LOMINA
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Lomina CRP 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-CRP-Pro/1B or 1P	La-CRP--Pro/2B	La-CRP--Pro/25B	La-CRP-Pro /50B
IVD test strip in plastic cassette [pcs]	1	2	25	50
Sterile Lancet [pcs]	1	2	25	50
Reagent (buffer) bottle [pcs]	1	2	25	50
15 µl dropper [pcs]	1	2	25	50
Disinfecting pad [pcs]	1	2	25	50
IFU [ks]	1	1	1	1

[INTRODUCTION]

C-reactive protein (CRP) in the patient's serum occurs in association with acute infections, necrotic conditions and various inflammatory diseases. There is a strong correlation between serum CRP levels and the onset of the inflammatory process. Monitoring of the patient's serum CRP level indicates the effectiveness of treatment and assessment of patient recovery. It is mainly used to differentiate bacterial infections from viral infections.

[INTENDED USE]

The Lomina CRP Test is an in vitro diagnostic test based on the principle of immunochromatography for the semi-quantitative detection of human CRP in whole blood, serum or plasma as an aid in the diagnosis of inflammatory conditions.

[TEST PRINCIPLE]

The Lomina CRP Test detects C-reactive protein by visually interpreting the color development on the inner strip. During testing, the sample reacts with particles coated with anti-CRP antigen in the test strip. If the sample contains anti-CRP antibodies, a colored line appears in the test area. The mixture of blood/serum/plasma and buffer migrates across the membrane where an immunochemical reaction occurs during capillary migration and reacts with the anti-CRP antibody in the test area. The mixture then migrates across the membrane by capillary action and interacts with the buffers on the membrane. If the intensity of the test strip is weaker than the reference strip (R), this indicates that the CRP level in the sample is in the range of 10-30 mg/L. If the intensity of the test strip (T) is stronger than the reference strip (R), this indicates that the CRP level is greater than 30 mg/l. As a check on the procedure, a coloured line always appears in the control area to indicate 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 or wellion MED TRUST CE 0197; Type 23G double protection sterile STERILE R)
4. Stabilization fluid (buffer)
5. Dropper 15 µL
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 CRP Test is intended for professional in vitro diagnostic use and should only be used for semi-quantitative detection of C-reactive protein.
- Do not eat, drink or smoke in the area where samples or kits are handled.
- If the foil wrapper is damaged or has been opened, do not use it.
- Strictly follow the indicated time for reading results. Use the test only once.
- Do not disassemble or touch the test window of the test cassette.
- The kit should not be frozen or used beyond the expiry date on the packaging.
- Keep out of the reach of children.
- The used test should be disposed of in accordance with local regulations.

[STORAGE CONDITIONS]

- The package is stored at a temperature of 2 °C to 30 °C.
- The ingredients of different batches must not be mixed.
- The contents of the kit are stable until the expiry date marked on the packaging, with a shelf life of 18 months (based on stability studies).
- Prolonged exposure to heat and moisture renders the reagent unusable.

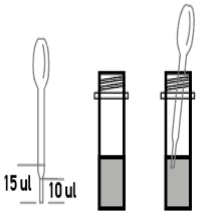
[SAMPLE PREPARATION AND COLLECTION]

Preparation

1. Make sure all components are at room temperature (15-30°C) before performing the test. Cold buffer solution or moisture condensation on the membrane may lead to invalid test results.
2. Remove the dilution buffer bottle from the kit. Label it with the patient's identifying information. Open the screw cap.

Collection of blood samples

1. Take a sample according to standard procedures.
2. Do not leave samples at room temperature for long periods of time. 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 used within 2 days of collection. Do not freeze whole blood samples. Whole blood drawn from the finger should be tested immediately.
3. Samples shall be brought to room temperature before testing. Frozen samples shall be completely thawed and well mixed before testing. Avoid repeated freezing and thawing of samples.
4. Blood with EDTA, citrate or heparin can also be used. It must be diluted appropriately with the buffer provided before the test is performed.



Sample dilution / stability

1. Use a dropper to draw 15 µl of blood - about 1 drop.
2. Add 10 µl of sample directly into the dilution buffer vial using a dropper.
3. Cap the vial and shake the sample vigorously for approximately 10 seconds to mix the sample and dilution buffer well.
4. Allow the diluted sample to rest for approximately 1 minute.
5. The diluted sample can then be used immediately or stored for up to 8 hours. Samples containing EDTA, citrate or heparin can also be used.

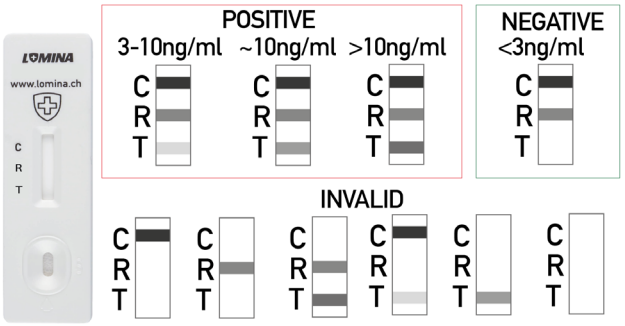
[INSTRUCTIONS FOR USE]

Warm the assays, samples, buffer and/or controls to room temperature (15-30 C) before use.

1. Remove the test cassette from the sealed bag and place it on a clean, flat surface. Label the device with the patient or control identification label. For best results, the test should be performed within one hour.
2. Open the sample vial. Transfer 3 drops of sample into the sample well. Start the timer.
3. Wait for the coloured lines to appear. The result should be read after 5 minutes. Do not interpret the result after 10 minutes.

[INTERPRETATION OF RESULTS]

1. The test should be considered in combination with clinical signs and other detection indicators.
2. After applying the sample, start the stopwatch, wait 5 minutes without handling the cassette and then read the result in the „R" and „T" section of the test cassette.
3. The result is interpreted by the presence of a visible stripe in the „R" and „T" area on the body of the test card (see figure below), the results of the visual inspection are as follows:



POSITIVE: Three coloured stripes appear on the membrane. Two stripes will appear in the control area (C) and in the reference area (R) and another stripe should appear in the test area (T).

- A test line (T) intensity that is weaker than reference line (R) indicates a CRP level between 10 and 30 mg/l.
- A test line (T) intensity that is closer to reference line (R) indicates a CRP level around 30 mg/l.
- A test line (T) intensity that is stronger than reference line (R) indicates a CRP level greater than 30 mg/l.

NEGATIVE: Colored lines appear in both the control (C) and reference (R) regions. No coloured stripe appears in the test area (T). This means that the CRP level is below 10 mg/l.

INVALID: The line in control area C or reference area R will not appear. If the test area (T) displayed a line at the specified time and the test area (C) or area (R) did not display a line, these tests shall be discarded. In this case, check the procedure and repeat the new test. If the problem persists, stop using the kit immediately and contact your local distributor.

NOTES:

1. The intensity of the colour in the test area (T) may vary depending on the concentration of CRP in the sample. Therefore, any shade of colour in the test area should be considered positive. Please note that this is only a semi-quantitative test and cannot determine the concentration of CRP in the sample.
2. The most likely causes of control band failure are insufficient sample volume, improper workflow or expired tests.

[QUALITY CONTROL]

Internal process controls are included in the test. Line displays in the control area (C) and reference area (R) are considered internal procedural controls that confirm sufficient sample volume and correct procedural procedure. External controls are not supplied with this kit.

[LIMITATION OF INSPECTION METHODS]

1. The Lomina CRP Test shows only a semi-quantitative level of CRP in the sample and should not be used as the sole criterion for evaluating inflammatory conditions.
2. CRP values close to the cut-off value (10 mg/l) and the reference strip (R: 30 mg/l) should be reported with caution as there is a degree of variability in all quantitative tests. Therefore, a test area T with a slightly higher intensity than R may also represent a value slightly lower than 30 mg/l. In such cases, a repeat test or another quantitative test is recommended.
3. High CRP concentrations can cause the so-called Hook effect, leading to misinterpretation of CRP levels. No effect of high doses up to 2 000 mg/l CRP was observed in this test.

[CROSS-REACTIVITY]

Lomina CRP Test was tested with positive samples for rheumatoid factor, HAMA, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-H.pylori, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis. The results showed no cross-reactivity.

[SENSITIVITY/SPECIFICITY]

Method		EIA		Total
The Lomina CRP Test	Results	Positive	Negative	
	Positive	79	4	83
	Negate	1	296	297
Total		80	300	380

Sensitivity: 98.8% (95% CI: 95.6%-100%)
Specificity: 98.7% (95% CI: 96.6%-99.6%)
Accuracy: 98.7% (95% CI: 97.0%-99.6%)

[INTERFERENCE SUBSTANCES]

No interference with the following substances has been detected: Acetaminophen: 20 mg/ dL, Acetylsalicylic Acid: 20 mg/dL, Ascorbic Acid: 20mg/dL, Creatin: 200 mg/dL, Bilirubin: 1,000mg/dL, Cholesterol: 800mg/dL, Caffeine: 20 mg/dL, Gentisic Acid: 20 mg/dL, Albumin: 10,500mg/dL, Hemoglobin 1,000 mg/dL, Oxalic Acid: 600mg/dL, Triglycerides: 1,600mg/dL.

[CAUTION]

- A negative test result may occur if the antigen level in the sample is below the detection limit of the test.
- False negative results can occur if the sample is incorrectly 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).
- Do not mix different batches (LOT) of tests and reagents!
- Read the Instructions for Use (IFU) carefully before testing and follow the procedures in the manual carefully.
- Insert the test sample into the test cassette very slowly and observe exactly the amount of sample specified in these instructions!
- The reaction time of the test is 5 minutes. After the reaction is complete, do not read the result later than 10 minutes. In other words, the result is invalid 10 minutes after the test solution is loaded.
- The Lomina CRP test is intended for in vitro diagnostic use by healthcare professionals and should only be used to qualitatively detect the presence of C-reactive protein in a sample.
- The intensity of the colour or the thickness of the positive stripe cannot be considered „quantitative or semi-quantitative".

[SYMBOLS DESCRIPTION]

	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 2°C	Temperature limit 2-30 °C
	Keep dry	STERILE R	Sterilised by radiation		

MANUFACTURER:
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CE

REF La-CRP-Pro

IVD 2°C 30°C

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Version: La-CRP-Pro/ CZ-IFU-1.0