ТОВ «ХЕМА» код ЄДРПОУ 36038442
Адреса 03179, м. Київ, вул. Академіка Єфремова, 23
Для кореспонденції: 03179, а/с 49
З питань замовлення продукції: 050-422-62-16, 067-422-62-16
Тел.: +38 (095) 60-99-555 Факс: +38 (044) 422-62-16
e-mail:info@xema.com.ua
www.xema.in.ua

STATEMENT

We, XEMA LLC, as a manufacturer of in vitro diagnostic medical devices, having a registered office at Akademika Yefremova St. 23, Kyiv, Ukraine assign SRL SANMEDICO having a registered office at A. Corobceanu Street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in correspondence with legislative requirements of the Republic of Moldova.

We declare that the company mentioned above is authorized to register, notify, renew, or modify the registration of medical devices on the territory of the Republic of Moldova.

This Statement shall come into force on the date of its signing. The duration of this Statement is 3 years from the date of signing.

Date: 06.09.2023

Signature:

Director Xema LLC
Oleksandra Zavaliei

Digitally signed by Dolgopol Iulian
Date: 2026.03.09 12:16:27 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

UkrMedCert

8О047
Сертифікація
систем менеджменту

CERTIFICATE

on compliance of Quality Management System

Registration Date:
August 02, 2024
No. UA.SM.214-21
Expiry Date: August 01, 2027
First edition: August 04, 2021

THIS IS TO CERTIFY THAT
QUALITY MANAGEMENT SYSTEM CONCERNING

The Design and Development, Manufacture, Storage and Distribution medical devices for in vitro diagnostics

was implemented by: XEMA LLC
at the address: Akademika Yefremova St. 23, Kyiv, Ukraine, 03179

meets the requirements of DSTU EN ISO 13485:2018 (EN ISO 13485:2016, IDT; ISO 13485:2016, IDT); ISO 13485:2016.

Compliance control of the certified quality management system with the requirements of the specified standard is carried out through supervision, the frequency and procedures of which are regulated by the procedures of the conformity assessment body.

The conformity assessment body UKRMEDCERT LLC, address: str. Drahomanova, building 1-A, office 2, Kyiv, 02059, Ukraine, phone: +38-067-595-02-30, https://ukrmedcert.org.ua

Head of CAB **Tetiana SUKHENKO**

The validity of a certificate of compliance can be verified in the online Register https://ukrmedcert.org.ua or by phone +38-067-595-02-30.
The original version of this Certificate is issued in Ukrainian.

EC DECLARATION OF CONFORMITY
EU- KONFORMITATSERKLARUNG

98/79/EC in connection with article 110(3) IVDR
98/79/EG in Verbindung mit Artikel 110 (3) IVDR

No.**XEMA_LLC- DC-01/2025**

Manufacturer: Hersteller:	**XEMA LLC** UKRAINE, 03179 KYIV Akademika Yefremova St. 23 Tel./Fax: +38 044 294-69-78 Email: qa@xema.com.ua www.xema.com.ua	**Single registration number (SRN)** Einmalige Registrierungsnummer: **UA-MF-000032959**
EC Authorized Representative: EU-Bevollmächtigte:	**Polmed.de Beata Rozwadowska** Fichtenstr. 12A 90763 Fürth Germany/Deutschland Tel: +49 911 931 639 67 www.polmed.de	**Single registration number (SRN)** Einmalige Registrierungsnummer: **DE-AR-000006947**
Product name: Produktbezeichnung:	**see annex / siehe Anhang**	
Classification (Risk class): Klassifizierung (Risikoklasse):	**Common/ Other IVD** Sonstige IVD-Produkte	
Conformity assessment procedure: Konformitatsbewertungsverfahren:	**Appendix III (points 1-5) of Directive 98/79/EC** Anhang III (Nr. 1-5) der Richtlinie 98/79/EG	

Standards applied/Angewandte Normen:

ISO 9000:2015	Quality management systems — Fundamentals and vocabulary
ISO 19011:2018	Guidelines for auditing management systems
ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971:2019	Medical devices. Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
EN ISO 18113-1:2024	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements (ISO 18113-1:2022)
EN ISO 18113-2:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022)

We hereby declare under our the sole responsibility, that the devices listed in the Annex meet all applicable provision of the EU (IVDD). The procedure according to Annex III of the Regulation (EU) 2017/746 (IVDR) has been followed.

Wir erklären hiermit in unserer alleinigen Verantwortung, dass die im Anhang genannten Produkte alle anwendbaren Bestimmungen der EG-Richtlinie 98/79/WG (IVDD)entsprechen. Das Verfahren gemäß Anhang III der Verordnung (EU) 2017/746 (IVDR) wurde eingehalten.

If the product is changed/transformed without the consent of the undersigned, this declaration becomes invalid with regard to the modified/converted product.

Wenn das Produkt ohne Zustimmung des Unterzeichneten geändert/transformiert wird, wird diese Erklärung in Bezug auf das modifizierte/konvertierte Produkt ungültig.

Validity/Gültigkeit: **until**/ bis: **31.12.2028**

Signature/ Unterschrift:
Name: **Oleksandra Zavaliei**
Position: Director "XEMA LLC"

Place and date of issue:
Ort und Datum der Ausgabe: Kyiv
26.05. 2025

EC DECLARATION OF CONFORMITY
EU- KONFORMITATSERKLARUNG

98/79/EC in connection with article 110(3) IVDR
98/79/EG in Verbindung mit Artikel 110 (3) IVDR

No.**XEMA_LLC- DC-01/2025**

Annex to Declaration of conformity
Anhang zur Konformitätserklärung

Product list /Produktliste

#	**Nomenclature term** Nomenklaturbezeichnung **EDMA**	**Cat. #** Katalog-Nr.:	**Name of device** Produktbezeichnung	**Nomenclature Code** Nomenklaturcode **EDMA**	**Category IVDD** Kategorie IVDD
1.	ASPERGILLUS	K021	GalMAg EIA	15-06-01-01-00	other
2.	HSV IgG	K104	HSV 1/2 IgG EIA	15-04-03-05-00	other
3.	HSV IgM	K104M	HSV 1, 2 IgM EIA	15-04-03-06-00	other
4.	HSV 2 IgG	K104B	HSV 2 IgG EIA	15-04-03-11-00	other
5.	MYCOPLASMA ANTIBODY ASSAYS	K106	Mycoplasma IgG EIA	15-01-08-03-00	other
6.	SYPHILIS ANTIBODY ASSAYS TOTAL	K111	anti-Treponema pallidum EIA	15-01-03-03-00	other
7.	SYPHILIS ANTIBODY IGG	K111G	Treponema pallidum IgG EIA	15-01-03-05-00	other
8.	H. PYLORI ANTIBODY ASSAYS	K119G	Helicobacter pylori IgG EIA	15-01-04-03-00	other
9.	OTHER OTHER BACTERIOLOGY IMMUNOASSAY	K126	Ureaplasma IgG EIA	15-01-90-90-00	other
10.	THYROID PEROXIDASE (INCL. MICROSOMAL) ANTIBODIES	K131	aTPO EIA	12-10-03-01-00	other
11.	THYROGLOBULIN AUTOANTIBODIES	K132	aTG EIA	12-10-03-04-00	other
12.	MPO ANCA	K133	aMPO EIA	12-10-90-09-00	other
13.	TISSUE TRANSGLUTAMINASE ANTIBODIES	K160 K161	anti-TGlu IgG EIA anti-TGlu IgA EIA	12-10-90-21-00	other
14.	GIARDIA LAMBLIA	K171	anti-Giardia lamblia EIA	15-05-10-08-00	other
15.	OTHER PARASITOLOGY	K174	Ascaris IgG EIA	15-05-10-90-00	other
16.	ECHINOCOCCUS	K175	Echinococcus IgG EIA	15-05-10-04-00	other
17.	DISTOMATOSIS	K176	Opisthorchis IgG EIA	15-05-10-03-00	other
18.	GLIADIN ANTIBODIES	K180 K181	Gliadin IgG EIA Gliadin IgA EIA	12-10-90-06-00	other
19.	IMMUNOGLOBULIN E – TOTAL	K200	Total IgE EIA	12-02-01-02-00	other
20.	THYROID STIMULATING HORMONE	K201	TSH EIA	12-04-01-11-00	other
21.	LUTEINISING HORMONE	K202	LH EIA	12-05-01-05-00	other
22.	FOLLICLE STIMULATING HORMONE	K203	FSH EIA	12-05-01-04-00	other
23.	HUMAN GROWTH HORMONE	K204	GH EIA	12-06-04-02-00	other
24.	HUMAN CHORIONIC GONADOTROPIN TOTAL	K205	hCG EIA	12-05-02-05-00	other
25.	PROLACTIN	K206	Prolactin EIA	12-05-01-08-00	other
26.	PROGESTERONE	K207	Progesterone EIA	12-05-01-06-00	other
27.	ESTRADIOL	K208	Estradiol EIA	12-05-01-03-00	other
28.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K209	Testosterone EIA	12-05-01-10-00	other
29.	CORTISOL	K210	Cortisol EIA	12-06-02-04-00	other
30.	TRIIODOTHYRONINE	K211	T3 EIA	12-04-01-05-00	other
31.	THYROXINE	K212	T4 EIA	12-04-01-07-00	other
32.	FREE TRIIODOTHYRONINE	K213	fT3 EIA	12-04-01-01-00	other
33.	FREE THYROXINE	K214	fT4 EIA	12-04-01-02-00	other
34.	DEHYDRO-EPIANDROSTERONE SULPHATE (INCL. DHEA)	K215	DHEAS EIA	12-05-01-02-00	other
35.	17 OH PROGESTERONE	K217	17-OH-progesterone EIA	12-05-01-07-00	other
36.	ESTRIOL	K218	free Estriol EIA	12-05-02-02-00	other
37.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K219	free Testosterone EIA	12-05-01-10-00	other
38.	CANCER ANTIGEN 125	K222	CA 125 EIA	12-03-01-06-00	other

#	Nomenclature term EDMA	Cat. #	Name of device	Nomenclature Code EDMA	Category IVDD
42.	CANCER ANTIGEN 15-3	K226	CA 15-3 (M12) EIA	12-03-01-02-00	other
43.	OTHER OTHER TUMOUR MARKERS	K232	Thyroglobulin EIA	12-03-90-90-00	other
44.	ß HUMAN CHORIONIC GONADOTROPIN (INCL. SUBUNIT)	K235	free β-HCG EIA	12-05-02-06-00	other
45.	CYFRA 21-1	K236	CYFRA 21-1 EIA	12-05-02-10-00	other
46.	SQUAMOUS CELL CARCINOMA ANTIGEN	K237	SCC (A) EIA	12-03-01-35-00	other
47.	PREGNANCY ASSOCIATED PLASMA PROTEIN - A (DOWNS)	K238	PAPP-A EIA	12-05-02-10-00	other
48.	OTHER OTHER TUMOUR MARKERS	K239	HE4 EIA	12-03-90-90-00	other
49.	CANCER ANTIGEN 242	K243	CA242 EIA	12-03-01-08-00	other
50.	OTHER PREGNANCY TESTING HORMONES	K245	AMH EIA	12-05-02-90-00	other
51.	HUMAN PLACENTAL LACTOGEN HPL	K246	Placental lactogen EIA	12-05-02-07-00	other
52.	C-REACTIVE PROTEIN	K250	CRP EIA	12-11-01-09-00	other
53.	C-PEPTIDE	K267C	C-peptide EIA	12-06-01-01-00	other
54.	INSULIN	K267N	Insulin EIA	12-06-01-03-00	other
55.	SEX HORMONE BINDING GLOBULIN	K268	SHBG EIA	12-05-01-09-00	other
56.	TROPONIN (T + I)	K291	Troponin I EIA	12-13-01-07-00	other
57.	LYME ANTIBODY IGG	K118G	Borelia burgdorferi IgG EIA	15-01-06-05-00	other
58.	LYME ANTIBODY IGM	K118M	Borelia burgdorferi IgM EIA	15-01-06-06-00	other
59.	EBV ANTIBODIES	K108V K108VM K108N	Epstein-Barr virus VCA IgG EIA Epstein-Barr virus VCA IgM EIA Epstein-Barr virus EBNA IgG EIA	15-04-04-04-00	other

Instruction for use
A solid-phase enzyme immunoassay kit
for the qualitative detection of IgG antibodies
to *Borelia burgdorferi sensu lato*
in human serum or plasma

Borelia burgdorferi IgG EIA

Catalogue number REF **K118G**

Σ 96 For 96 determinations

IVD *In vitro* diagnostic medical device

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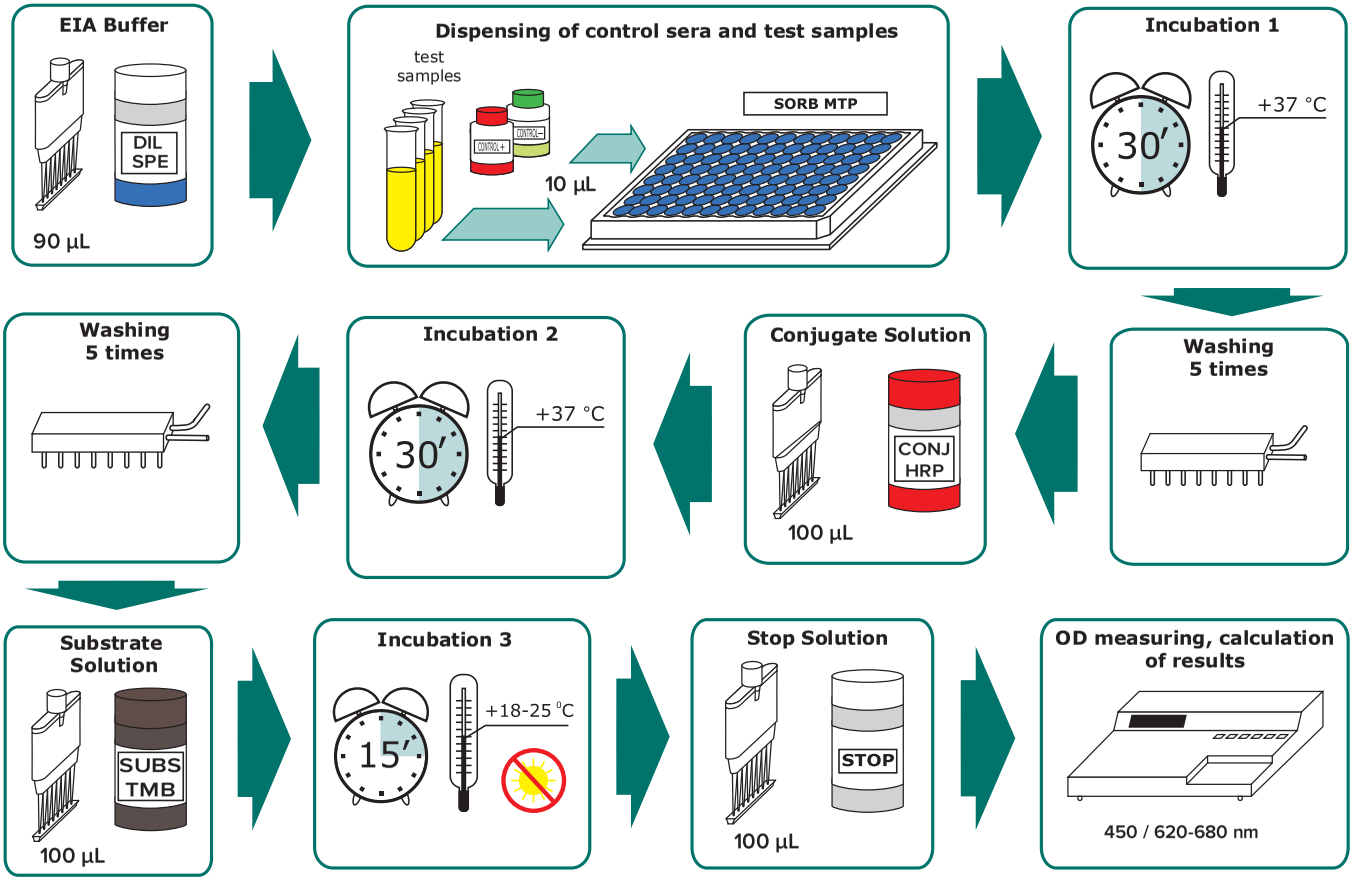
ASSAY PROCEDURE



During performing several independent series of tests, Positive and Negative Control Serum should be used **each time**.

CONTENT

Instruction for use
A solid-phase enzyme immunoassay kit for the qualitative detection of IgG antibodies to *Borelia burgdorferi sensu lato* in human serum or plasma

Borelia burgdorferi IgG EIA

1. INTENDED USE

ELISA reagent kit Borelia burgdorferi IgG EIA is a solid-phase enzyme immunoassay for the qualitative detection of IgG antibodies to *Borelia burgdorferi sensu lato* in human serum or plasma.

The field of application is clinical laboratory diagnostics.

2. GENERAL INFORMATION

Borrelia burgdorferi sensu lato - is a group of borreliosis or Lyme disease pathogens, a common infection, the main host and vector of which is the ixodid tick. The disease is transmitted only through a tick bite.

In the early stages of borreliosis, fatigue, chills and headaches may be observed, and later more serious symptoms may occur, such as joint pain, meningitis, numbness in the extremities, facial nerve paralysis, memory disorders, and eye and heart damage. After the spirochete penetrates the skin, a creeping erythema occurs, and after several days or weeks, it reaches many organs by haematogenous or lymphatic means. In general, the incubation period is from 3 to 45 days.

Early diagnosis of the disease is based on clinical and epidemiological data. The diagnosis is confirmed by laboratory, usually by serological methods - the detection of specific antibodies to *Borrelia burgdorferi* in the blood.

IgM antibodies appear in the blood first, a few days after infection, but can be detected by laboratory tests in 2-3 weeks. After about 6 weeks, the concentration of antibodies reaches a maximum and then gradually decreases. IgG antibodies begin to be detected 4-6 weeks after infection and the maximum amount of IgG antibodies is synthesised 2-3 months after the onset of early symptoms of the disease. Then their number gradually decreases, but they remain in the body for several years.

3. TEST PRINCIPLE

The detection of IgG antibodies to *Borrelia burgdorferi* is based on the indirect enzyme immunoassay principle. On the inner surface of the microplate wells are immobilized recombinant *Borrelia burgdorferi* antigen. The analysis procedure includes three stages of incubation:

- during the first stage specific to *Borrelia burgdorferi* antibodies from the specimen are bound onto the microwell surface;
- during the second stage horseradish peroxidase-conjugated specific monoclonal anti-IgG antibodies bind to the antigen-antibody complexes, fixed in the formed at the previous stage complexes;
- during the third stage, the complexes formed due to the reaction with the chromogen 3,3',5,5'-tetramethylbenzidine are visualized.

After stopping the reaction with a stop solution, the intensity of the color of the microwells is measured. The optical density (OD) in the microwell is directly related to the concentration of the measured IgG antibodies to *Borrelia burgdorferi* in test specimen.

4. KIT COMPONENTS

Code of component	Symbol	Name	Volume	Qty, pcs.	Description
P118GZ	SORB MTP	**Microplate**	-	1	96-well polystyrene strip microplate coated with recombinant antigen of *Borrelia burgdorferi*, ready to use
CN118GZ	CONTROL -	**Negative Control Serum K-**	0.5 mL	1	Solution based on human serum, free of IgG antibodies to *Borrelia burgdorferi*, with preservative, ready to use (yellow liquid)
CP118GZ	CONTROL +	**Positive Control Serum K+**	0.2 mL	1	Solution based on human serum, containing of IgG antibodies to *Borrelia burgdorferi*, with preservative, ready to use (red liquid)
T118GZ	CONJ HRP	**Conjugate Solution**	12 mL	1	Solution of monocnoclonal antibodies to IgG conjugated to the horseradish peroxidase, ready to use (red liquid)
SP118GZ	DIL SPE	**EIA Buffer**	12 mL	1	Buffer solution with detergent and preservative, ready to use (purple liquid)
R055Z	SUBS TMB	**Substrate Solution**	12 mL	1	Tetramethylbenzidine (TMB) substrate solution, ready to use (colourless liquid)
S008Z	BUF WASH 26X	**26x Concentrate Washing Solution**	30 mL	1	Buffer solution with detergent, 26x concentrate (colourless liquid)
R050Z	STOP	**Stop Solution**	12 mL	1	5.0% solution of sulphuric acid, ready to use (colourless liquid)
The kit also includes instruction for use, quality control data sheet and plate sealing tape (2 pcs).					

K118GIE

5. EQUIPMENT AND MATERIAL REQUIRED BUT NOT PROVIDED

– microplate photometer with 450/620-680 nm wavelength;
– dry thermostat for +37°C±1°C;
– automatic plate washer (optional);
– micropipettes with variable volume, range volume 5-1000 µL;
– graduated cylinder of 1000 mL capacity;
– distilled or deionized water;
– timer;
– vortex mixer;
– disposable gloves;
– absorbent paper.

6. WARNING AND PRECAUTIONS

In order to prevent incorrect results, strictly follow the recommended order and duration of the analysis procedure.

6.1. The kit is for *in vitro* diagnostic use only. For professional laboratory use.

6.2. Follow the rules mentioned below during the kit using:

- do not use kit beyond expire date;
- do not use the kit if its packaging is damaged;
- in order to avoid contamination, use new tips to pipette samples and reagents;
- use only verified equipment;
- close each vial with its own cap, after using the reagent;
- do not use components of other kits or reagents of other manufacturers;
- do not let wells dry after completing the rinsing step; immediately proceed to the next stage;
- avoid bubbles when adding reagents.

ATTENTION! The TMB substrate solution is light sensitive. Avoid prolonged exposure of the component to light.

6.3. Some kit components, such as stop solution, substrate solution, and washing solution, may cause toxic or irritant effects. If they get on the skin or mucosa, the affected area should be washed with plenty of running water.

6.4. All human products, including patient samples, should be considered potentially infectious. Handling and disposal should be in accordance with the procedures defined by an appropriate national biohazard safety guidelines or regulations.

6.5. The positive and negative control serum included in the kit are negative for antibodies to HIV 1,2, hepatitis C virus and HBsAg, but the reagents should be considered as potentially infectious material and handled carefully.

6.6. Specimens must not contain any azide compounds, as they inhibit activity of peroxidase.

6.7. Wear protective gloves, protective clothing, eye protection, face protection.

6.8. Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.

6.9. Safety Data Sheet for this product is available upon request directly from XEMA LLC.

6.10. Serious incidents related to the kit must be reported to the manufacturer, Authorized Representative, and to the Competent Authority of the EU member state(s) where the incident has occurred.

7. SPECIMEN COLLECTION, TRANSPORTATION AND STORAGE OF SAMPLES

7.1. Blood sampling should be carried out from the cubital vein with a disposable needle using a vacuum blood sampling system. Serum or plasma specimens should be clearly labeled and identified. Serum must be separated from the clot as early as possible to avoid hemolysis of red blood cells. If there are any visible particles in the sample, they should be removed by centrifugation at 3000-5000 rpm for 20 minutes at room temperature or by filtration.

Don't use samples with high lipidemia, hemolysis as they may give false test results.

7.2. Specimen should be stored at +2…+8°C up to 3 days. Specimen held for a longer time, should be placed in a freezer at -15°C or below, do not refreeze/thaw samples.

7.3. For the transportation of samples, it is recommended to use triple packaging. The primary package is the labeled tube containing the sample. Secondary packaging is a polyethylene bag that is hermetically closed with a zip-lock. The outer packaging is a heat-insulating container, while the secondary packaging is placed in the outer packaging for transportation in the center of the thermal container. Frozen refrigerants are placed on the bottom, along the side walls of the thermal container, and cover the samples with them.

8. TRANSPORTATION AND STORAGE TERMS OF KIT, WASTE DISPOSAL

Information about the singularity storage conditions, transportation of the kit, and disposal of waste should be taken into account by all persons who participate in these processes.

8.1. Transportation

The Borrelia burgdorferi IgG EIA kit should be transported in the manufacturer's packaging at +2...+8°C. Single transportation at the temperature up to 25ºC for 5 days is acceptable.

8.2. Storage

The Borrelia burgdorferi IgG EIA kit should be stored in the manufacturer's packaging at +2...+8°C. Do not freeze.

The kit contains reagents sufficient for 96 determinations including Positive and Negative Control Serum.

Once opened test-kit is stable for 2 months when stored properly as intended by manufacturer at 2-8°C.

In case of partial use of the kit, the components should be stored in the following way:

- the remaining strips should be immediately resealed in the bag along with the silica gel, closed with the zip-lock, and stored at +2...+8°C within 2 months;
- EIA Buffer, Substrate Solution, Stop Solution, and Washing Solution concentrate after opening the vial, can be stored tightly closed at +2...+8°C until the kit's shelf life;
- Conjugate Solution, Positive and Negative Control Serum after opening the vial, can be stored tightly closed at +2...+8°C within 2 months;
- diluted Washing Solution can be stored at room temperature (+18…+25°C) for up to 5 days or at +2…+8°C for up to 14 days.

Kits that were stored in violation of the storage condition cannot be used.

8.3. Disposal

Expired kit components, used reagents and materials, as well as residual samples must be inactivated and disposed of in accordance with legal requirements.

9. REAGENTS PREPARATION

9.1. All reagents (including microstrips) and test samples should be allowed to reach room temperature (+18…+25 °C) for at least 30 minutes before use.

9.2. Microplate preparation

Open the package with the microplate and install the required number of strips into the frame. The remaining strips should be immediately resealed in the bag along with the silica gel and closed with the zip-lock to prevent moisture from affecting the plate's strips.

9.3. Washing solution preparation

Add the contents of the 30 mL washing solution concentrate vial to 750 mL of distilled or deionized water and mix thoroughly. In case of partial use of the kit, take the necessary amount of washing solution concentrate and dilute it 26 times with distilled or deionized water.

The spending of the components in case of partial use of the kit is given in the table:

Quantity of strips	1	2	3	4	5	6	7	8	9	10	11	12
Volume of the washing solution concentrate, mL	2.5	5	7.5	10	12.5	15	17.5	20	22.5	25	27.5	30
Volume of water, mL	62.5	125	187.5	250	312.5	375	437.5	500	562.5	625	687.5	750

10. ASSAY PROCEDURE

10.1. Put the desired number of strips into the frame based on the number of test samples and 4 wells for Positive and Negative Control Serum (1 well for Positive Control (CP) and 3 wells for Negative Control Serum (CN)).

10.2. Dispense **90 µL of EIA Buffer** to all wells.

10.3. Dispense **10 µL of Positive and Negative Control Serum as well as 10 µL of test serum/plasma samples** (SAMP) to the wells of the microplate according to the scheme below. The introduction of Positive and Negative Control Serum and test samples should be carried out within 5 minutes to ensure equal incubation time for the first and last samples.

During performing several independent series of tests, Positive and Negative Control Serum should be used each time.

Scheme of introduction of samples

	1	2	3	4	5	6	7	8	9	10	11	12
A	CP	SAMP5	SAMP13	SAMP21								
B	CN	SAMP6	SAMP14	SAMP22								
C	CN	SAMP7	SAMP15	SAMP23								
D	CN	SAMP8	SAMP16									
E	SAMP1	SAMP9	SAMP17									
F	SAMP2	SAMP10	SAMP18									
G	SAMP3	SAMP11	SAMP19									
H	SAMP4	SAMP12	SAMP20									

10.4. Carefully mix the contents of the microplate in a circular motion on a horizontal surface, cover strips with a plate sealing tape and incubate for **30 minutes at +37°C**.

10.5. At the end of the incubation period, remove and discard the plate cover. Aspirate and wash each well **5 times** using an automatic washer or an 8-channel dispenser. For each washing, add 300 µL of Washing Solution (see 9.3) to all wells, then remove the liquid by aspiration or decantation. The residual volume of the Washing Solution after each aspiration or decantation should be no more than 5 µL. After washing, carefully remove the remaining liquid from the wells on the absorbent paper. For the automatic washer/analyzer, the Washing Solution volume can be increased to 350 µL.

10.6. Add **100 µL of Conjugate Solution** to all wells.

10.7. Cover strips with a plate sealing tape and incubate for **30 minutes at +37°C**.

10.8. At the end of the incubation period, aspirate and wash each well **5 times** as described in 10.5.

10.9. Add **100 µL of Substrate Solution** to all wells. The introduction of the Substrate Solution into the wells must be carried out within 2-3 minutes. Incubate the microplate in the dark **at room temperature (+18...+25°C) for 15 minutes**.

10.10. Add **100 µL of Stop Solution** to all wells in the same order as the Substrate Solution. After adding the Stop Solution, the contents of the wells turn yellow.

10.11. Read the optical density (OD) of the wells at 450 nm and reference light filters 620–680 nm using a microplate photometer within 5 minutes of adding the stop solution.

11. TEST VALIDITY AND CALCULATION OF RESULTS

11.1. The test results are valid only if Positive and Negative Control Serum are within the specified ranges and if all other test parameters are also within the given assay specifications, namely:

- OD of CONTROL- < 0.15;
- OD of CONTROL+ > 1.5;
- OD(CN) x 0,5 < OD(CN) < OD(CN) x 2.

11.2. Calculate the mean OD value of the Negative Control Serum:

meanOD(CN) = (OD1(CN) + OD2(CN) + OD3(CN))/3

11.3. Calculate the Cut Off value by adding to the mean OD value of the Negative Control Serum the coeficient 0.3.

Cut off = meanOD(CN) + 0.3

11.4. Calculate Positivity Index (PI) for each sample by dividing the OD of the sample by Cut off value:

PI = ODsample/Cut off

12. INTERPRETATION OF THE RESULTS

If PI value > 1.1 the result is **POSITIVE**,
If PI value is between 0.9 and 1.1 the result is **EQUIVOCAL**,
If PI value < 0.9 the result is **NEGATIVE**.

If equivocal results are obtained, it is recommended to retest the sample in several replicates. If the result is equivocal again, a new sample should be obtained within 5-7 days and retested. If the result remains equivocal, the sample should be considered negative.

13. PERFORMANCE CHARACTERISTICS

13.1. Analytical performance characteristics

13.1.1. Precision of Measurement

Reproducibility (Intra assay repeatability) was determined by evaluation the coefficient of variation (CV) for 2 different samples, with different levels of IgG antibodies to the *Borrelia burgdorferi sensu lato* antigen, during 1 day in 43 replicates on one series of ELISA kit.

№ serum	mean OD	mean PI	CV PI, %
1	0.31	1.02	8.29
2	1.08	3.59	6.65

Reproducibility (Inter assay reproducibility) was determined by evaluating the coefficients of variation (CV) for 2 samples of each serum for 4 days in 8-replicate determinations.

№ serum	mean OD	mean PI	CV PI, %
1	0.27	0.9	8.1
2	1.1	3.66	6.8

13.1.2. Analytical specificity

For the analysis result is not affected by the presence in the sample of bilirubin in a concentration of up to 0.21 mg/mL, hemoglobin in a concentration of up to 10 mg/mL and triglycerides in a concentration of up to 10 mg/mL.

13.2. Diagnostic performance characteristics

The clinical sensitivity and specificity of the assay were evaluated using a serum panel with 8 positive and 8 negative clinical serum samples and were 100%. The relative sensitivity and specificity of the assay were investigated in a sample of 96 donor sera characterised for the content of IgG antibodies to *Borrelia burgdorferi* antigen in commercical Kits, and the ressults were 99.7% and 97.5%, respectively.

14. LIMITATIONS

A positive result is evidence of the presence of IgG antibodies to *Borrelia burgdorferi sensu lato* antigen. The diagnosis cannot be based on the results of an IgG antibody test to *Borrelia burgdorferi* alone and requires confirmation, including an assessment of the patient's clinical presentation and history, the detection of IgM antibodies to *Borrelia burgdorferi* and perform an immunoblot test.

A negative result indicates the absence of IgG antibodies to *Borrelia burgdorferi sensu lato* or antibody levels below the sensitivity of the kit.

The results of serum tests in patients with immunosuppression and immunological disorders should be interpreted with caution.

15. REFERENCES

1. Lyme Borreliosis (Lyme disease). In: International travel and health. Geneva: World Health Organization; 2014.
2. M Cinco 1, R Murgia, M Ruscio, B Andriolo. IgM and IgG significant reactivity to Borrelia burgdorferi sensu stricto, Borrelia garinii and Borrelia afzelii among Italian patients affected by Lyme arthritis or neuroborreliosis. FEMS Immunol Med Microbiol . 1996 Jun;14(2-3):159-66. doi: 10.1111/j.1574-695X.1996.tb00283.x.
3. Наказ МОЗ України №1827 від 31.10.2024 «Про затвердження Державних санітарних норм та правил «Порядок управління медичними відходами, у тому числі вимоги щодо безпечності для здоров'я людини під час утворення, збирання, зберігання, перевезення, оброблення таких відходів».
4. Постанова КМУ від 02 жовтня 2013р. №754 «Про затвердження технічного регламенту щодо медичних виробів для діагностики in vitro».
5. НПАОП 85.14-1.09-81. Правила облаштування, техніки безпеки, виробничої санітарії, протиепідемічного режиму і особистої гігієни при роботі в лабораторіях (відділеннях, відділах) санітарноепідеміологічних установ системи Міністерства охорони здоров`я СРСР (НАОП 9.1.50-1.09-81).

SAMPLES IDENTIFICATION PLAN

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K118GIE

	Manufacturer
IVD	*In vitro* diagnistic medical device
REF	Catalogue number
	Use-by date
LOT	Batch code
	Temperature limit
	Contains sufficient for <n> tests
	Caution
	Consult instructions for use
	Conformity Marking with technical regulations in Ukraine
EC REP	Authorized representative in the European Community/European Union
CE	CE Conformity Marking

For any issues related to operation of the kit and technical support, please contact by telefon number

+38 044 294-69-78

or write to:

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Instruction for use
A solid-phase enzyme immunoassay kit
for the qualitative detection of IgM antibodies
to *Borelia burgdorferi sensu lato*
in human serum or plasma

Borelia burgdorferi IgM EIA

Catalogue number REF **K118M**

Σ 96 For 96 determinations

IVD *In vitro* diagnostic medical device

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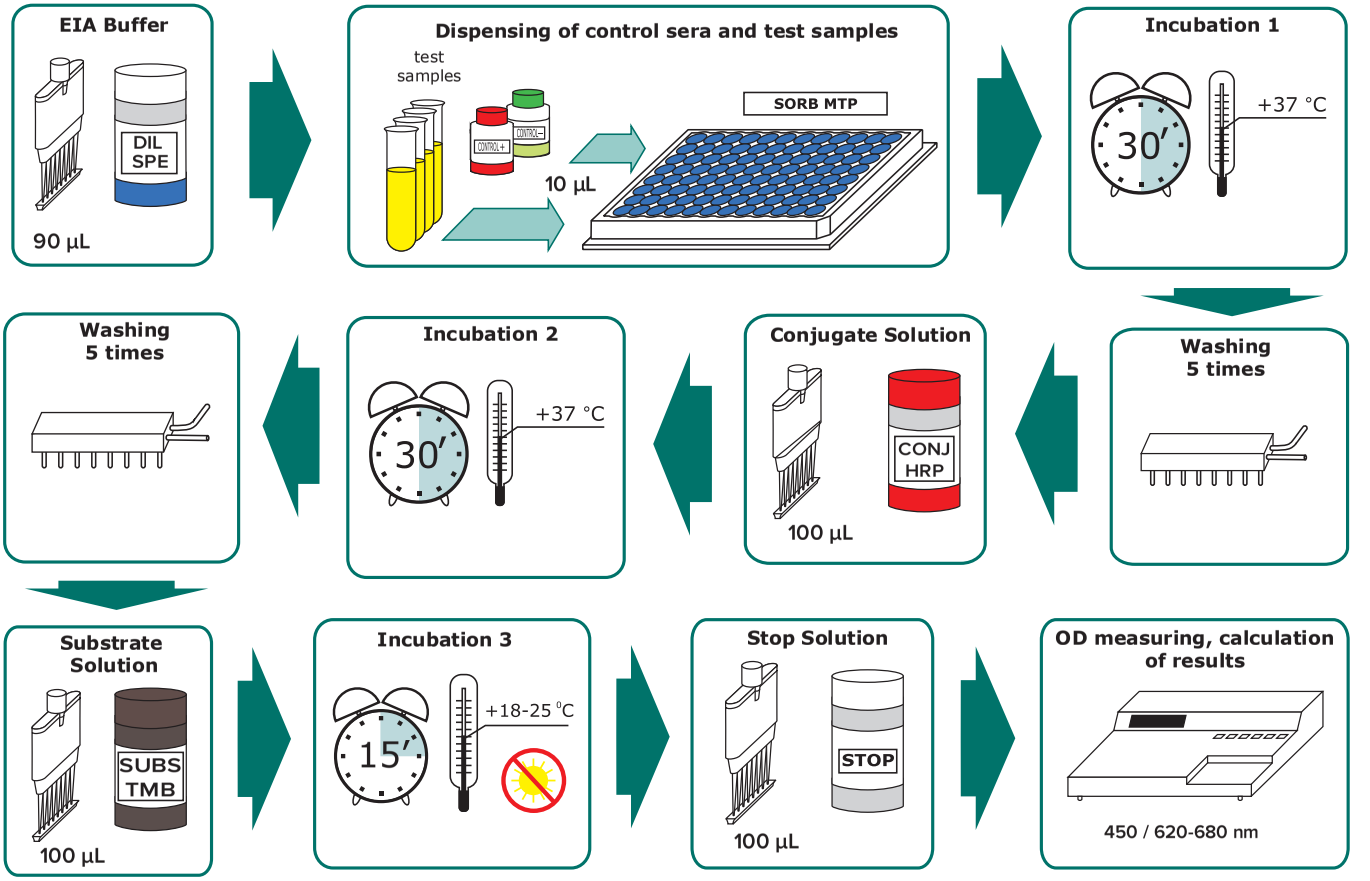
ASSAY PROCEDURE



During performing several independent series of tests, Positive and Negative Control Serum should be used **each time**.

K118M

CONTENT

Instruction for use
A solid-phase enzyme immunoassay kit for the qualitative detection of IgM antibodies to *Borelia burgdorferi sensu lato* in human serum or plasma

Borelia burgdorferi IgM EIA

1. INTENDED USE

ELISA reagent kit Borelia burgdorferi IgM EIA is a solid-phase enzyme immunoassay for the qualitative detection of IgM antibodies to *Borelia burgdorferi sensu lato* in human serum or plasma.

The field of application is clinical laboratory diagnostics.

2. GENERAL INFORMATION

Borrelia burgdorferi sensu lato - is a group of borreliosis or Lyme disease pathogens, a common infection, the main host and vector of which is the ixodid tick. The disease is transmitted only through a tick bite.

In the early stages of borreliosis, fatigue, chills and headaches may be observed, and later more serious symptoms may occur, such as joint pain, meningitis, numbness in the extremities, facial nerve paralysis, memory disorders, and eye and heart damage. After the spirochete penetrates the skin, a creeping erythema occurs, and after several days or weeks, it reaches many organs by haematogenous or lymphatic means. In general, the incubation period is from 3 to 45 days.

Early diagnosis of the disease is based on clinical and epidemiological data. The diagnosis is confirmed by laboratory, usually by serological methods - the detection of specific antibodies to *Borrelia burgdorferi* in the blood.

IgM antibodies appear in the blood first, a few days after infection, but can be detected by laboratory tests in 2-3 weeks. After about 6 weeks, the concentration of antibodies reaches a maximum and then gradually decreases. IgG antibodies begin to be detected 4-6 weeks after infection and the maximum amount of IgG antibodies is synthesised 2-3 months after the onset of early symptoms of the disease. Then their number gradually decreases, but they remain in the body for several years.

3. TEST PRINCIPLE

The detection of IgM antibodies to *Borrelia burgdorferi* is based on the indirect enzyme immunoassay principle. On the inner surface of the microplate wells are immobilized recombinant *Borrelia burgdorferi* antigen. The analysis procedure includes three stages of incubation:

- during the first stage specific to *Borrelia burgdorferi* antibodies from the specimen are bound onto the microwell surface;
- during the second stage horseradish peroxidase-conjugated specific monoclonal anti-IgM antibodies bind to the antigen-antibody complexes, fixed in the formed at the previous stage complexes;
- during the third stage, the complexes formed due to the reaction with the chromogen 3,3',5,5'-tetramethylbenzidine are visualized.

After stopping the reaction with a stop solution, the intensity of the color of the microwells is measured. The optical density (OD) in the microwell is directly related to the concentration of the measured IgM antibodies to *Borrelia burgdorferi* in test specimen.

4. KIT COMPONENTS

Code of component	Symbol	Name	Volume	Qty, pcs.	Description
P118MZ	SORB MTP	**Microplate**	-	1	96-well polystyrene strip microplate coated with recombinant antigen of *Borrelia burgdorferi*, ready to use
CN118MZ	CONTROL -	**Negative Control Serum K-**	0.5 mL	1	Solution based on human serum, free of IgM antibodies to *Borrelia burgdorferi*, with preservative, ready to use (yellow liquid)
CP118MZ	CONTROL +	**Positive Control Serum K+**	0.2 mL	1	Solution based on human serum, containing of IgM antibodies to *Borrelia burgdorferi*, with preservative, ready to use (red liquid)
T118MZ	CONJ HRP	**Conjugate Solution**	12 mL	1	Solution of monocnoclonal antibodies to IgM conjugated to the horseradish peroxidase, ready to use (red liquid)
SP118MZ	DIL SPE	**EIA Buffer**	12 mL	1	Buffer solution with detergent and preservative, ready to use (purple liquid)
R055Z	SUBS TMB	**Substrate Solution**	12 mL	1	Tetramethylbenzidine (TMB) substrate solution, ready to use (colourless liquid)
S008Z	BUF WASH 26X	**26x Concentrate Washing Solution**	30 mL	1	Buffer solution with detergent, 26x concentrate (colourless liquid)
R050Z	STOP	**Stop Solution**	12 mL	1	5.0% solution of sulphuric acid, ready to use (colourless liquid)
The kit also includes instruction for use, quality control data sheet and plate sealing tape (2 pcs).					

5. EQUIPMENT AND MATERIAL REQUIRED BUT NOT PROVIDED

– microplate photometer with 450/620-680 nm wavelength;
– dry thermostat for +37°C±1°C;
– automatic plate washer (optional);
– micropipettes with variable volume, range volume 5-1000 µL;
– graduated cylinder of 1000 mL capacity;
– distilled or deionized water;
– timer;
– vortex mixer;
– disposable gloves;
– absorbent paper.

6. WARNING AND PRECAUTIONS

In order to prevent incorrect results, strictly follow the recommended order and duration of the analysis procedure.

6.1. The kit is for *in vitro* diagnostic use only. For professional laboratory use.

6.2. Follow the rules mentioned below during the kit using:

- do not use kit beyond expire date;
- do not use the kit if its packaging is damaged;
- in order to avoid contamination, use new tips to pipette samples and reagents;
- use only verified equipment;
- close each vial with its own cap, after using the reagent;
- do not use components of other kits or reagents of other manufacturers;
- do not let wells dry after completing the rinsing step; immediately proceed to the next stage;
- avoid bubbles when adding reagents.

ATTENTION! The TMB substrate solution is light sensitive. Avoid prolonged exposure of the component to light.

6.3. Some kit components, such as stop solution, substrate solution, and washing solution, may cause toxic or irritant effects. If they get on the skin or mucosa, the affected area should be washed with plenty of running water.

6.4. All human products, including patient samples, should be considered potentially infectious. Handling and disposal should be in accordance with the procedures defined by an appropriate national biohazard safety guidelines or regulations.

6.5. The positive and negative control serum included in the kit are negative for antibodies to HIV 1,2, hepatitis C virus and HBsAg, but the reagents should be considered as potentially infectious material and handled carefully.

6.6. Specimens must not contain any azide compounds, as they inhibit activity of peroxidase.

6.7. Wear protective gloves, protective clothing, eye protection, face protection.

6.8. Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.

6.9. Safety Data Sheet for this product is available upon request directly from XEMA LLC.

6.10. Serious incidents related to the kit must be reported to the manufacturer, Authorized Representative, and to the Competent Authority of the EU member state(s) where the incident has occurred.

7. SPECIMEN COLLECTION, TRANSPORTATION AND STORAGE OF SAMPLES

7.1. Blood sampling should be carried out from the cubital vein with a disposable needle using a vacuum blood sampling system. Serum or plasma specimens should be clearly labeled and identified. Serum must be separated from the clot as early as possible to avoid hemolysis of red blood cells. If there are any visible particles in the sample, they should be removed by centrifugation at 3000-5000 rpm for 20 minutes at room temperature or by filtration.

Don't use samples with high lipidemia, hemolysis as they may give false test results.

7.2. Specimen should be stored at +2…+8°C up to 3 days. Specimen held for a longer time, should be placed in a freezer at -15°C or below, avoid no more than three cycles of thawing-freezing samples.

7.3. For the transportation of samples, it is recommended to use triple packaging. The primary package is the labeled tube containing the sample. Secondary packaging is a polyethylene bag that is hermetically closed with a zip-lock. The outer packaging is a heat-insulating container, while the secondary packaging is placed in the outer packaging for transportation in the center of the thermal container. Frozen refrigerants are placed on the bottom, along the side walls of the thermal container, and cover the samples with them.

8. TRANSPORTATION AND STORAGE TERMS OF KIT, WASTE DISPOSAL

Information about the singularity storage conditions, transportation of the kit, and disposal of waste should be taken into account by all persons who participate in these processes.

8.1. Transportation

The Borrelia burgdorferi IgM EIA kit should be transported in the manufacturer's packaging at +2...+8°C. Single transportation at the temperature up to 25ºC for 5 days is acceptable.

8.2. Storage

The Borrelia burgdorferi IgM EIA kit should be stored in the manufacturer's packaging at +2...+8°C. Do not freeze.

The kit contains reagents sufficient for 96 determinations including Positive and Negative Control Serum.

Once opened test-kit is stable for 2 months when stored properly as intended by manufacturer at 2-8°C.

In case of partial use of the kit, the components should be stored in the following way:

- the remaining strips should be immediately resealed in the bag along with the silica gel, closed with the zip-lock, and stored at +2...+8°C within 2 months;
- EIA Buffer, Substrate Solution, Stop Solution, and Washing Solution concentrate after opening the vial, can be stored tightly closed at +2...+8°C until the kit's shelf life;
- Conjugate Solution, Positive and Negative Control Serum after opening the vial, can be stored tightly closed at +2...+8°C within 2 months;
- diluted Washing Solution can be stored at room temperature (+18…+25°C) for up to 5 days or at +2…+8°C for up to 14 days.

Kits that were stored in violation of the storage condition cannot be used.

8.3. Disposal

Expired kit components, used reagents and materials, as well as residual samples must be inactivated and disposed of in accordance with legal requirements.

9. REAGENTS PREPARATION

9.1. All reagents (including microstrips) and test samples should be allowed to reach room temperature (+18…+25 °C) for at least 30 minutes before use.

9.2. Microplate preparation

Open the package with the microplate and install the required number of strips into the frame. The remaining strips should be immediately resealed in the bag along with the silica gel and closed with the zip-lock to prevent moisture from affecting the plate's strips.

9.3. Washing solution preparation

Add the contents of the 30 mL washing solution concentrate vial to 750 mL of distilled or deionized water and mix thoroughly. In case of partial use of the kit, take the necessary amount of washing solution concentrate and dilute it 26 times with distilled or deionized water.

The spending of the components in case of partial use of the kit is given in the table:

Quantity of strips	1	2	3	4	5	6	7	8	9	10	11	12
Volume of the washing solution concentrate, mL	2.5	5	7.5	10	12.5	15	17.5	20	22.5	25	27.5	30
Volume of water, mL	62.5	125	187.5	250	312.5	375	437.5	500	562.5	625	687.5	750

10. ASSAY PROCEDURE

10.1. Put the desired number of strips into the frame based on the number of test samples and 4 wells for Positive and Negative Control Serum (1 well for Positive Control (CP) and 3 wells for Negative Control Serum (CN)).

10.2. Dispense **90 µL of EIA Buffer** to all wells.

10.3. Dispense **10 µL of Positive and Negative Control Serum as well as 10 µL of test serum/plasma samples** (SAMP) to the wells of the microplate according to the scheme below. The introduction of Positive and Negative Control Serum and test samples should be carried out within 5 minutes to ensure equal incubation time for the first and last samples.

During performing several independent series of tests, Positive and Negative Control Serum should be used each time.

Scheme of introduction of samples

	1	2	3	4	5	6	7	8	9	10	11	12
A	CP	SAMP5	SAMP13	SAMP21								
B	CN	SAMP6	SAMP14	SAMP22								
C	CN	SAMP7	SAMP15	SAMP23								
D	CN	SAMP8	SAMP16									
E	SAMP1	SAMP9	SAMP17									
F	SAMP2	SAMP10	SAMP18									
G	SAMP3	SAMP11	SAMP19									
H	SAMP4	SAMP12	SAMP20									

10.4. Carefully mix the contents of the microplate in a circular motion on a horizontal surface, cover strips with a plate sealing tape and incubate for **30 minutes at +37°C**.

10.5. At the end of the incubation period, remove and discard the plate cover. Aspirate and wash each well **5 times** using an automatic washer or an 8-channel dispenser. For each washing, add 300 µL of Washing Solution (see 9.3) to all wells, then remove the liquid by aspiration or decantation. The residual volume of the Washing Solution after each aspiration or decantation should be no more than 5 µL. After washing, carefully remove the remaining liquid from the wells on the absorbent paper. For the automatic washer/analyzer, the Washing Solution volume can be increased to 350 µL.

10.6. Add **100 µL of Conjugate Solution** to all wells.

10.7. Cover strips with a plate sealing tape and incubate for **30 minutes at +37°C**.

10.8. At the end of the incubation period, aspirate and wash each well **5 times** as described in 10.5.

10.9. Add **100 µL of Substrate Solution** to all wells. The introduction of the Substrate Solution into the wells must be carried out within 2-3 minutes. Incubate the microplate in the dark **at room temperature (+18...+25°C) for 15 minutes**.

10.10. Add **100 µL of Stop Solution** to all wells in the same order as the Substrate Solution. After adding the Stop Solution, the contents of the wells turn yellow.

10.11. Read the optical density (OD) of the wells at 450 nm and reference light filters 620–680 nm using a microplate photometer within 5 minutes of adding the stop solution.

11. TEST VALIDITY AND CALCULATION OF RESULTS

11.1. The test results are valid only if Positive and Negative Control Serum are within the specified ranges and if all other test parameters are also within the given assay specifications, namely:

- OD of CONTROL- < 0.2;
- OD of CONTROL+ > 0.8;
- OD(CN) x 0,5 < OD(CN) < OD(CN) x 2.

11.2. Calculate the mean OD value of the Negative Control Serum:

meanOD(CN) = (OD1(CN) + OD2(CN) + OD3(CN))/3

11.3. Calculate the Cut Off value by adding to the mean OD value of the Negative Control Serum the coeficient 0.25.

Cut off = meanOD(CN) + 0.25

11.4. Calculate Positivity Index (PI) for each sample by dividing the OD of the sample by Cut off value:

PI = ODsample/Cut off

12. INTERPRETATION OF THE RESULTS

If PI value > 1.1 the result is **POSITIVE**,
If PI value is between 0.9 and 1.1 the result is **EQUIVOCAL**,
If PI value < 0.9 the result is **NEGATIVE**.

If equivocal results are obtained, it is recommended to retest the sample in several replicates. If the result is equivocal again, a new sample should be obtained within 5-7 days and retested. If the result remains equivocal, the sample should be considered negative.

13. PERFORMANCE CHARACTERISTICS

13.1. Analytical performance characteristics

13.1.1. Precision of Measurement

Reproducibility (Intra assay repeatability) was determined by evaluation the coefficient of variation (CV) for 2 different samples, with different levels of IgM antibodies to the *Borrelia burgdorferi sensu lato* antigen, during 1 day in 43 replicates on one series of ELISA kit.

№ serum	mean OD	mean PI	CV OD, %
1	2.0	1.92	6.9
2	4.9	5.09	7.8

Reproducibility (Inter assay reproducibility) was determined by evaluating the coefficients of variation (CV) for 2 samples of each serum for 4 days in 8-replicate determinations.

№ serum	mean OD	mean PI	CV OD, %
1	2.1	2.2	8.79
2	4.8	5.1	3.07

13.1.2. Analytical specificity

For the analysis result is not affected by the presence in the sample of bilirubin in a concentration of up to 0.21 mg/mL, hemoglobin in a concentration of up to 10 mg/mL and triglycerides in a concentration of up to 10 mg/mL.

13.2. Diagnostic performance characteristics

The clinical sensitivity and specificity of the assay were evaluated using a serum panel with 19 positive and 30 negative clinical serum samples and were 95% and 100%, respectively. The relative sensitivity and specificity of the assay were investigated in a sample of 150 donor sera characterised for the content of IgM antibodies to *Borrelia burgdorferi* antigen in commercical Kits, and the ressults were 98.7%.

14. LIMITATIONS

A positive result is evidence of the presence of IgM antibodies to *Borrelia burgdorferi sensu lato* antigen. The diagnosis cannot be based on the results of an IgM antibody test to *Borrelia burgdorferi* alone and requires confirmation, including an assessment of the patient's clinical presentation and history, the detection of IgG antibodies to *Borrelia burgdorferi* and perform an immunoblot test.

A negative result indicates the absence of IgM antibodies to *Borrelia burgdorferi sensu lato* or antibody levels below the limit of sensitivity of the kit.

The results of serum tests in patients with immunosuppression and immunological disorders should be interpreted with caution.

15. REFERENCES

1. Lyme Borreliosis (Lyme disease). In: International travel and health. Geneva: World Health Organization; 2014.
2. M Cinco 1, R Murgia, M Ruscio, B Andriolo. IgM and IgG significant reactivity to Borrelia burgdorferi sensu stricto, Borrelia garinii and Borrelia afzelii among Italian patients affected by Lyme arthritis or neuroborreliosis. FEMS Immunol Med Microbiol . 1996 Jun;14(2-3):159-66. doi: 10.1111/j.1574-695X.1996.tb00283.x.
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	Manufacturer
IVD	*In vitro* diagnistic medical device
REF	Catalogue number
	Use-by date
LOT	Batch code
	Temperature limit
	Contains sufficient for <n> tests
	Caution
	Consult instructions for use
	Conformity Marking with technical regulations in Ukraine
EC REP	Authorized representative in the European Community/European Union
CE	CE Conformity Marking

For any issues related to operation of the kit and technical support, please contact by telefon number

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