LOMINA
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Lomina Lyme borreliosis IgG/IgM Test
Instructions for use (IFU)

[PACKING DESCRIPTION]

Variants	1 pc in package - box/pouch	2 pcs in package - box	25 pcs in package - box	50 pcs in package - box
REF	La-LYME-Pro /1B or 1P	La-LYME-Pro /2B	La-LYME-Pro /25B	La-LYME-Pro /50B
IVD test strip in plastic cassette [pcs]	1	2	25	50
Sterile Lancet [pcs]	1	2	25	50
Stabilization fluid - buffer [pcs]	1	2	25	50
15 µl dropper [pcs]	1	2	25	50
Disinfecting pad [pcs]	1	2	25	50
IFU [pcs]	1	1	1	1

[INTRODUCTION]
Lyme borreliosis is an infectious disease caused by bacteria of the genus Borrelia, which are transmitted by ticks. The most common sign of infection is a spreading area of redness on the skin, known as erythema migrans, which begins at the site of the tick bite about a week after it occurs. The rash is usually not itchy or painful. Approximately 25-50% of infected persons do not develop the rash. Other early symptoms may include fever, headache and feeling tired. If left untreated, symptoms may include, but are not limited to, loss of the ability to move one or both sides of the face, joint pain, severe headaches with neck stiffness or heart palpitations. Months to years later, repeated episodes of pain and swelling in the joints may occur. Occasionally, people experience shooting pains or tingling in the hands and feet. Despite appropriate treatment, about 10 to 20 % of people develop joint pain, memory problems and fatigue for at least six months. Lyme disease is transmitted to humans by the bite of an infected tick of the genus Ixodes. Usually, the tick must be attached for 36 to 48 hours for the bacteria to spread. The disease does not appear to be transmitted between humans, other animals or through food. Diagnosis is based on a combination of symptoms, a history of contact with the tick, and possibly testing for specific antibodies in the blood. Blood tests are often negative in the early stages of the disease.

[INTENDED USE]
The Lomina Lyme Borreliosis IgG/IgM Test is a qualitative membrane immunoassay for the detection of IgG and IgM antibodies to Borrelia in whole blood, serum or plasma.

[TEST PRINCIPLE]
This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in the IgG test area. In the IgM component, the anti-human IgM is coated in the IgG test area. The anti-Borrelia antibodies are immobilized on the test area of the membrane. The mixture then migrates across the membrane by capillary action and interacts with reagents on the membrane. During testing, the sample reacts with the anti-IgG antibodies conjugated to the coloured particles in the IgG test area. As a result, a coloured line appears in the IgG test region. Similarly, the sample reacts with anti-IgM antibodies conjugated to coloured particles in the IgM test region. As a result, a coloured line appears in the IgM test region. Thus, if the sample contains IgG antibodies against Borrelia, a coloured line appears in the IgG test area - the sample is positive. If the sample contains IgM antibodies to Borrelia, a coloured line appears in the IgM test area - the sample is positive. If the sample does not contain Borrelia antibodies, no coloured line appears in the test area, indicating a negative result. As a check on the procedure, a coloured line always appears in the control area, indicating that the correct volume of sample has been added and the membrane has been activated.

[PACKAGE CONTENTS]
1. IVD test strip in plastic cassette
2. Desiccant
3. Lancet for disposable blood sample collection (HTL-Strefa S.A. CE 0344; Type Actilance STERILE R nebo wellion MED TRUST CE 0197; Type 23G double protection STERILE R)
4. Stabilization fluid (buffer)
5. 15 µl dropper
6. Disinfecting pad (alcohol-based disinfection)
7. Instructions for use

[NOT INCLUDED IN THE PACKAGE]
Stopwatch/clock for measuring the duration of the test.

⚠ [ATTENTION!]
- Please read all information in this package insert before performing the test.
- The Lomina Lyme IgG/IgM Test is intended for in vitro diagnostic use by healthcare professionals and should only be used for the qualitative detection of the presence of IgG and IgM antibodies to Borrelia in a sample.
- Do not eat, drink or smoke in the area where samples or kits are handled.
- Do not mix different lots (LOTs) of tests and reagents!
- Strictly observe the stated time for interpretation of results.
- Do not disassemble or touch the test window of the test cassette.
- The kit should not be frozen or used beyond the expiry date stated on the packaging.
- Keep out of the reach of children.
- The used test should be disposed of in accordance with local regulations.

[STORAGE CONDITIONS]
1. Store in a dry place at a temperature of 2-30 °C, avoid places with excessive humidity.
2. he contents of the kit are stable until the expiry date marked on the packaging, the shelf life is set at 18 months (based on a stability study).
3. Prolonged exposure to heat and moisture renders the reagent unusable.

[SAMPLE PREPARATION AND COLLECTION]
The Lomina Lyme borreliosis IgG/IgM test can be performed from whole blood, serum or plasma.

Sampling from the finger:
- Take the lancet and carefully remove and discard the loose lancet cap.
- Using the included disinfecting pad, clean the tip of the middle finger or ring finger as the injection site. Allow to air dry.
- Squeeze the lancet on the side from which the cap has been pulled; the tip will automatically and securely retract after use. Massage the patient's hand without touching the puncture site by massaging the hand towards the tip of the middle or ring finger to be punctured.
- Hold the patient's hand down and massage the end that has been punctured to obtain a drop of blood.
- Without squeezing the bulb of the dropper, bring it into contact with the blood. If you do not get enough blood, you can massage the finger again to get more blood. Avoid air bubbles.

Collection of whole blood samples from venepuncture:
- Collect anticoagulant blood sample (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) according to standard laboratory procedures.

Collection of serum/plasma samples:
- Collection of whole blood samples from venepuncture.
- Separate serum or plasma from blood as soon as possible to prevent haemolysis. Use only clear, unhemolyzed samples.

Serum and plasma samples can be stored at 2-8 °C for up to 3 days. For long-term storage, samples should be stored at temperatures below -20 °C. Whole blood collected by venepuncture should be stored at 2-8 °C if the test is to be performed within 2 days of collection. Do not freeze whole blood samples. Warm samples to room temperature before testing. Frozen samples should be thawed completely and mixed well before testing. Samples should not be repeatedly frozen and thawed. If specimens are to be transported, they should be packaged in accordance with local regulations for the transport of etiological agents.

[SAMPLE QUALITY REQUIREMENTS]
1. The sample should be treated with stabilization fluid (buffer) immediately after sample collection. It is recommended to detect immediately after sample collection.
2. Stabilization fluid (buffer) should not be opened until the sample has been applied.
3. Long-term storage of samples is not recommended.

[APPLICATION PROCEDURE]
Allow the assay, sample, stabilization fluid (buffer) and/or controls to reach room temperature (15-30 C) before testing.
1. Warm the bag to room temperature before opening. Remove the test cassette from the sealed bag and use it as soon as possible.
2. Place the cassette on a clean, flat surface.

For the serum/plasma sample:
- To use the pipette: Transfer 5 µl of serum/plasma to the sample well (S) and add 3 drops of stabilization fluid (buffer)

(approximately 120 µl) to the buffer well (B).

- To use the dropper: Hold the dropper vertically and insert the tip into the sample and draw the sample. Transfer the sample to the sample well (S) - 1 drop, then add 3 drops of stabilization fluid (buffer) (approximately 120 µl) to the buffer well (B) and start the timer.

For whole blood sample:

- Use the pipette (not included): Transfer 10 µl of whole blood to the sample well (S) and add 3 drops of stabilization fluid (buffer) (approximately 120 µl) to the buffer well (B).

3. **Using the dropper:** Hold the dropper vertically, draw the sample and transfer 1 full drop (approximately 10 µl) of sample into the sample well. Then add 3 drops of buffer (approximately 120 µl) to the buffer well (B) and start the timer.

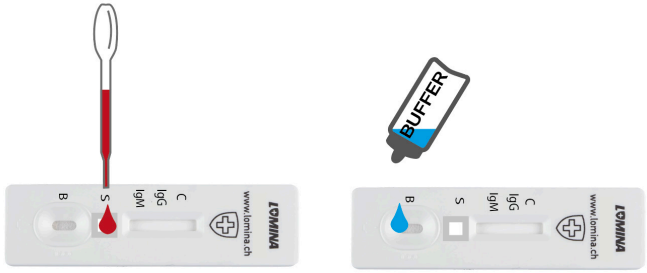
Wait for the colored lines to appear. Read the results after 10 minutes. Do not interpret the result after 20 minutes. Note: It is recommended not to use the buffer for more than 3 months after opening the vial.

[INTERPRETATION OF TEST RESULTS]

After applying the sample, start the stopwatch, wait 10 minutes without moving the cassette and then read the result. The result is interpreted by the presence of a visible line in the „IgG" or „IgM" area on the body of the test cassette (see figure below), the results of the visual inspection are as follows:

IgG POSITIVE:*Two coloured lines appear. One coloured line should always appear in the control area (C) and the other in the IgG test area.

IgM POSITIVE:* Two coloured lines appear. One coloured line should always appear in the control area (C) and the other in the IgM test area.

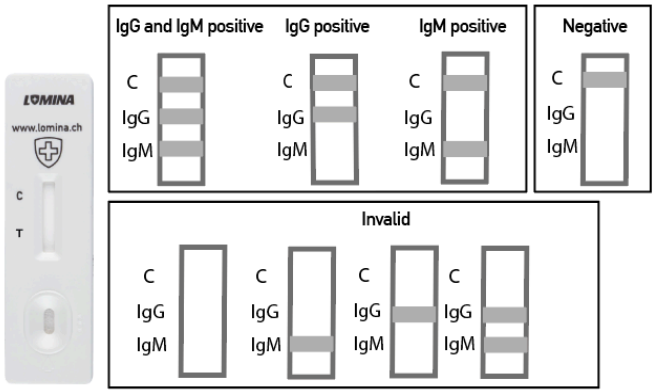


IgG and IgM POSITIVE:* Three coloured lines will appear. One colored line should always appear in the control area (C) and two lines should appear in the IgG and IgM test areas.

***NOTE:** The intensity of the color in the test line areas may vary depending on the concentration of Lyme antibodies present in the sample. Therefore, any shade of colour in the test line area should be considered positive.

NEGATIVE: A single coloured line appears in the control area (C). No line will appear in the IgG or IgM area.

INVALID: No line will appear in the control area (C). The most likely cause of control line failure is insufficient sample volume or incorrect procedure. Check the procedure and repeat the test with a new test. If the problem persists, stop using the test kit immediately and contact your local distributor.



[LIMITATION OF INSPECTION METHODS]

1. The Lomina Lyme Borreliosis IgG/IgM Test only indicates the presence of IgG and IgM antibodies to Borrelia in the sample and should not be used as the sole criterion for the diagnosis of Borrelia infection.
2. As with all diagnostic tests, all results must be considered along with other clinical information available to the physician.
3. If the test result is negative and clinical symptoms persist, further follow-up testing using other clinical methods is recommended. A negative result in no way excludes the possibility of Lyme infection.
4. The level of haematocrit in whole blood may affect the results of the test.
5. The haematocrit level must be between 25% and 65% for the results to be accurate.

[CROSS-REACTIVITY]

The Lomina IgG/IgM test was tested for anti-HAV IgM, HBsAg, anti-HCV IgG, anti-HIV IgG, anti-RF IgG, anti-Syphilis IgG, anti-H. Pylori IgG, anti-Rubella IgG, anti-Toxo IgG, anti-HSV 1 IgG, anti-HSV 2 IgG , anti-CMV IgG, anti-Rubella IgM, anti-Toxo IgM, anti-HSV 1 IgM, anti-HSV 2 IgM and anti-CMV IgM positive samples. The results showed no cross-reactivity.

[INTERFERENCE FACTORS]

No interference with the following substances has been detected: Acetaminophen: 20 mg/dL, Acetylsalicylic Acid: 20 mg/dL, Ascorbic Acid: 2g/dL, Creatin: 200 mg/dL, Bilirubin: 1g/dL, Caffeine: 20 mg/dL, Gentisic Acid: 20 mg/dL, Albumin: 2 g/dL, Hemoglobin 1000mg/dL, Oxalic Acid: 60mg/dL.

[SENSITIVITY/SPECIFICITY]

Method		ELISA		Total
The Lomina Lyme Borreliosis IgG/IgM Test for IgG	Results	Positive	Negative	
	Positive	21	1	22
	Negative	1	89	90
Total		22	90	112

Sensitivity: 95.5% (95%CI:77.2%-99.9%)
Specificity: 98.9% (95%CI: 94.0%-100%)
Accuracy: 98.2% (95% CI: 93.7%-99.8%)

Method		ELISA		Total
The Lomina Lyme Borreliosis IgG/IgM Test for IgM	Results	Positive	Negative	
	Positive	17	1	18
	Negative	1	89	90
Total		18	90	108

Sensitivity: 94.4% (95%CI: 72.7%-99.9%)
Specificity: 98.9% (95%CI: 96.7%-100%)
Accuracy: 98.2% (95%CI*: 93.5%-99.8%)

[CAUTION!]

- A negative test result can occur if the antibody level in the sample is below the detection limit of the test.
- False negative results can occur if the sample is improperly collected, transported or handled - in other words, if these instructions for use are not followed.
- If samples are tested later than 1 hour after collection, false results may occur. (Samples should be tested as soon as possible after collection).
- Insert the test sample into the test card very slowly and observe the exact amount of sample!
- The test reaction time is 10 minutes. After the reaction is complete, do not read the result later than 20 minutes. In other words, the result is invalid 20 minutes after the test solution is loaded.
- The intensity of the color or the thickness of the positive strip cannot be considered „quantitative or semi-quantitative".

[SYMBOL INDEX]

	Consult instructions for use		Caution		Use by date
IVD	In vitro diagnostic medical device		Do not use if package is damaged		Do not re-use/Intended for one use
	Manufacturer	LOT	Batch code	REF	Catalogue number
	Keep away from sunlight	Σ	Contains sufficient for <n> tests	30°C	Temperature limit 2-30 °C
	Keep dry	STERILE R	Sterilised by radiation		

MANUFACTURER:
LOMINA SUPERBIO a.s.
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REF
La-LYME-Pro

IVD

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