Instructions for Use

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Borrelia 14kDa + OspC IgM ELISA

Enzyme immunoassay for the qualitative or quantitative determination of IgM antibodies against the 14 kDa and OspC antigens of Borrelia burgdorferi in human serum, plasma and CSF.

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REVISION HISTORY OF INSTRUCTIONS FOR USE

Changes from the previous version 2014-05 to actual version **2020-01**	
Cover page	Layout change
Chapter 1	Reduction to intended use only
Chapter 4	Additional information
Symbol page	Layout change

1. INTENDED USE

Enzyme immunoassay for the qualitative or quantitative determination of IgM antibodies against the 14 kDa and OspC antigens of Borrelia burgdorferi in human serum, plasma and CSF.

2. SUMMARY AND EXPLANATION

Borrelia burgdorferi, a bacterium of the Spirochaetaceae, is the ethiologic agent of Lyme disease (Borreliosis) being the most common disease in Europe and the USA transmitted by tics (Ixodes sp.). Lyme borreliosis is a multi-systemic disease with a broad spectrum of clinical symptoms. A typical symptom of the acute phase is the erythema chronicum migrans (ECM), often accompanied by flue-like symptoms. In later stages of the disease arthritis, carditis, as well as neurological and dermatological manifestations may occur. Lyme borreliosis can be treated with antibiotics in all stages. Therefore, a safe and sensitive laboratory diagnosis of Lyme borreliosis, also detecting the early stage of diseases, is of major importance, since an early treatment is most appreciated.

IgM antibodies usually appear approximately three weeks after the infection, IgG antibodies after four to six weeks. The early immune reaction is mainly directed against the flagellin peptide (41 kDa) and the OspC (Outer surface protein C, 23 kDa) and is then spread on more and more bacterial proteins.

In this test Borrelia burgdorferi-specific 14 kDa fragment of the flagellin is used as a recombinant protein for antibody binding. This recombinant, in E. coli produced flagellin fragment is found to be identical in all three subspecies of borrelia. Results of extensive comparative studies with ELISA, IFA and agglutination tests as well as Western Blot demonstrate that the 14 kDa IgM ELISA shows a higher diagnostic specificity as well as an increased sensitivity for the early immune response in Lyme borreliosis. In addition to the recombinant 14 kDa flagellin fragment the native OspC protein is used as coating antigen in the IBL Borrelia 14 kDa + OspC IgM ELISA.

Usually the acute phase is indicated by high titers of IgM antibodies. High IgG titers with low or without IgM antibodies occur when borreliosis is subsiding (due to therapy or spontaneously) or during the chronic stage. The Borrelia IgM test can be used for the diagnosis of Lyme borreliosis in the acute and chronic stage of the disease both requiring a therapy. Patients with a subsided borreliosis which does not require therapy any more will not show positive results.

Infections with all three B. burgdorferi subspecies (garinii, afzelii and senso strictu) are detected.

3. TEST PRINCIPLE

Solid phase enzyme-linked immunosorbent assay (ELISA) based on the sandwich principle. The wells are coated with antigen. Specific antibodies of the sample binding to the antigen coated wells are detected by a secondary enzyme conjugated antibody (E-Ab) specific for human IgM. After the substrate reaction the intensity of the color developed is proportional to the amount of IgM-specific antibodies detected. Results of samples can be determined directly using the standard curve or Cut-off standard.

4. WARNINGS AND PRECAUTIONS

1. For *in-vitro diagnostic* use only. For professional use only.
2. Before starting the assay, read the instructions completely and carefully. Use the valid version of the package insert provided with the kit. Be sure that everything is understood.
3. In case of severe damage of the kit package please contact IBL or your supplier in written form, latest one week after receiving the kit. Do not use damaged components in test runs, but keep safe for complaint related issues.
4. Obey lot number and expiry date. Do not mix reagents of different lots. Do not use expired reagents.
5. Follow good laboratory practice and safety guidelines. Wear lab coats, disposable latex gloves and protective glasses where necessary.
6. Reagents of this kit containing hazardous material may cause eye and skin irritations. See MATERIALS SUPPLIED and labels for details. Material Safety Data Sheets for this product are available on the IBL-Homepage or upon request directly from IBL.
7. Chemicals and prepared, used, unused or expired reagents have to be treated as hazardous waste according to national biohazard and safety guidelines or regulations.
8. The cleaning staff should be guided by the professionals regarding potential hazards and handling.
9. The device contains material of animal origin and may transmit infectious agents and should be handled with extreme caution.
10. All reagents of this kit containing human serum or plasma have been tested and were found negative for anti-HIV I/II, HBsAg and anti-HCV. However, a presence of these or other infectious agents cannot be excluded absolutely. For this reason reagents should be treated as potential biohazards in use and for disposal.
11. Avoid contact with Stop solution. It may cause skin irritations and burns.

5. STORAGE AND STABILITY

The kit is shipped at ambient temperature and should be stored at 2-8°C. Keep away from heat or direct sunlight. The storage and stability of specimens and prepared reagents is stated in the corresponding chapters.

The microtiter strips are stable up to 3 months after the first opening when stored at 2-8°C in the tightly closed bag.

6. SPECIMEN COLLECTION AND STORAGE

Serum, Plasma (EDTA)

<table>
<tr><td colspan="4">The usual precautions for venipuncture should be observed. It is important to preserve the chemical integrity of a blood specimen from the moment it is collected until it is assayed. Do not use grossly hemolytic, icteric or grossly lipemic specimens. Samples appearing turbid should be centrifuged before testing to remove any particulate material.</td></tr>
<tr><td>Storage Serum/Plasma/CSF:</td><td>2-8°C</td><td>≤ -20°C
(Aliquots)</td><td rowspan="2">Keep away from heat or direct sunlight.
Avoid repeated freeze-thaw cycles.</td></tr>
<tr><td>Stability Serum/Plasma/CSF:</td><td>5 days</td><td>12 months</td></tr>
</table>

7. MATERIALS SUPPLIED

Quantity	Symbol	Component
1 x 12 x 8	MTP IgM	**Microtiter Plate** Break apart strips. Coated with specific antigen.
1 x 12 mL	ENZCONJ IgM	**Enzyme Conjugate** Ready to use. Red colored. Contains: anti-human IgM, conjugated to peroxidase.
1 x 4 x 1.5 mL	CAL A-D	**Standard A-D** 2; 10; 25; 100 U/mL Standard B = Cut-off Standard Ready to use. Contains: IgM antibodies against B. burgdorferi, stabilizers.
1 x 1.5 mL	CONTROL +	**Positive Control** Ready to use. Contains: IgM antibodies against B. burgdorferi, stabilizers.
1 x 1.5 mL	CONTROL -	**Negative Control** Ready to use. Contains: Human serum, stabilizers.
1 x 100 mL	DILBUF M	**Diluent Buffer IgM** Ready to use. Blue colored. Contains: RF-Absorbent (goat anti-human IgG).
1 x 100 mL	WASHBUF CONC	**Wash Buffer, Concentrate (10x)** Contains: phosphate buffer.
1 x 15 mL	TMB SUBS	**TMB Substrate Solution** Ready to use. Contains: TMB, Buffer, stabilizers.
1 x 15 mL	TMB STOP	**TMB Stop Solution** Ready to use. 1 M H_2SO_4.
2 x	FOIL	**Adhesive Foil**

8. MATERIALS REQUIRED BUT NOT SUPPLIED

1. Micropipettes (Multipette Eppendorf or similar devices, < 3 % CV).
   Volume: 5; 10; 100; 1000 µL (adjustable)
2. Vortex mixer
3. Tubes (≥ 1 mL) for sample dilution
4. Incubator, 37°C
5. 8-Channel Micropipettor with reagent reservoirs
6. Wash bottle, automated or semi-automated microtiter plate washing system
7. Microtiter plate reader capable of reading absorbance at 450 nm (reference wavelength 600-650 nm)
8. Bidistilled or deionised water
9. Paper towels, pipette tips and timer

9. PROCEDURE NOTES

1. Any improper handling of samples or modification of the test procedure may influence the results. The indicated pipetting volumes, incubation times, temperatures and pretreatment steps have to be performed strictly according to the instructions. Use calibrated pipettes and devices only.
2. Once the test has been started, all steps should be completed without interruption. Make sure that required reagents, materials and devices are prepared ready at the appropriate time. Allow all reagents and specimens to reach room temperature (18-25°C) and gently swirl each vial of liquid reagent and sample before use. Mix reagents without foaming.
3. Avoid contamination of reagents, pipettes and wells/tubes. Use new disposable plastic pipette tips for each component and specimen. Do not interchange caps. Always cap not used vials. Do not reuse wells/tubes or reagents.
4. Use a pipetting scheme to verify an appropriate plate layout.
5. Incubation time affects results. All wells should be handled in the same order and time sequences. It is recommended to use an 8-channel Micropipettor for pipetting of solutions in all wells.
6. Microtiter plate washing is important. Improperly washed wells will give erroneous results. It is recommended to use a multichannel pipette or an automatic microtiter plate washing system. Do not allow the wells to dry between incubations. Do not scratch coated wells during rinsing and aspiration. Rinse and fill all reagents with care. While rinsing, check that all wells are filled precisely with Wash Buffer, and that there are no residues in the wells.
7. Humidity affects the coated wells/tubes. Do not open the pouch until it reaches room temperature. Unused wells/tubes should be returned immediately to the resealed pouch including the desiccant.

10. PRE-TEST SETUP INSTRUCTIONS

10.1. Preparation of concentrated components

Dilute / dissolve	Component		Diluent	Relation	Remarks	Storage	Stability
100 mL	**WASHBUF CONC**	ad 1000 mL	bidist. water	1:10	Resolve crystals at 18-25°C.	2-8°C	2 months

10.2. Dilution of Samples

10.2.1. Serum, Plasma

Sample	to be diluted	with	Relation	Remarks
Serum, Plasma	generally	**DILBUF**	1:101	e.g. 10 µL + 1 mL

Samples containing concentrations higher than the highest standard have to be diluted further.

10.2.2. Serum/CSF

For diagnostics of cerebrospinal fluid (CSF) according to Reiber, it is necessary to use approximately similar concentrations or Cutt-off indices (COI) in the OD range of 2.0 to 0.3 for serum and CSF. This is generally ensured with the following dilutions:

Sample	to be diluted	with	Relation	Remarks
Serum	generally	**DILBUF**	1:401	e.g. 5 µL + 2 mL
CSF	generally	**DILBUF**	1:4	50 µL + 150 µL

The Cut-off indices are corrected by the dilution factors of each dilution in relation to the 1:101 dilution: The Cut-off index for the 1:401 serum dilution must be multiplied by 4 and the 1:4 CSF dilution must be divided by 25.

The set of dilutions should be performed, if the test sample results are not within the range of 2.0 to 0.3 OD. The following dilutions are recommended:

Serum	1:100	1:200	1:400	1:800	1:1600
CSF	1:2	1:4	1:8	1:16	1:32

⚠ **IgM samples must not be treated with RF-Absorbent, because the RF-Absorbent is already part of the Diluent Buffer.**
The time until the samples are dispensed should be < 15-20 min.

11. TEST PROCEDURE

1.	Pipette **100 µL** of **each Standard, Control and diluted sample** into the respective wells of the Microtiter Plate. In the qualitative test only Standard B (Cut-off Standard) is used.
2.	**Incubate 1 hour** at **37°C**. Use cover or moisture chamber.
3.	Remove adhesive foil. Discard incubation solution. Wash plate 3 x with 300 µL of diluted Wash Buffer. Remove excess solution by tapping the inverted plate on a paper towel.
4.	Pipette 100 µL of Enzyme Conjugate into each well.
5.	**Incubate 30 minutes** at **37°C.** Use cover or moisture chamber.
6.	Remove adhesive foil. Discard incubation solution. Wash plate 3 x with 300 µL of diluted Wash Buffer. Remove excess solution by tapping the inverted plate on a paper towel.
7.	For adding of Substrate and Stop Solution use, if available, an 8-channel Micropipettor. Pipetting should be carried out in the same time intervals for Substrate and Stop Solution. Use positive displacement and avoid formation of air bubbles.
8.	Pipette 100 µL of TMB Substrate Solution into each well.
9.	**Incubate 30 minutes at room temperature in the dark.**
10.	Stop the substrate reaction by adding 100 µL of TMB Stop Solution into each well. Briefly mix contents by gently shaking the plate.
11.	Measure optical density with a photometer at 450 nm (Reference-wavelength: 600-650 nm) within 60 minutes after pipetting of the Stop Solution.

12. QUALITY CONTROL

The test results are only valid if the test has been performed following the instructions. Moreover the user must strictly adhere to the rules of GLP (Good Laboratory Practice) or comparable standards/laws. User and/or laboratory must have a validated system to get diagnosis according to GLP. All kit controls must be found within the acceptable ranges as stated on the labels and the QC certificate. If the criteria are not met, the run is not valid and should be repeated. Each laboratory should use known samples as further controls. It is recommended to participate at appropriate quality assessment trials.

In case of any deviation the following technical issues should be proven: Expiration dates of (prepared) reagents, storage conditions, pipettes, devices, incubation conditions and washing methods.

13. CALCULATION OF RESULTS

The evaluation of the test can be performed either qualitatively or quantitatively.

13.1. Qualitative Evaluation

The Cut-off value is given by the optical density (OD) of the Standard B (Cut-off standard). The Cut-off index (COI) is calculated from the mean optical density of the sample and Cut-off value. If the optical density of the sample is within a range of 10 % around the Cut-off value (grey zone), the sample has to be considered as borderline. Samples with higher ODs are positive, samples with lower ODs are negative.

Typical Example:
Cut-off = OD (Standard B, Cut-off standard) = 0.45
Sample OD = 0.60
Cut-off index (COI): 0.60 / 0.45 = 1.33. The sample has to be considered positive.

13.2. Quantitative Evaluation

The obtained OD of the standards (y-axis, linear) are plotted against their concentration (x-axis, logarithmic) either on semi-logarithmic graph paper or using an automated method. A good fit is provided with cubic spline, 4 Parameter Logisitcs or Logit-Log.

For the calculation of the standard curve, apply each signal of the standards (one obvious outlier of duplicates might be omitted and the more plausible single value might be used).

The concentration of the samples can be read from the standard curve.

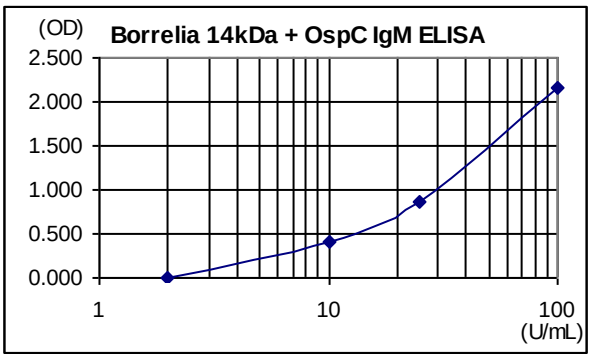
The initial dilution has been taken into consideration when reading the results from the graph. Results of samples of higher predilution have to be multiplied with the dilution factor.

Samples showing concentrations above the highest standard can be diluted as described in PRE-TEST SETUP INSTRUCTIONS and reassayed.

Typical Calibration Curve

(Example. Do not use for calculation!)

Standard	U/mL	OD_{Mean}
A	2	0.011
B	10	0.414
C	25	0.856
D	100	2.167



14. INTERPRETATION OF RESULTS / EXPECTED VALUES

Method	Range	Interpretation
Quantitative (Standard curve):	> 11 U/mL	positive
	9 – 11 U/mL	borderline
	< 9 U/mL	negative
Qualitative (Cut-off Index, COI):	> 1.1	positive
	0.9 – 1.1	borderline
	< 0.9	negative

The results themselves should not be the only reason for any therapeutical consequences. They have to be correlated to other clinical observations and diagnostic tests.

In case of **IgM negative results** with negative IgG an acute borreliosis is unlikely. However, a fresh infection can not be fully excluded if the sample has been collected within less than three weeks after infection as no specific antibodies are formed within this period. If the sample is borderline or positive for IgG, the result indicates a late or chronic infection as well as polyclonal antibody stimulation caused by other infections. A polyclonal stimulation can be excluded by a Western Blot analysis. Results should be confirmed by a follow-up control after 14 days.

IgM borderline results accompanied by negative IgG results may occur in acute infection and should be confirmed by a follow-up control after 14 days (titers constant or increasing) or by Western Blot analysis. If IgG results are positive or borderline, this result is indicative for a persisting acute infection requiring therapy. However, polyclonal stimulation should be excluded as above.

IgM positive values with coincident negative IgG results are indicative for an acute infection in the early phase. IgM positive results with positive or borderline IgG are indicative for a persisting acute infection.

The Borrelia 14 kDa + OspC IgM ELISA shows high sensitivity and specificity for the detection of the early immune response to Borrelia burgdorferi infection. Due to the use of the recombinant 14 kDa fragment of Borrelia flagellin and the purified native OspC, to which the early immune response is mainly directed, this test recognizes a Borrelia infection much earlier than other ELISA, hemagglutination or Western Blot techniques which employ an antigen prepared from ultrasonicated Borreliae. During further course of infection antibodies are formed against various other antigens. This results in a decrease of the absolute concentration of antibodies against the 14 kDa fragment and the OspC. However, these antibodies will not disappear totally, so that also persisting or chronic infections are detected with high reliability.

The Borrelia 14 kDa + OspC IgM ELISA is also suitable for the **follow-up control of a successful therapy**. In this case it has to be taken into account that antibody titers do not decrease significantly until 2 - 4 months after the infection is cured. The results for the IgM assay may be increased unspecifically in **pregnants**. In such a case a reconfirmation of the results with a blot and observation of the course after 14 days is advised.

15. LIMITATIONS OF THE PROCEDURE

Specimen collection and storage have a significant effect on the test results. See SPECIMEN COLLECTION AND STORAGE for details.

For cross-reactivities, see PERFORMANCE.

Azide and thimerosal at concentrations > 0.1 % interfere in this assay and may lead to false results.

The following blood components do not have a significant effect (+/- 20% of expected) on the test results up to the below stated concentrations:

Hemoglobin	2.0 mg/mL
Bilirubin	0.3 mg/mL
Triglyceride	2.5 mg/mL

16. PERFORMANCE

Analytical Specificity (Cross Reactivity)	Patient Group	Negative Results / tested samples	
	Lues (Treponema pallidum)	8/8	
	Rubella IgM positive	7/9	
	Parvovirus IgM positive	18/19	
	Measles IgM positive	8/8	
	CMV IgM/IgG positive	8/8	
	HSV IgM/IgG positive	8/8	
	VZV IgM positive	15/18	
	EBV IgM positive	6/8	
Precision	Range COI / U/mL	CV (%)	
Intra-Assay n = 20	< 1 / < 10	4.4	
	> 1 / > 10	1.3	
Inter-Assay n = 20	0.3 / 3.3	9.9	
	0.5 / 5	8.3	
	2.8 / 35	4.3	
	5.2 / 89	6.6	
Linearity	Range (OD)	Serial dilution range	Range (%)
	2.0 – 0.3	1:1 – 1:16	80 – 120

Method Comparison versus ELISA & Western Blot	Rel. Sensitivity	100 %	
	Rel. Specificity	> 95 %	
Automation	This test has been validated with, e.g., BEPIII (Dade Behring), TRITURUS (Grifols)		
CSF Determination	The ELISA for Lyme specific IgM has been performed with serum and CSF in 5 appropriate dilutions each: Serum 1:100-1:1600 and CSF 1:2-1:32. Serum/CSF pairs have been taken from the same day and the determination has been based on the evaluation program for CSF diagnosis by Prof. Reiber. For the evaluation serum/CSF pairs with intrathecally produced Lyme specific IgM with and without pathologic diffusion rate from blood to brain were taken. All IBL International ELISA test results were in accordance to the clinical symptoms and reference test results.		

17. PRODUCT LITERATURE REFERENCES

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Symbols / Symbole / Symbôles / Símbolos / Símbolos / Σύμβολα

REF	Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.º Cat.: / N.–Cat.: / Αριθμός-Κατ.:
LOT	Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: / Αριθμός -Παραγωγή:
	Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Usar até: / Da utilizzare entro: / Χρησιμοποιείται από:
	No. of Tests: / Kitgröße: / Nb. de Tests: / No. de Determ.: / N.º de Testes: / Quantità dei tests: / Αριθμός εξετάσεων:
CONC	Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato / Συμπύκνωμα
LYO	Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizado / Liofilizzato / Λυοφιλιασμένο
IVD	In Vitro Diagnostic Medical Device. / In-vitro-Diagnostikum. / Appareil Médical pour Diagnostics In Vitro. / Dispositivo Médico para Diagnóstico In Vitro. / Equipamento Médico de Diagnóstico In Vitro. / Dispositivo Medico Diagnostico In vitro. / Ιατρική συσκευή για In-Vitro Διάγνωση.
	Evaluation kit. / Nur für Leistungsbewertungszwecke. / Kit pour évaluation. / Juego de Reactivos para Evaluació. / Kit de avaliação. / Kit di evaluazione. / Κιτ Αξιολόγησης.
	Read instructions before use. / Arbeitsanleitung lesen. / Lire la fiche technique avant emploi. / Lea las instrucciones antes de usar. / Ler as instruções antes de usar. / Leggere le istruzioni prima dell'uso. / Διαβάστε τις οδηγίες πριν την χρήση.
	Keep away from heat or direct sun light. / Vor Hitze und direkter Sonneneinstrahlung schützen. / Garder à l'abri de la chaleur et de toute exposition lumineuse. / Manténgase alejado del calor o la luz solar directa. / Manter longe do calor ou luz solar directa. / Non esporre ai raggi solari. / Να φυλάσσεται μακριά από θερμότητα και άμεση επαφή με το φως του ηλίου.
	Store at: / Lagern bei: / Stocker à: / Almacene a: / Armazenar a: / Conservare a: / Αποθήκευση στους:
	Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγός:
	Caution! / Vorsicht! / Attention! / ¡Precaución! / Cuidado! / Attenzione! / Προσοχή!

Symbols of the kit components see MATERIALS SUPPLIED.
Die Symbole der Komponenten sind im Kapitel KOMPONENTEN DES KITS beschrieben.
Voir MATERIEL FOURNI pour les symbôles des composants du kit.
Símbolos de los componentes del juego de reactivos, vea MATERIALES SUMINISTRADOS.
Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS.
Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT.
Για τα σύμβολα των συστατικών του κιτ συμβουλευτείτε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ.

COMPLAINTS: Complaints may be submitted initially written or vocal. Subsequently they need to be filed including the test performance and results in writing in case of analytical reasons.

WARRANTY: The product is warranted to be free from material defects within the specific shelf life and to comply with product specifications delivered with the product. The product must be used according to the Intended use, all instructions given in the instructions for use and within the product specific shelf life. Any modification of the test procedure or exchange or mixing of components of different lots could negatively affect the results. These cases invalidate any claim for replacement.

LIMITATION OF LIABILITY: IN ALL CIRCUMSTANCES THE EXTENT OF MANUFACTURER'S LIABILITY IS LIMITED TO THE PURCHASE PRICE OF THE KIT(S) IN QUESTION. IN NO EVENT SHALL MANUFACTURER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS, LOST SALES, INJURY TO PERSON OR PROPERTY OR ANY OTHER INCIDENTAL OR CONSEQUENTIAL LOSS.

The labelling of hazardous substances is according to European directive.
For further country-specific classifications, please refer to the corresponding safety data sheet.

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