LOMINA
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Lomina Malaria Test
Instructions for use (IFU)

[PACKAGING SPECIFICATION]

Variants	1 pc in package - box/pouch	2 pcs in package - box	25 pcs in package - box	50 pcs in package - box
REF	La-M3/1B or 1P	La-M3/2B	La--M3/25B	La--M3/50B
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]

Malaria is caused by a protozoan that attacks human red blood cells. Malaria is one of the most widespread diseases in the world. According to the WHO, the global incidence of the disease is estimated at 300-500 million cases and more than 1 million deaths per year. Most of these victims are infants and young children. More than half of the world's population lives in areas where malaria occurs. Microscopic analysis has been the standard diagnostic technique for identifying malaria infections for more than a century. This technique is capable of accurate and reliable diagnosis when performed by qualified laboratory technicians following standard procedures. The Lomina Malaria Test is a rapid test that qualitatively detects the presence of P. falciparum - specific HRP-II, P. vivax (P.v.) and the four circulating species Plasmodium falciparum (P.f.), P. vivax (P.v.), P. ovale (P.o.) and P. malariae (P.m.). The test uses a colloidal gold conjugate to selectively detect antigens specific for P.f., P. vivax (P.v.) and panmalariae (P.f., P.v., P.o. and P.m.) in whole blood.

[INTENDED USE]

The Lomina Malaria Test is a rapid test based on the principle of chromatographic immunoassay for the qualitative detection of four species of circulating Plasmodium falciparum (P.f.), P. vivax (P.v.), P. ovale (P.o.) and P. malariae (P.m.) in whole blood**.**

[TEST PRINCIPLE]

The membrane is pre-coated with anti-HRP-II, anti-p.v. LDH and anti-pan LDH antibodies. During testing, the mixture migrates through the membrane where an immunochemical reaction occurs during capillary migration. The mixture then reacts with anti-histidine rich protein II (HRP-II) antibodies in the P.f. test region, with anti-p.v. LDH antibodies on the membrane in the P.v. test region, and with anti-Pan LDH antibodies on the membrane in the Pan test region. If the sample contains HRP-II, p.v. LDH and/or pan LDH, coloured lines will appear in the P.f., P.v. and/or Pan test region. The absence of coloured lines in the P.f., P.v. and/or Pan region indicates that the sample does not contain HRP-II, P.v. LDH and/or plasmodium-specific LDH. As a check on the procedure, a coloured line C always appears in the control region, indicating that the correct volume of sample has been added and that membrane activation has occurred.

[PACKAGE CONTENTS]

1. IVD test strip in plastic cassette
2. Desiccant
3. Lancet for disposable blood sample collection (HTL-Strefa S.A. CE0344; Type Actilance STERILE R nebo wellion MED TRUST CE0197; 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 manual before performing the test.
- The Lomina Malaria Test is intended for in vitro diagnostic use by healthcare professionals and should only be used for the qualitative detection of one to four species of Malaria or circulating Plasmodium falciparum (P.f.), P. vivax (P.v.), P. ovale (P.o.) and P. malariae (P.m.) in a sample.
- Do not eat, drink or smoke in the area where samples or kits are handled.
- Store in a dry place at 2-30 °C, avoid areas with excessive humidity.
- Do not disassemble or touch the test window of the test cassette.
- Do not freeze or use the kit after the expiry date on the packaging.
- Keep out of the reach of children.
- Dispose of the used test in accordance with local regulations.
- Do not mix different batches (LOT) of tests and reagents!

[STORAGE CONDITIONS]

1. The test pack shall be stored at a temperature of 2 °C to 30 °C.
2. The contents of the kit are stable until the expiry date marked on the packaging and the expiry date is set at 18 months (based on a stability study).
3. Prolonged exposure to heat and moisture will render the reagent unusable.

[SAMPLE QUALITY REQUIREMENT]

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

[APPLICATION INSTRUCTIONS]

- The Lomina Malaria Test can be performed on whole blood.
- Either whole blood from the finger or whole blood from a venepuncture can be used.
- Collection of whole blood samples from the finger:
- Wash the patient's hands with soap and warm water or clean them with an alcohol swab. Allow them to dry.
- Massage the hand without touching the puncture site by rubbing the hand down to the tip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Rub the hand gently from the wrist to the palm of the hand to the finger to form a round drop of blood at the puncture site.
- Testing should be done immediately after the specimen is collected. Do not leave samples at room temperature for long periods of time. Whole blood collected by venepuncture should be stored at 2-8°C if the test is to be performed within 2 days of collection. For long-term storage, samples should be stored at temperatures below -20 °C. Whole blood collected by finger prick should be tested immediately.
- Warm the samples to room temperature before testing. Frozen samples must be completely thawed and mixed well before testing. Specimens should not be frozen and thawed more than three times repeatedly.
- If specimens are to be transported, they should be packaged in accordance with federal regulations for transporting etiologic agents.
- Use standard procedures for venepuncture specimen collection.

[INSTRUCTIONS FOR USE]

Allow the assay, sample, buffer and/or controls to reach room temperature (15-30°C) before testing.

1. Warm to room temperature before opening the bag. Remove the test cassette from the sealed bag and use it as soon as possible.
2. Place the cassette on a clean and level surface.
- Use the dropper: Transfer 5 µl (one drop) of whole blood into the sample slot (S), then add 5 drops of buffer (approximately 180 µl) into the buffer slot (B) and start the time.
3. Wait for the colored streaks to appear. Evaluate the results after 10 minutes. Do not evaluate the result after 20 minutes.

[INTERPRETATION OF RESULTS]

- After applying the sample, start the stopwatch, wait 10 minutes without moving the card and then read the result in the „T" section of the test card. The line may appear within a few seconds for strong infections, weaker infections will pull the line a little later.
- The result is interpreted by the presence of a visible line in the „T" area on the body of the test cassette (see figure below), the results of the visual inspection are as follows:

POSITIVE:* Two or three or four distinctive coloured LINES will appear.

IP. falciparum infection (applies to any of the outcomes listed below):

- One line appears in the control area (C), one line appears in the P.f. test area.
- One line appears in the control area (C), one line appears in the P.f. test area and one line appears in the Pan area.

P. vivax infection (applies to any of the results listed below):

- One line appears in control area (C), one line appears in test area P.v.
- One line appears in the control area (C), one line appears in the P.v. test area, and one line appears in the Pan test area.

Non-P. falciparum/ Non-P. vivax Infection:

- One line appears in the control area (C), one line appears in the Pan test area.

Mixed malarial infection:

- One line appears in the control area (C), one line appears in the P.f. test area, and one line appears in the P.v. test area.
- One line appears in the control area (C), one line appears in the P.f. test area, one line appears in the P.v. test area, and one line appears in the Pan area.

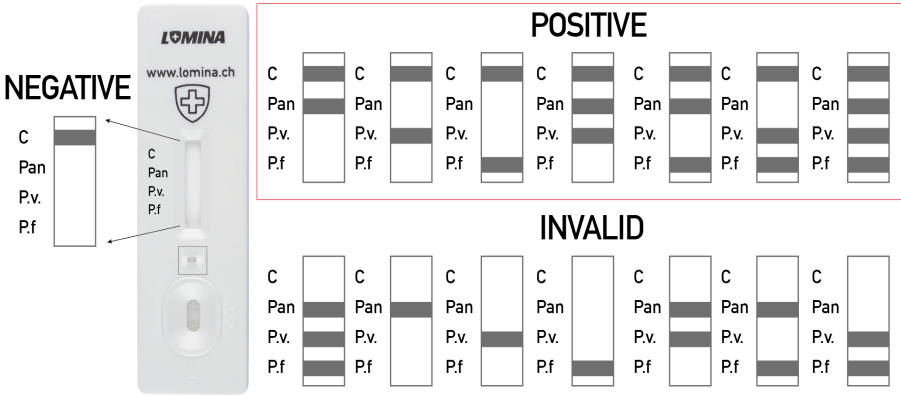
*NOTE: The colour intensity of the P.f., P.v. or Pan line may vary depending on the concentration, i.e. HRP-II, P.v. LDH or plasmodium-specific LDH, present in the sample.

NEGATIVE:

Only one coloured line appears in the control area (C).

INVALID:

The control line is not displayed. The most likely cause of control line failure is insufficient sample volume or incorrect procedures. Check the procedure and repeat the test with new test equipment. If the problem persists, stop using the test kit immediately and contact your local distributor.



[TEST LIMITATIONS]

1. The Lomina Malaria Test is intended for in vitro diagnostic use only. This test should only be used to detect P.f., P.v., P.o., P.m. antigens in whole blood samples. This qualitative test cannot determine the quantitative value or the rate of increase of P.f., P.v., P.o. and P.m. concentrations.
2. The Lomina Malaria Test only indicates the presence of Plasmodium sp. antigens (P.f., P.v., P.o., P.m.) in the sample and should not be used as the sole criterion for diagnosing malarial infection.
3. As with all diagnostic tests, all results must be interpreted in conjunction with other clinical information available to the physician.
4. If the test result is negative and clinical signs persist, further testing using other clinical methods is recommended. A negative result in no way excludes the possibility of malaria infection.

[CROSS-REACTIVITY]

Lomina Malaria Test was tested for HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-Syphilis, anti-HIV, anti-HCV, anti-H. Pylori, anti-MONO, anti-CMV IgM, anti-Rubella IgM and anti-TOXO IgM positive samples. The results showed no cross-reactivity.

[INTERFERENCE FACTORS]

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

[ANALYTICAL ACCURACY]

Within batch (Intra-Assay): analytical precision within batch was determined by 3 replicates of ten samples: negative, P.f. low positive, P.f. medium positive, P.f. high positive, P.v. low positive, P.v. medium positive, P.v. high positive, Pan low positive, Pan medium positive, Pan high positive. Samples were correctly identified >99% of the time.

Inter-batch (Intra-Assay): Inter-batch precision was determined by 10 replicates in 3 different batches on the same three samples: negative, P.f. low positive, P.f. medium positive, P.f. high positive, P.v. low positive, P.v. medium positive, P.v. high positive, P.v. low positive, Pan medium positive, Pan high positive. Samples were correctly identified > 99% of the time.

[PERFORMANCE CHARACTERISTICS]

Method		Microscopy		Total
Lomina Malaria Test	Results	Positive	Negative	
	Positive	77	1	78
	Negative	1	148	149
Total		78	149	227

Sensitivity: 98.7% (95%CI: 93.1%~100%);
Specificity: 99.3% (95%CI: 96.3%~100%)
Accuracy: 99.1% (95%CI: 96.8%~99.9%)

[CAUTION]

- A negative test result may occur if the level of infection in the sample is below the detection limit of the test.
- False negative results may occur if the sample is improperly collected, transported or handled - in other words, if these instructions for use are not followed.
- False results can occur if samples are tested later than 1 hour after collection. (Samples should be tested as soon as possible after sample collection).
- Insert the test sample into the test card very slowly and observe the exact amount of sample drops and reagents indicated!
- The reaction time of the test 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 has been inserted.
- The intensity of the colour 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	2℃ 30℃	Temperature limit 2-30 °C
	Keep dry	STERILE R	Sterilised by radiation		

MANUFACTURER:
LOMINA SUPERBIO a.s.
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CE

REF
La-M3-PRO

IVD 2℃ 30℃

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