the working-strength enzyme conjugate the amount required should be removed from the bottle using a clean pipette tip and diluted 1:10 with the working-strength universal buffer. Example: For 1 test strip dilute 0.15 ml anti-human IgM concentrate with 1.35 ml working-strength universal buffer. The working-strength enzyme conjugate should be used on the same working day.
- **Enzyme conjugate:** ready for use.
  Note: only for DN 2131-5001-2 M!
- **Universal buffer:** The universal buffer is supplied as a 10x concentrate. For the preparation of the working-strength universal buffer, shake the bottle. The amount required should be removed from the bottle using a clean pipette tip and diluted 1:10 with deionised or distilled water. Example: for 1 test strip add 1.5 ml universal buffer (10x concentrate) to 13.5 ml deionised or distilled water. The working-strength universal buffer should be used at the same working day.
- **Substrate solution:** Ready for use. Close the bottle immediately after use, as the contents are sensitive to light.

Storage and stability: The test kit must be stored at a temperature between +2°C and +8°C. Do not freeze. Unopened, all test kit components are stable until the indicated expiry date.

Waste disposal: Patient samples, controls and incubated test strips should be handled as infectious waste. Other reagents do not need to be collected separately, unless stated otherwise in official regulations.

Warning: The control of human origin has tested negative for HBsAg, anti-HCV, anti-HIV-1 and anti-HIV-2. Nonetheless all materials should be treated as being a potential infection hazard and should be handled with care. Some of the reagents contain sodium azide in a non-declarable concentration. Avoid contact with skin.

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Preparation and stability of the patient samples

Samples: Human serum or EDTA, heparin or citrate plasma.

Additionally, there are methods for the investigation of CSF/serum pairs which are validated for the Anti-Borrelia EUROLINE-RN-AT-adv.
For this, please request the respective test instruction DN_2131-2LM_A_UK_ZXX.

Stability: Patient samples to be investigated can generally be stored at +2°C to +8°C for up to 14 days. Diluted samples should be incubated within one working day.

Sample dilution: The **patient samples** for analysis are diluted **1:51** with working-strength universal buffer using a clean pipette tip. For example, add 30 µl of sample to 1.5 ml working-strength universal buffer and mix well by vortexing. Sample pipettes are not suitable for mixing.

Incubation

If using Immunoblot-PreQ (DN 2131-5001-2 M), manual incubation is not possible. Please see options below.

Blocking:	Fill the channels of the incubation tray according to the number of serum samples to be tested with 1.5 ml working-strength universal buffer each. Remove the required amount of test strips from the packaging using a pair of tweezers and place them one by one in the channels containing the buffer (Make sure that the surface of the test strips is not damaged!). The number on the test strip should be visible. Use of Immunoblot-PreQ: Set up the required incubation trays according to the work protocol and insert into the incubation device. Incubate for **15 minutes** at room temperature (+18°C to +25°C) on a rocking shaker. Afterwards aspirate off all the liquid.
Sample incubation: (1st step)	Fill each channel with 1.5 ml of the diluted serum samples using a clean pipette tip. Incubate for **30 minutes** at room temperature (+18°C to +25°C) on a rocking shaker.
Wash:	Aspirate off the liquid from each channel and wash **3 x 5 minutes** each with 1.5 ml working-strength universal buffer on a rocking shaker.
Conjugate incubation: (2nd step)	Pipette 1.5 ml diluted enzyme conjugate (alkaline phosphatase-conjugated anti-human IgM) into each channel. Incubate for **30 minutes** at room temperature (+18°C to +25°C) on a rocking shaker.
Wash:	Aspirate off the liquid from each channel. Wash as described above.
Substrate incubation: (3rd step)	Pipette 1.5 ml substrate solution into the channels of the incubation tray. Incubate for **10 minutes** at room temperature (+18°C to +25°C) on a rocking shaker.
Stop:	Aspirate off the liquid from each channel and wash each strip **3 x 1 minute** with deionised or distilled water.
Evaluate:	Place test strip on the evaluation protocol, air dry and evaluate.

For automated incubation with the **EUROBlotMaster** select the program **Euro02 Inf WB30**.

For automated incubation with the **EUROBlotOne** select the program **Euro 01/02.**

For automated incubation of Immunoblot-PreQ with the **EUROBlotOne** see instruction manual EUROBlotOne (YG_0153_A_UK_CXX).

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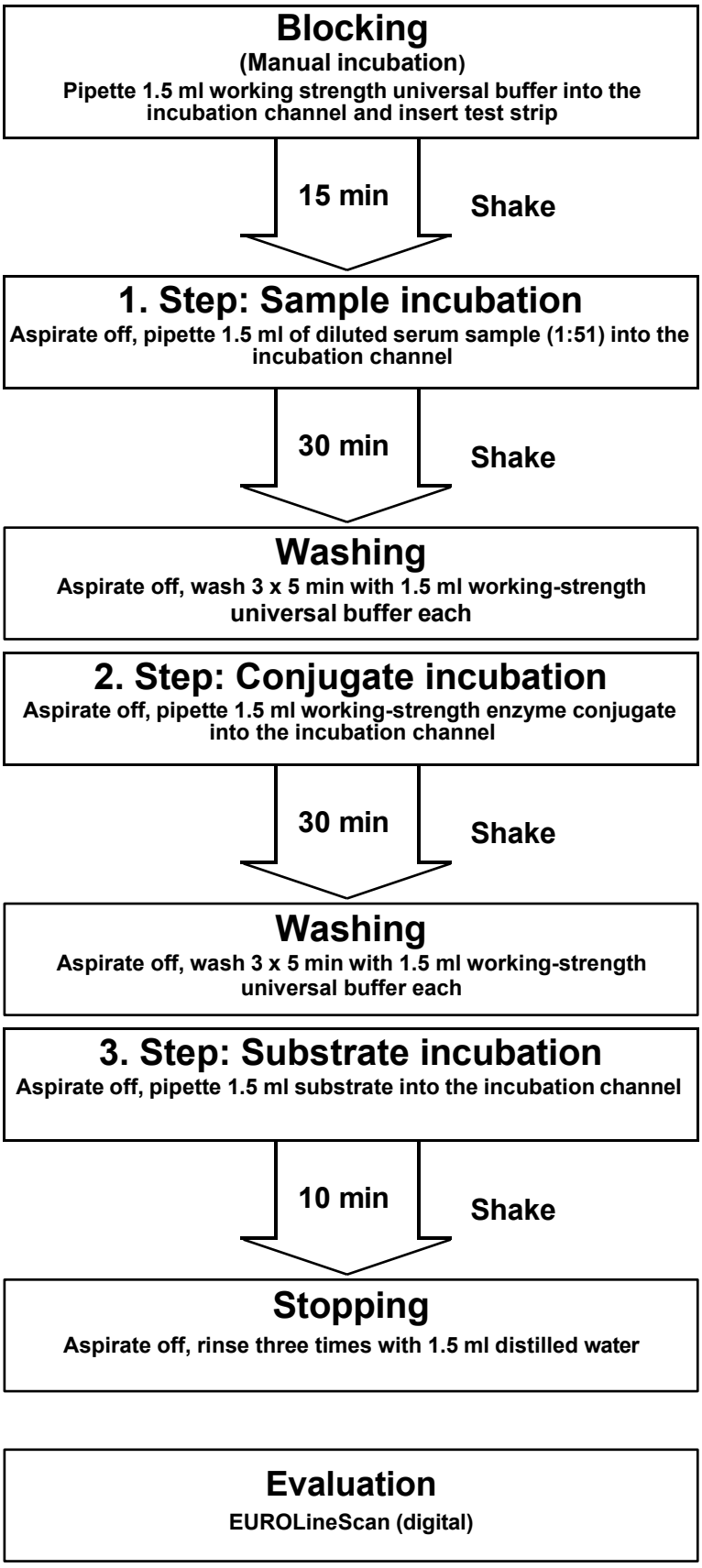
Anti-Borrelia EUROLINE-RN-AT-adv (IgM)

Incubation protocol



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Evaluation and interpretation of the results obtained by the Anti-Borrelia EUROLINE-RN-AT-adv (IgM)

Handling: For the evaluation of incubated test strips we generally recommend using the **EUROLineScan** software. After stopping the reaction using deionised or distilled water, place the incubated test strips onto the adhesive foil of the green work protocol using a pair of tweezers. The position of the test strips can be corrected while they are wet. As soon as all test strips have been placed onto the protocol, they should be pressed hard using filter paper and left to air-dry. After they have dried, the test strips will be stuck to the adhesive foil. The dry test strips are then scanned with a flatbed scanner (EUROIMMUN) and evaluated using the **EUROLineScan** software. Alternatively, imaging and evaluation are possible directly from the incubation trays (EUROBlotCamera and EUROBlotOne). For general information about the EUROLineScan program please refer to the EUROLineScan user manual (EUROIMMUN document no. YG_0006_A_UK_CXX). The code for entering the **test** into EUROLineScan is **BorrELadv_IgM**. For evaluation of the incubated test strips, the current version of the EUROLineScan software provided by EUROIMMUN is recommended.

If a visual evaluation must be performed, place the incubated test strips onto the respective work protocol for visual evaluation. This protocol is available at EUROIMMUN under the order no. ZD 2131-0101-2 M.

If using Immunoblot-PreQ (DN 2131-5001-2 M), the strips should stay in the EUROTrays during evaluation. For the evaluation we generally recommend using a EUROIMMUN camera system connected to EUROLineScan software. Strips need to be dry before starting the evaluation.

Note: A correctly performed test for class IgM antibodies against Borrelia antigens is indicated by a positive reaction of the control band and an at least weak positive reaction of the IgM band. If one of these bands shows a very weak reaction or none at all, the result must not be used for evaluation.

Antigens and their arrangement on the strips:

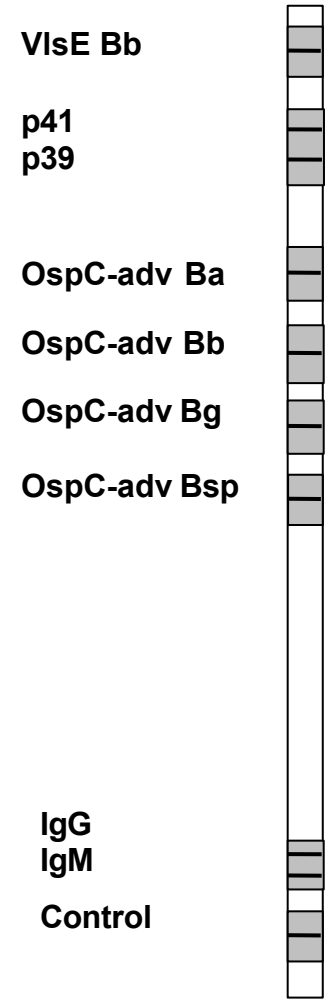
Antigens
VlsE Bb:
Highly purified recombinant VlsE antigen from Borrelia burgdorferi (Bb).

p41 and p39:
Highly purified recombinant flagellin (p41) and BmpA (p39) from Borrelia.

OspC-adv Ba, OspC-adv Bb, OspC-adv Bg und OspC-adv Bsp:
Highly purified recombinant, highly specific, dimeric OspC (p25) antigens from Borrelia afzelii (Ba), Borrelia burgdorferi (Bb), Borrelia garinii (Bg) and Borrelia spielmanii (Bsp).

Control bands:
IgG or IgM

Control: Incubation control indicating a correctly performed incubation.



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Antibodies of class IgM against Borrelia burgdorferi sensu lato

The OspC advanced antigens (European patent application EP 2 199 303 A1) contained in the Anti-Borrelia EUROLINE-RN-AT-adv represent a key innovation from EUROIMMUN. Owing to their dimeric molecular structure, these recombinant antigens correspond almost completely to native OspC and are over 30% more specific than conventional recombinant OspC. The Anti-Borrelia EUROLINE-RN-AT-adv contains OspC advanced from Borrelia afzelii, Borrelia burgdorferi, Borrelia garinii and Borrelia spielmannii, so that antibodies against all relevant human pathogenic genospecies can be reliably detected. Internal EUROIMMUN comparison studies show that the OspC advanced antigens in the Anti-Borrelia EUROLINE-RN-AT-adv possess the highest sensitivity and specificity for the detection of antibodies of class IgM in the early stage of a Borrelia infection. This allows a quick and precise visual evaluation of the Anti-Borrelia EUROLINE-RN-AT-adv test strips.

Quick evaluation IgM:

Antigen band OspC-adv Ba or OspC-adv Bb or OspC-adv Bg or OspC-adv Bsp positive → **Antibody result IgM positive**

In rare cases, the IgM antibody response against OspC may be negative or borderline in the early stages of a Borrelia infection. In these cases the evaluation should be performed according to the following scheme:

Reference evaluation IgM:

Antibody result		Specific antigen bands: p39, VlsE Bb	
		1 band positive	no band
OspC-adv Ba or OspC-adv Bb or OspC-adv Bg or OspC-adv Bsp	one antigen band positive	positive	positive
	two or more antigen bands borderline	positive	borderline
	all antigen bands negative or one antigen band borderline	positive	negative

Occasionally, an isolated reaction against the flagellin band p41 may indicate an acute Borrelia infection. However, an unspecific cross reaction should be ruled out.

For diagnosis, the clinical picture of the patient always needs to be taken into account along with the serological findings.

Test characteristics

Measurement range: The EUROLINE is a qualitative method. No measurement range is provided.

Inter- and intra-assay variation: The inter-assay variation and intra-assay variation were determined by multiple analyses of characteristic samples in several test runs over several days. In every case, the intensity of the bands was within the specified range. This EUROLINE displays excellent inter- and intra-assay repro-ducibility.

Interference: Haemolytic, lipaemic and icteric sera up to concentrations of 5 mg/ml haemoglobin, 20 mg/ml triglycerides and 0.4 mg/ml bilirubin showed no effect on the analytical results of the present EUROLINE.

Sensitivity and specificity of the antigens used: The Anti-Borrelia EUROLINE-RN-AT-adv is a line blot containing a combination of diagnostically relevant Borrelia antigens for the detection of specific antibodies of class IgM. IgM antibodies against OspC are the most important serological marker for the detection of acute Borrelia infections. Numerous research results have shown that native OspC (dimeric form) purified from Borrelia is the ideal antigen substrate. However, the standardised production of native OspC dimers is complicated, and recombinant monomeric OspC is often used in commercial test systems. But since Borrelia infections cannot be detected using only moderate quantities of this antigen, it must be applied in high concentrations. In this way an acceptable detection rate is achieved, but at the cost of a substantial number of unspecific reactions. Scientists at EUROIMMUN AG have successfully produced recombinant, covalently bonded dimeric OspC (European patent application EP 2 199 303 A1) using molecular biological methods. This OspC advanced is over 30% more specific than conventional recombinant OspC (Probst et al., ICLB, 2010) with the same sensitivity as native OspC (Ott et al., ECCMID/ICC, 2011). Moreover, the Anti-Borrelia EUROLINE-RN-AT-adv also contains the recombinantly produced antigens p39 and p41, as well as the Borrelia antigen VlsE expressed only in vivo.

The performance characteristics of the Anti-Borrelia EUROLINE-RN-AT-adv (IgM) were determined by comparing the results with those of a CE-certified reference test which contains native OspC antigens from Borrelia afzelii, Borrelia burgdorferi and Borrelia garinii (Anti-Borrelia EUROLINE-RN-AT, EUROIMMUN AG). The following panels were investigated: sera from patients with borreliosis cases (n = 277), sera from healthy blood donors and pregnant women (n = 163) and sera from patients with other infections or with autoimmune diseases (n = 75).

n = 484		**CE-notified reference test**	
		positive	**negative**
Anti-Borrelia EUROLINE-RN-AT-adv (IgM)	**positive**	158	2
	negative	0	324

Borderline results are not taken into account.

In comparison with the reference test, the Anti-Borrelia EUROLINE-RN-AT-adv achieved a sensitivity of 100% at a specificity of 99.4%.

Cross-reactions and control groups: The high analytical specificity of the test system is guaranteed by the quality of the antigen substrates used (antigens and antigen sources). The cross-reactivity of the antigens used in the Anti-Borrelia EUROLINE-RN-AT-adv determined by comparing the results achieved with a blood donor panel, a panel of healthy pregnant women and a panel of patients with acute Epstein-Barr virus infections:

		Prevalence (%)
Serum samples	**Number**	**IgM positive**
Blood donors	113	6.2
Healthy pregnant women	50	4.0
Epstein-Barr virus (acute infections)	10	10

Clinical significance

Lyme disease is the most frequent tick-borne infectious disease in Europe and North America. The pathogenic agent *Borrelia burgdorferi sensu lato (s. l.)* includes the human pathogenic species *B. afzelii*, *B. burgdorferi sensu stricto, B. garinii*, *B. spielmanii* and *B. bavariensis*. In North America *B. burgdorferi s. s.* is detected almost exclusively, while in Europe various members of the *B. burgdorferi s. l.* complex are found. This results in a larger spectrum of clinical manifestations in Europe than in North America.

B. burgdorferi s. l. belongs to the family of Spirochaetaceae, constituting gram-negative, spiral-shaped, motile bacteria. The vectors are predominantly ticks (Ixodidae) at every development stage (larvae, nymphs, adults). Following the bite, the ticks transmit the Borrelia bacteria during the blood meal. The most important hosts for ticks are roe deer and red deer, while natural reservoirs for Borrelia are birds and small mammals.

Lyme disease is divided into **early and late stages** (formerly stages I, II, III). The most frequent localised manifestation is **erythema migrans**, a circular reddening around the site of the bite, which forms up to weeks after the tick bite and can vary greatly in dimension, colour intensity and duration. The erythema may be accompanied by flu-like generalised symptoms. Multiple erythema is observed rarely in Europe and more frequently in America. Especially in children **Borrelia lymphocytoma** is typically observed on the earlobes, nipples or genital region, and is usually caused by *B. afzelii*.

The most frequent disseminated early manifestation is **neuroborreliosis**, in particular lymphocytic meningoradiculitis (Bannwarth syndrome). **Lyme carditis** and various forms of **ophthalmoborreliosis** are rarer.

The most frequent late manifestations are **Lyme arthritis** and **acrodermatitis chronica athrophicans** (ACA). Lyme arthritis affects mainly the large joints. Spontaneous remission is frequent, progression to the chronic stage rare. The complete picture of ACA encompasses perivascular plasma cell-rich inflammatory infiltrates in all skin layers, as well as epidermal and connective tissue atrophy. ACA is virtually only observed in Europe. Chronic progressive **Borrelia encephalomyelitis** with para- and tetraparesis is very rare.

New infections occur mainly in early summer to autumn. The prevalence of specific antibodies against Borrelia in the German population amounts to between 5 and 25% depending on age, place of residence and exposure. The majority of infections proceed subclinically. The incidence of Lyme disease in Europe ranges from under 1 per 100,000 inhabitants (e.g. Portugal, Ireland), to 69 (South Sweden [1]), 111 (Germany, around Würzburg) or over 300 (Slovenia). The incidence in the USA for 2016 was reported as 8.1 cases per 100,000 inhabitants on average [2].

The detection of specific antibodies supports diagnosis in all stages of infection. The **immune response in Lyme disease** does not always follow the same pattern. In erythema migrans, especially of short duration, a measurable antibody titer may not be present. Moreover, in re-infections there is often no IgM response. In typical cases an IgM response occurs 3 weeks after infection, followed by an IgG response from around the 6th week. IgG and IgM antibodies can persist after a previous infection, either one that was treated or has spontaneously healed. Together with the clinical picture, the indications of an early acute infection are positive IgM antibody detection, a significant increase in antibodies within a few weeks and seroconversion of IgM to IgG. It is expedient to determine the serological baseline status immediately after a tick bite and then monitor the Borrelia antibodies in the ensuing weeks.

Pathogen detection in patient samples by microscopy or culture does not play a major role in the diagnostics of Lyme disease. **PCR** is used to detect Borrelia DNA in joint aspirates in suspected cases of Lyme arthritis and in skin in cases of ambiguous manifestation. The investigation of ticks for Borrelia by PCR is not recommended, since this does not allow an infection in the patient to be reliably confirmed or excluded.

The **serological diagnosis of Lyme disease** is performed in two steps. In the first step a screening test (ELISA or comparable method, also indirect immunofluorescence) with high sensitivity and acceptable specificity is used. Positive and borderline results are confirmed in a second step using a specific immunoblot (IgG and IgM) based on separated or purified antigens (native, recombinant).

The evaluation of the band reactions on the immunoblot can also help to differentiate between early and late infections. As part of the early response, antibodies (primarily IgM) against flagellin p41, OspC and VlsE are formed. Antibodies of the late immune response (primarily IgG) are additionally directed against for example p83/100, p58, p39, p30 and p21. VlsE and OspC are considered the most sensitive antigens for the detection of IgG or IgM antibodies and should be included in all serological test systems. The antibody reaction with VlsE has a high significance, as it correlates with the floridity of the infection. In over 85% of cases, Lyme disease can be diagnosed across species by the detection of IgG antibodies against VlsE alone. After the infection has ended; the reaction with VlsE antigen declines.

If the antibody reactions with VlsE and OspC in patients with characteristic symptoms are negative, additional tests with a wider spectrum should be used, above all those that detect more Borrelia species. This may yield positive results in individual cases.

Immunoblots are evaluated using differing criteria in Europe and in the USA, since there is a wider pathogen spectrum in Europe. In the USA, the interpretation criteria of the Centers for Disease Control and Prevention (CDC) [3] are used.

Antibody detection from synovial fluid is not recommended [4].

To **diagnose neuroborreliosis** and to distinguish it from other neurological diseases such as multiple sclerosis, the detection of intrathecal *B. burgdorferi*-specific antibody production (determination of the specific CSF-serum quotient) in combination with inflammatory CSF changes is currently the most reliable marker. This is especially relevant for patients in Europe, since neurological manifestations are predominantly associated with *B. garinii* (*B. burgdorferi s. l.* complex) [5]. In neuroborreliosis, if *B. afzelii* whole cell lysate blot is negative, an additional blot with *B. garinii* or with recombinant antigens (in particular VlsE from various species) can increase the detection rate. It should be noted that a positive IgM reaction in CSF is generally persistent and cannot be taken as evidence of an acute infection. To support the laboratory diagnostic confirmation or exclusion of neuroborreliosis, the chemokine CXCL13 can be determined quantitatively in CSF as an activity marker.

In suspected cases of Lyme disease the following diseases are important for differential diagnostics: post-infectious reactive arthritis (caused by *Salmonella, Shigella, Yersinia, Chlamydia, Campylobacter, Mycoplasma* or various viral pathogens), autoimmune diseases (rheumatoid arthritis, lupus erythematosus) and inflammatory diseases of the central nervous system [6].

Literature

This text is largely based on the guidelines of the German Society for Hygiene and Microbiology (DGHM) for the diagnosis of Lyme disease (MiQ 12/2017). Additional passages are referenced.

1. Kaiser R, Fingerle V, Hofmann H, Krause A. **Topical aspects of Lyme Borreliosis (Lyme disease).** Arbeitsmed. Sozialmed. Umweltmed. (2011) 46, 426-437.
2. https://www.cdc.gov/lyme/stats/tables.html
3. Centers for Disease Control and Prevention (CDC). **Recommendations for test performance and interpretation from the Second National Conference on Serologic Diagnosis of Lyme Disease.** MMWR Morb Mortal Wkly Rep. (1995) 44, 590-591.
4. Barclay SS, Melia MT, Auwaerter PG. **Misdiagnosis of late-onset Lyme arthritis by inappropriate use of Borrelia burgdorferi immunoblot testing with synovial fluid.** Clin Vaccine Immunol. (2012) 19, 1806-1809.
5. Marques AR. **Laboratory diagnosis of Lyme disease: advances and challenges**. Infect Dis Clin North Am. (2015) 29, 295-307.
6. **Lexikon der Infektionskrankheiten des Menschen.** 3. Auflage, 2009, Springer Medizin Verlag Heidelberg.

Liability

The test kit, including original accessories, must only be used in accordance with the intended use. EUROIMMUN accepts no liability for any other use (e.g. non-compliance with the instructions for use and improper use) or for resulting damages.

Technical Support

In case of technical problems you can obtain assistance via the EUROIMMUN website (https://www.euroimmun.de/en/contact/).

Additional information

Regulatory information for customers in the European Union: Please observe the obligation to report any serious incidents occurring in connection with this product to the competent authorities and to EUROIMMUN.