premier®

WB Lyme IgG

CLIA Complexity: High

REF **612030**

IVD

Rx Only

ORDER NO.	ANTIBODIES AGAINST	IG CLASS	SUBSTRATE	FORMAT
612030	Borrelia burgdorferi (whole cell antigens)	IgG	Antigen coated membrane strips	30 x 01 (30)

Intended use: The Premier WB Lyme IgG test kit is intended for the qualitative determination of immunoglobulin class IgG antibodies against Borrelia burgdorferi in human serum and plasma (K^+-EDTA, Li^+-heparin, Na^+-citrate) samples, that have been found positive or borderline/equivocal using an enzyme immunoassay (EIA) or immunofluorescence assay (IFA) test procedure for B. burgdorferi antibodies. Results can be read manually or automated utilizing EUROLineScan. This test is used as an aid in the diagnosis of infections with B. burgdorferi and the associated diseases, in conjunction with other laboratory and clinical findings.

Summary and Explanation

Clinical significance: Lyme disease is a condition caused by Borrelia burgdorferi. A B. burgdorferi infection can manifest itself in the areas of dermatology, neurology, ophthalmology, rheumatology and internal medicine [1, 2, 3]. The clinical expression of borreliosis can be divided into three stages:

Stage I: The typical primary manifestation of a B. burgdorferi infection is erythema migrans (EM) (80%), a reddening of the skin which appears around the area of the tick bite and spreads in a circular manner. The erythema is accompanied by influenza-like general symptoms with fever, shaking chill, headaches and vomiting. Lymphadenopathies are observed in a few cases (lymphadenosis benigna cutis) [2, 3]. The leading clinical types of the erythema-free borreliosis (20%) are neurological, arthromyalgic, influenza-like, cardiovascular borreliosis and borreliosis with hepatitis, with regional lymphadenitis and mixtures of these [1, 2, 3].

Stage I can result in spontaneous healing or can develop into a generalized borreliosis. The transition phase is generally symptom-free. IgM antibodies against B. burgdorferi can be detected serologically in 50% to 90% of patients during stage I. Humans produce specific antibodies against the outer surface protein C (OspC) shortly after infection with B. burgdorferi [4, 5, 6]. VlsE antigen from B. burgdorferi is found to be sensitive for IgG antibody detection, whereas OspC is found to be the sensitive antigen for IgM antibody detection [7, 8, 9].

Stage II: A variety of symptoms can develop several weeks to some months after receiving the tick bite. In the foreground of these are neurological manifestations: meningitis, encephalitis, asymmetric poly-neuritis, cranial nerve paresis, and Bannwarth's lymphocytic meningoradiculoneuritis. One of the most frequent neurological symptoms of borreliosis in children is the peripheral facial palsy. Usually the paresis of the facial nerve appears at one side and after several weeks on the opposite side. Also arthritis, particularly of the knee joints, and non-localized pains in the bones, joints and muscles are frequently found. Less frequently are cardiological manifestations such as myocarditis and pericarditis [1, 3]. Antibodies against B. burgdorferi can be detected in 50% to 90% of patients in stage II. In the early phase of this stage mainly IgM antibodies are found but in the late phase often only IgG antibodies occur. However, IgM antibodies can persist for a long time [3, 10]. VlsE based detection systems were found to be convenient in detecting anti-B. burgdorferi IgG antibodies [7, 8, 11].

Stage III: The typical manifestations of a B. burgdorferi infection in stage III are chronic-relapsing erosive arthritis, acrodermatitis chronica atrophicans and progressive encephalomyelitis, which can proceed in a similar way to multiple sclerosis [1, 3, 12]. Without treatment, the tertiary stage can develop over a period of years to decades after the original infection. In this stage, IgG antibody titers are significantly increased in 90% to 100% of patients, while IgM antibodies are only rarely detectable [11, 12, 13].

Serological diagnosis should follow the principle of a two-step procedure: ELISA as a first step, which, if reactive, is followed by an immunoblot [11, 15, 16].

Antigens: The antigen source for the Premier WB Lyme IgG is provided by B. burgdorferi strain B31. The proteins from the B. burgdorferi extract have been separated according to their molecular masses, using discontinuous polyacrylamide gel electrophoresis and were finally transferred onto nitrocellulose.

Principles of the test: The test kit contains test strips with electrophoretically separated antigen extracts of B. burgdorferi. The blot strips will be blocked and incubated in the first reaction step with diluted patient samples. In the case of positive samples, specific antibodies of the class IgG (and IgA, IgM) will bind to the antigens. To detect the bound antibodies, a second incubation is carried out using an enzyme-labelled anti-human IgG (enzyme conjugate), catalyzing a color reaction.

Materials

Contents of the test kit:

Component	Format	Symbol
1. Test strips strips with electrophoretically separated B. burgdorferi antigens	30 x 1	STRIPS
2. Evaluation matrix with control strip 1 test strip incubated with a positive control serum	1 sheet	---
3. Enzyme conjugate alkaline-phosphatase labelled anti-human IgG (goat), 10x concentrate	2 x 3 mL	CONJ 10X
4. Universal buffer 10x concentrate	1 x 100 mL	BUF 10X
5. Substrate solution nitroblue tetrazolium chloride/5-bromo-4-chloro-3-indolylphosphate (NBT/BCIP), ready for use	1 x 50 mL	SUBS

Additional materials and equipment (not supplied):

- Pipettes with a range of 10 µL to 1000 µL with single-use tips
- Tweezers (for handling of the strips)
- Multistep pipette with top for dispensing up to 1.5 mL per pass
- Rocker
- Vortex mixer
- Distilled or deionized water for buffer preparation, stopping
- Glass/plastic tubes for dilution or samples and reagents
- Lint-free towel
- Filter paper
- Black tray (*Please note, each channel within the tray is for single use only)*
  - For Visual Evaluation or use with use with automated sample processors, order tray only (catalog # 11768)
  - For Automated Evaluation, the tray is included in Automated Evaluation Accessory Pack (catalog # 610216A)

For **visual evaluation of the strips**, please use the required Premier Western Blot Reaction Control Card (catalog # 11764) and the Premier Western Blot Lyme IgG Evaluation Form (available on the Meridian Bioscience, Inc. website).

For **automated evaluation of the strips with EUROLineScan** only:

- For automation purposes, it is necessary to order the Premier Western Blot Automated Evaluation Accessory Pack (catalog # 610216A). This pack contains the following items:
  - Green paper (5 sheets)
  - Adhesive foil for approx 30 test strips (2 foils)
  - Black tray for 30 strips (1 tray). *Please note, each channel within the tray is for single use only*
- For the creation of work protocols and the evaluation of test strips using EUROLineScan:
  - Catalog # 610216: EUROLineScan scanner
  - Catalog # 610214: EUROLineScan software

Warnings and Precautions

1. For in vitro diagnostic use. For use by laboratory professionals in a clinical or research laboratory setting.
2. Before starting the assay, carefully read the instructions. Use only the valid version provided with the kit.
3. Do not substitute or mix with reagents from other manufacturers.
4. Observe prudent laboratory practice and safety guidelines. Avoid eye and skin contact with specimens and reagents. In case of eye or skin contact, wash off thoroughly with plenty of clean running water. Remove and wash contaminated clothing. In case of ingestion, obtain medical attention.
5. The controls of human origin have 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 decontaminated or disposed of with proper biohazard precautions. Some of the reagents contain sodium azide in a non-declarable concentration as an antibacterial agent. Avoid skin contact.
6. **Waste disposal:** Patient samples and incubated blot strips should be handled as infectious waste. Follow local, state and federal regulations regarding handling and disposal of hazardous waste, including potentially explosive materials such as accumulated or concentrated sodium azide.

Preparation and Stability of the Reagents

Storage and Stability: The test kit has to be stored at a temperature between +2 C to +8 C. Do not freeze. Unopened, all test kit components are stable until the indicated expiry date. All reagents must be brought to room temperature (+18 C to +25 C) approx. 30 minutes before use. Unopened, the reagents are stable until the indicated expiry date when stored at +2 C to +8 C. After initial opening, the reagents are stable until the indicated expiry date, if stored at +2 C to +8 C and protected from contamination, unless stated otherwise below.

- **Coated test strips:** Ready for use. Do not open until the test strips have reached room temperature to prevent condensation on the strips. After removal of the strips the packing should be sealed tightly and stored at +2 C to +8 C. To ensure correct evaluation of results, the strip lot number must match the number on the evaluation matrix.

- **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 and diluted 1:10 with working-strength universal buffer.
  For example: For 1 test strip dilute 0.15 mL anti-human IgG concentrate with 1.35 mL of the working-strength universal buffer.
  The working-strength enzyme conjugate should be used at the same working day.

- **Universal buffer:** The universal buffer is supplied as a 10x concentrate. For the preparation of the working-strength universal buffer the amount required should be removed from the bottle using a clean pipette and diluted 1:10 with deionized or distilled water.
  For example: For the incubation of 1 test strip 1.5 mL buffer concentrate should be diluted with 13.5 mL deionized or distilled water.
  The working-strength 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  .

Preparation and Stability of the Patient Samples

Samples: Human serum or plasma (K^+-EDTA, Li^+-heparin, Na^+-citrate). Samples are to be obtained by venipuncture, following CLSI (formerly NCCLS) document H03-A6.
Use of hemolyzed, hyperlipemic, hemolytic, heat-treated or contaminated samples should be avoided.

Stability: The Clinical and Laboratory Standards Institute (CLSI GP44-A4) recommends the following storage conditions for samples: Samples should be stored at room temperature no longer than 8 hours. If the assay will not be completed within 8 hours, the samples should be refrigerated at +2 C to +8 C. If the assay will not be completed within 48 hours, or if the samples will be stored beyond 48 hours, samples should be frozen at -20 C or lower. Samples should not be repeatedly frozen and thawed. Frozen samples must be mixed well after thawing and prior to testing. Diluted samples should be incubated within 8 hours. Do not use bacterially contaminated samples. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine its own specific stability criteria.

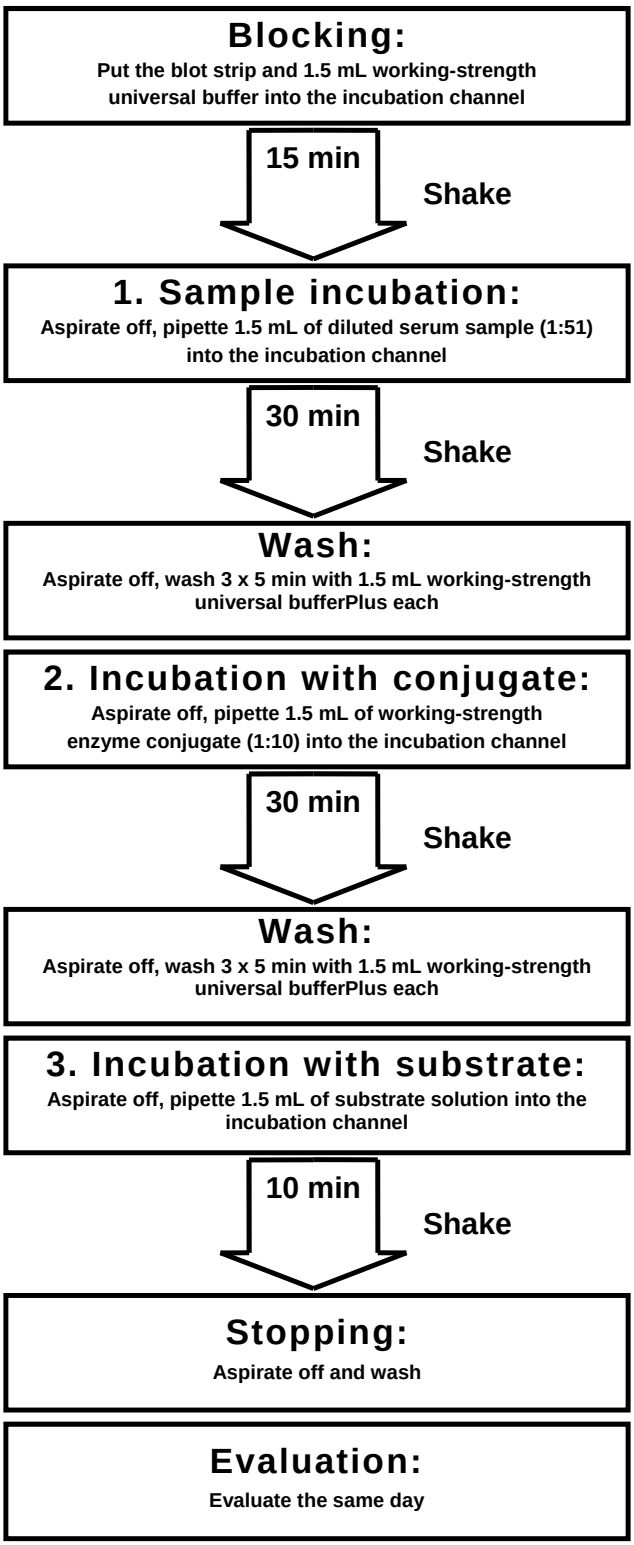
Sample dilution: The **patient samples** to be investigated are diluted **1:51** in ready for use diluted universal buffer. For example: Add 30 µL of sample to 1.5 mL ready for use diluted universal buffer and mix well by vortexing (sample pipettes are not suitable for mixing).

Procedure

Blocking:	According to the number of serum samples to be tested fill each channel of the incubation tray with 1.5 mL ready for use diluted universal buffer. Remove the required amount of blot strips from the packing using a pair of tweezers. Insert the blot strip in the incubation tray such that the number on the test strip is visible. 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. One serum sample per channel. Incubate at room temperature (+18 C to +25 C) for **30 minutes** on a rocking shaker.
Washing:	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 ready for use diluted enzyme conjugate (alkaline phosphatase conjugated anti-human IgG) into each channel. Incubate for **30 minutes** at room temperature (+18 C to +25 C) on a rocking shaker.
Washing:	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.
Stopping:	Aspirate off the liquid from each channel and wash each strip **3 x 1 minute** with deionized or distilled water.
Evaluation:	Results should be read once strips have dried. Results can be read either by manual/visual interpretation or automated using EUROLineScan. It is recommended to evaluate the strips at the day of incubation. See Evaluation of Results section below.

Premier WB Lyme IgG

Incubation Protocol



Evaluation of Results

After stopping the reaction using deionized or distilled water, apply adhesive foil to the Lyme IgG Evaluation Form. (Note: for Automated Evaluation, print an evaluation protocol on green paper using the EUROLineScan software; refer to EUROLineScan user manual). Place the incubated blot strips onto the corresponding field of the Evaluation Form using a pair of tweezers. The position of the blot strips can be corrected while they are wet. As soon as all blot strips have been placed onto the Evaluation Form, they should be blotted using filter paper to remove excess moisture. After they have dried for 1 hour, the blot strips will be fixed to the adhesive foil.

The test strip lot-specific evaluation matrix included in the kit is fitted with a blot strip originating from the same gel as the other blot strips in the test kit. This blot strip has been incubated with a positive control serum and indicates the exact position of the relevant bands. The blot strips are labelled with a specific number. This number refers to the strip lot and is also printed on the corresponding evaluation matrix. **The strip lot number on the evaluation matrix must match the strip lot number on the blot strip.**

For evaluation, put the evaluation matrix against the blot strip and align the black band above the strip lot number with the alignment bar of the evaluation matrix.

Antigens on the test strips:

Band	Antigen	CDC Relevant Bands
83/93 kDa	**Membrane-vesical protein, p 83/93 degradation product of p 100**	**X**
66 kDa	**p 66**	**X**
60 kDa	p 60	-
58 kDa	**p 58**	**X**
45 kDa	**p 45**	**X**
41 kDa	**Flagellin, p 41**	**X**
39 kDa	**Borrelia membrane protein A, BmpA, p 39**	**X**
34 kDa	Outer surface protein B, OspB, p 34	-
31 kDa	Outer surface protein A, OspA, p 31	-
30 kDa	**p 30**	**X**
28 kDa	**p 28**	**X**
25 kDa	**Outer surface protein C, OspC, p 25**	**X**
18/21 kDa	**p 18/21**	**X**

Visual evaluation with Reaction Control Card: Hold the reaction control card (catalog # 11764) next to the incubated strip and compare the band intensity with the two color bars of the card. Band intensities weaker than the positive color bar are evaluated as negative. Band intensities stronger than the positive color bar are evaluated as positive. Band intensities stronger than the negative color bar and weaker than the positive color bar are evaluated as borderline.

Note: When blot strips are evaluated visually with the Reaction Control Card, staining could occasionally completely or partially mask the bands making them unreadable. Masking may appear as heavy back-ground staining, heavy speckling or blotching. Due to variations in test performance and the uncertainty associated with unreadable Western blots, it is recommended that all unreadable blots be retested, using the original specimen. If the original specimen repeatedly yields unreadable blots, and symptoms persist, a fresh specimen should be tested in 2 to 4 weeks. By utilizing EUROLineScan for automated evaluation of the strips, the software calculates and considers the background intensity to avoid misinterpretation.

Automated evaluation with EUROLineScan: The evaluation protocol (printed on green paper) with the test strips is scanned using a flatbed scanner (catalog # 610216) and evaluated with EUROLineScan software (catalog # 610214). For use of the EUROLineScan program please refer to the EUROLineScan user manual. The code for entering the test into EUROLineScan is **B.b._WB_US_G**.

Quality control: Each blot strip contains a control band. This must show an intense staining after the incubation, in order for the results to be valid.
Additional controls may be tested in accordance with local, state and/or federal regulations or accreditation requirements and your laboratory's quality control procedures. It is recommended that the user refer to CLSI document C24-A and 42 CFR 493.1256 for guidance on appropriate quality control practices.

Interpretation of Results

Band cut-off determination
The cut-off of the Premier WB Lyme IgG test system is defined as the lowest limit of a clearly visible band. Since visual examination by the operator might be subjective, the reaction control card was developed to standardize strip evaluation. Alternatively the EUROLineScan software was established to allow for automated evaluation.

IgG class antibodies against B. burgdorferi
Positive: According to the CDC criteria, the IgG blot is considered as positive if any 5 of the following 10 bands are positive: p18/21, p25 (OspC) p28, p30, p39 (BmpA), p41, p45, p58, p66 and p83/93.

Negative: A negative interpretation denotes that IgG antibodies against less than 5 of the 10 significant B. burgdorferi proteins were detected, or no IgG antibodies against significant B. burgdorferi proteins were detected. If a negative result is obtained and infection with B. burgdorferi is clinically suspected, a new sample should be tested 3 to 4 weeks later.

Note: Borderline results are considered as negative. It is known that B. burgdorferi-infected individuals who have recently seroconverted may display incomplete patterns, but may develop increased reactivity (both in intensity and number) when followed for a period of four to six months.

Limitations of the Procedure

1. This kit is used as an aid in diagnosis only. A positive result should be interpreted together with clinical findings and other serological tests. The results obtained from this assay are not diagnostic proof of the presence or absence of a disease.
2. Negative results do not exclude the possibility of infection with B. burgdorferi.
3. Interference from albumin, intralipids and cholesterol with the assay performance has not been investigated.
4. Insufficient washing (e.g. too small wash buffer volumes, or shortened reaction times) can lead to incorrect results.
5. The test is only to be performed by laboratory professionals in a clinical laboratory setting. Strictly adhere to the test procedure. Deviations from the indicated volumes, times etc. can lead to incorrect results.
6. Adaptation of this assay for use with automated sample processors and other liquid handling devices, in whole or in part, may yield in differences in test results from those obtained using the manual procedure. It is the responsibility of each laboratory to validate that its automated procedure yields test results within acceptable limits.

Expected Values

The range of values and positivity of different populations among different studies are presented below with available patient demographics.

Population	n	Sex	Mean age & range	Premier WB Lyme IgG										
				p18/21	p25	p28	p30	p39	p41	p45	p58	p66	p83/93	Anti-B. burgd. positive (%)

Prospective study

EIA positive	304	169 men, 133 women, 2 unknown	56 yrs 4 - 88 yrs 4 unknown	239	197	111	130	251	297	184	190	176	190	233 (76.6%)

Lyme disease

Sensitivity study	101	35 men, 58 women, 8 unknown	45 yrs 16 - 87 yrs 9 unknown	47	33	5	31	49	96	27	28	49	28	56 (55.4%)

Normal population study

Endemic	98	89 men, 9 women	34 yrs 18 - 56 yrs	10	3	1	7	4	84	6	14	14	10	3 (3.1%)
Non-endemic	100	82 men, 18 women	38 yrs 3 - 62 yrs	9	2	0	13	2	87	4	5	16	8	0 (0.0%)

Note: It is recommended that each laboratory determine its own normal range based on the population and the equipment used.

Performance Characteristics

Clinical/diagnostic sensitivity study: A study consisting of 101 clinically characterized Lyme disease specimens was conducted at the manufacturer's site with the Premier WB Lyme IgG test device in parallel with the predicate device. The clinically characterized specimens encompassed samples from early, early disseminated and late phases of the disease. (Initial (acute) and convalescent samples from patients with documented erythema migrans (EM), and of known Lyme disease patients with presentations other than EM, e.g., neuro-, arthritic, etc.) The panel consisted of 35 men, 58 women and 8 unknowns. The age ranged from 16 to 87 years with a mean age of 45 years.

Interval	**n**	**Premier WB Lyme IgG**		**Predicate IgG WB**	
		Positive	**%**	**Positive**	**%**
< 1 month	11	6	54.5%	5	45.5%
> 1-3 months	23	13	56.5%	9	39.1%
> 3-12 months	38	25	65.8%	7	18.4%
> 12 months	29	12	41.4%	9	31.0%
Overall	101	56	55.4%	30	29.7%

Clinical sensitivity:

Premier WB Lyme IgG	56	/	101	=	55.4%	95% C.I.:	45.2%	-	65.3%
Predicate IgG WB	30	/	101	=	29.7%	95% C.I.:	21.0%	-	39.6%

Prospective study: A prospective study was performed at 3 different sites. All samples were initially tested with an FDA cleared first-step EIA. All ELISA positive and equivocal/borderline samples were then tested with the Premier WB Lyme IgG and the predicate IgG Western blot. All results from the device and predicate Western blot are interpreted in line with the CDC criteria.

n = 304*		**Predicate IgG WB**	
		Positive	Negative
Premier WB Lyme IgG	positive	233	6
	negative	8	57

**Pooled*

Negative agreement	57	/	63	=	90.5%	95% C.I.:	80.4%	-	96.4%
Positive agreement	233	/	241	=	96.7%	95% C.I.:	93.6%	-	98.6%

CDC panel results stratified by time after onset: 34 sera of patients with clinically characterized borreliosis in different disease stages and 5 normals, obtained from the Centers for Disease Control and Prevention, Atlanta, GA, USA, were tested with the Premier WB Lyme IgG in parallel with the predicate device.

Interval	n	Premier WB Lyme IgG		Predicate IgG WB	
		Positive	%	Positive	%
Normals	5	0	0.0%	0	0.0%
< 1 month	6	3	50.0%	3	50.0%
> 1-3 months	10	2	20.0%	2	20.0%
> 3-12 months	12	5	41.7%	5	41.7%
> 12 months	6	6	100.0%	6	100.0%
Overall	39	16	41.0%	16	41.0%

Note: The results are presented as a means to convey further information on the performance of this assay with a masked, characterized serum panel. This does not imply an endorsement of the assay by the CDC.

Normal population study: Testing of samples from an asymptomatic population in both endemic and non-endemic regions was performed. The presence of anti-B. burgdorferi antibodies was analyzed with the Premier WB Lyme IgG in a panel of 98 samples from an endemic region (Pennsylvania, 89 men and 9 women with an average age of 34 y, age range: 18 to 56 y) and in a panel of 100 samples from a non-endemic region (Tennessee, 82 men and 18 women with an average age of 38 y, age range: 3 to 62 y). 3.1% of the samples from the endemic region were found positive for anti-B. burgdorferi (IgG), whereas none of the samples from the non-endemic region were positive.

Panel	n	Premier WB Lyme (IgG	
		Positive (%)	Negative (%)
Endemic: Pennsylvania	98	3 (3.1%)	97 (96.9%)
Non-endemic: Tennessee	100	0 (0%)	100 (100%)

Cross-reactivity: Cross-reactivity was investigated using characterized samples from the following groups as shown in the table below. All the samples tested were found negative with the Premier WB Lyme IgG according to the CDC criteria.

Panel	n	Premier WB Lyme IgG
		Negative (%)
EBV	15	15 (100.0%)
HSV	14	14 (100.0%)
Influenza viruses	15	15 (100.0%)
Helicobacter pylori	11	11 (100.0%)
Measles	15	15 (100.0%)
Parvovirus B19	12	12 (100.0%)
Rubella	14	14 (100.0%)
Treponema	10	10 (100.0%)
CMV	10	10 (100.0%)
Babesiosis	3	3 (100.0%)
Anaplasmosis (ehrlichiosis)	10	10 (100.0%)
Rickettsial diseases	4	4 (100.0%)
Rheumatoid arthritis	22	22 (100.0%)
Total	155	155 (100.0%)

Note: The results obtained with babesiosis (3) and rickettsial diseases (4) samples are not conclusive as the number of tested samples was insufficient.

Interferences: Hemolytic, lipemic and icteric samples showed no influence at the result up to a concentration of 500 mg/dl for hemoglobin, 2000 mg/dl for triglycerides and 40 mg/dl for bilirubin in this test system. Interferences with albumin, intralipids and cholesterol have not been investigated.

Precision/repeatability: Repeatability was investigated by repeated determinations of 7 native characterized samples. [Negative (samples 1 and 2), low positive (sample 3), and moderate positive (samples 4, 5, 6 and 7)]. The samples were tested on 4 different days with 2 runs per day, 2 replicates per run according to the package insert. No positive sample was found negative and vice versa.

n = 16	Premier WB Lyme IgG						
	Sample 1	**Sample 2**	**Sample 3**	**Sample 4**	**Sample 5**	**Sample 6**	**Sample 7**
Characterization	negative	negative	positive	positive	positive	positive	positive
% negative	100.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%
% positive	0.0%	0.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Band(s)	Premier WB Lyme IgG									
	p18/21	**p25**	**p28**	**p30**	**p39**	**p41**	**p45**	**p58**	**p66**	**p83/93**
Sample 1	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%
Sample 2	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	81.3%	0.0%
Sample 3	75.0%	0.0%	0.0%	0.0%	100.0%	100.0%	100.0%	0.0%	100.0%	100.0%
Sample 4	87.5%	81.3%	0.0%	0.0%	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Sample 5	100.0%	87.5%	75.0%	0.0%	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Sample 6	81.3%	81.3%	0.0%	0.0%	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Sample 7	100.0%	0.0%	68.8%	50.0%	100.0%	100.0%	0.0%	100.0%	100.0%	100.0%

Reproducibility: Reproducibility was investigated by repeated determinations of 7 native characterized samples. [Negative (samples 1 and 2), low positive (sample 3) and moderate positive (samples 4, 5, 6 and 7)]. The samples were tested on 4 different days with 2 runs per day, 2 replicates per run at 3 different sites according to the package insert. No positive sample was found negative and vice versa.

n = 48	Premier WB Lyme IgG						
	Sample 1	**Sample 2**	**Sample 3**	**Sample 4**	**Sample 5**	**Sample 6**	**Sample 7**
Characterization	negative	negative	positive	positive	positive	positive	positive
% negative	100.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%
% positive	0.0%	0.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Band(s)	Premier WB Lyme IgG									
	p18/21	**p25**	**p28**	**p30**	**p39**	**p41**	**p45**	**p58**	**p66**	**p83/93**
Sample 1	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%
Sample 2	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	81.3%	0.0%
Sample 3	87.5%	0.0%	0.0%	0.0%	100.0%	100.0%	97.9%	0.0%	100.0%	100.0%
Sample 4	91.7%	85.4%	0.0%	0.0%	97.9%	100.0%	100.0%	97.9%	100.0%	0.0%
Sample 5	93.8%	87.5%	81.3%	0.0%	100.0%	100.0%	100.0%	97.9%	100.0%	0.0%
Sample 6	89.6%	85.4%	0.0%	0.0%	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Sample 7	100.0%	0.0%	81.3%	50.0%	97.9%	100.0%	0.0%	100.0%	100.0%	100.0%

Serum/plasma comparison: The use of K^+-EDTA, Li^+-heparin and Na^+-citrate plasma samples was confirmed by a correlation of 20 sample sets of serum and corresponding plasma. The sample sets were selected to cover both negative and positive results. The results of the plasma samples and the corresponding serum sample were compared and found to be sufficient as no positive sample was found negative and vice versa.

Literature References

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