LOMINA
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Lomina CA15-3 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-CA-153-Pro/1P or 1B	La-CA-153-Pro /2B	La-CA-153-Pro /25B	La-CA-153-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]
CA15-3 (Carcinoma Antigen 15-3) is a tumor marker for many types of cancer, especially breast cancer. It is derived from MUC1, which is a product of the breast cancer-associated gene MUC1, and CA15-3 and CA 27-29. Elevated levels of CA15-3 in association with alkaline phosphatase (ALP) have been associated with an increased likelihood of early recurrence in breast cancer. Both CA15-3 and CA 27-29 may be elevated in patients with benign ovarian cysts, benign breast disease, and benign liver disease. Elevated values may also be seen in cirrhosis, sarcoidosis, and lupus. CA 15-3 is now considered a reliable prognostic marker for breast cancer.

[INTENDED USE]
The Lomina CA15-3 Test is a rapid chromatographic immunoassay for the qualitative detection of CA15-3 in human whole blood, serum or plasma.

[TEST PRINCIPLE]
The Lomina CA15-3 Test is a qualitative membrane immunoassay for the detection of CA15-3 in whole blood, serum or plasma. The membrane is pre-coated with anti-CA15-3 in the test area of the strip. During testing, a sample of whole blood, serum or plasma reacts with the anti-CA15-3 coated particle. The mixture of blood/serum/plasma and reagent migrates across the membrane where an immunochemical reaction occurs during capillary migration and reacts with the anti-CA15-3 on the membrane to form a colored line. The presence of the coloured line in the test area indicates a positive result, while its absence indicates a negative result. As a check on the procedure, a colored line always appears in the control area, indicating that the correct volume of sample has been added and 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 package insert before performing the test.
- Lomina CA15-3 Test is intended for in vitro diagnostic use by healthcare professionals and should only be used for the qualitative detection of CA15-3.
- Do not eat, drink, or smoke in the area where samples or kits are handled.
- Strictly observe the specified time for sample readings.
- Do not disassemble or touch the test window of the test cassette.
- The kit should not be frozen or used beyond the expiration 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]
1. The package is stored at a temperature of 2 °C to 30 °C.
2. The contents of the kit are stable until the expiration date marked on the package, the shelf life is set at 18 months (based on stability studies).
3. Prolonged exposure to heat and moisture renders the reagent unusable.

[SAMPLE PREPARATION AND COLLECTION]
The Lomina CA15-3 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 and stabilization fluid (buffer) 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 and flat surface. For serum or plasma sample:

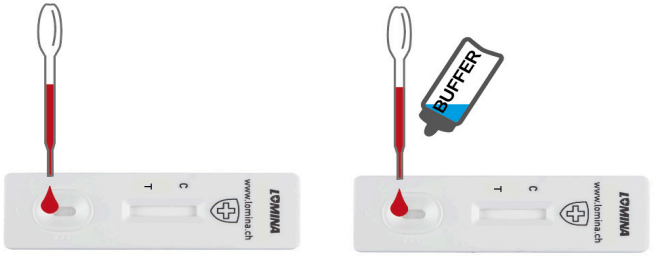
- Hold the dropper in an upright position and transfer 5 drops of serum or plasma (approximately 75 µl) into the sample slot (S) of the test cassette.

For venepuncture of whole blood sample and for finger prick blood collection:

- Hold the dropper vertically and transfer 5 drops of whole blood (approximately 75 µl) into the sample slot (S), then add 1 drop of stabilization fluid (buffer) (approximately 40 µl) into the buffer slot (B) and start the timer. See figure below.

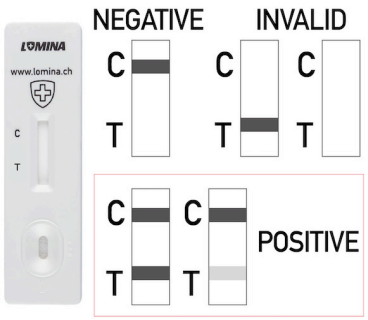
3. Wait for the coloured lines to appear. Read the results after 10 minutes. Do not interpret the result after 20 minutes.

Note: It is recommended not to use the stabilization fluid (buffer) for more than 6 months after opening the vial.



[INTERPRETATION OF TEST RESULTS]

After applying the sample, start the stopwatch, wait 5 minutes without handling the cassette and then read the result in the „T" area of the test cassette. The line may appear within a few seconds for strong concentrations, weaker concentrations will pull the line out a little later. The result is interpreted by the presence of a visible streak in the „T" area on the body of the test cassette (see figure), the results of the visual inspection are as follows:



POSITIVE:* Two coloured lines appear. One colour line should be in the control area (C) and the other colour line should be in the test area (T).*NOTE: The intensity of the colour in the test area (T) will vary depending on the concentration of antibodies present in the sample. Therefore, any shade of colour in the test area (T) should be considered positive.

NEGATIVE: A single coloured line appears in the control area (C). No coloured line appears in the test area (T).

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

[LIMITATION OF INSPECTION METHODS]

1. The Lomina CA15-3 Test is intended for in vitro diagnostic use only. The test should only be used to detect CA15-3 antibodies in whole blood, serum or plasma. Quantitative value cannot be determined with this qualitative test.
2. The Lomina CA15-3 Test only indicates the presence of CA15-3 in a sample and should not be used as the sole criterion for diagnosis.
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 by other clinical methods is recommended.
5. The whole blood haematocrit should be between 25% and 65%.

[SENSITIVITY/SPECIFICITY]

Method		CMIA		Total
Lomina CA15-3 Test	Results	Positive	Negative	
	Positive	54	3	57
	Negative	2	238	240
Total		56	241	297

Sensitivity: 96,4 % (95%CI: 87,7 % ~ 99,6 %)
Specificity: 98,8 % (95%CI: 96,4 % ~ 99,7 %);
Accuracy: 98,3 % (95%CI: 96,1 %~99,5 %).

[ANALYTICAL ACCURACY]

Within batch (Intra-Assay): Within batch analytical precision was determined by 10 replicates for three samples: negative, weakly positive and strongly positive. Negative, weakly positive and strongly positive values were correctly identified > 99% of the time.

Inter-batch (Intra-Assay): Inter-batch accuracy was determined by 10 replicates in 3 different batches on the same three samples: negative, weakly positive and strongly positive. Samples were correctly identified > 99% of the time.

[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.

[CROSS-REACTIVITY]

Lomina CA125 Test was tested for HBsAg, anti-HIV, anti-HCV, anti-RF, anti-Spyhilis, anti-H.pylori, anti-Toxo IgG, anti-Rubella IgG, anti-CMV IgG positive samples. No cross-reactivity was observed, indicating that the Lomina CA15-3 Test.

[CAUTION!]

- False negative results may 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.)
- Apply the sample very slowly to the test cartridge and observe the exact specified droplet amounts of sample and reagents!
- The reaction time of the test is 10 minutes.
- Once 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 loaded.
- The intensity of the colour or the thickness of the positive line 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°C 30°C	Temperature limit 2-30 °C
	Keep dry	STERILE R	Sterilised by radiation		

MANUFACTURER:
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IVD 2°C 30°C

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