

## Lomina Fecal Occult Blood (FOB) 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-FOB-Pro/1B or 1P	La-FOB-Pro/2B	La-FOB-Pro/2B	La-FOB-Pro/50B
IVD test strip in plastic cassette [pcs]	1	2	25	50
Stabilization fluid (buffer) with integrated dropper [pcs]	1	2	25	50
IFU [pcs]	1	1	1	1

### [ INTRODUCTION ]

The fecal occult blood test (FOB) is a simple and painless test that can detect serious diseases early by detecting fecal occult blood (blood hidden in the stool). In the early stages of gastrointestinal problems, such as colon cancer, ulcers, polyps, colitis, diverticulitis and fissures, there may be no clinical signs, but fecal occult blood is already present in the stool. Traditional guaiac-based methods lack sensitivity and specificity, and have dietary restrictions before testing. The Lomina Fecal Occult Blood (FOB) Test is a rapid test that qualitatively detects low levels of fecal occult blood. The test is based on the double antibody principle, which selectively detects fecal occult blood at concentrations of 50 ng/ml or higher, or 6 µg/g stool. In addition, unlike guaiac tests, the accuracy of the test is not affected by the patients' diet.

### [ INTENDED USE ]

The Lomina Fecal Occult Blood (FOB) Test is a rapid chromatographic immunoassay for the qualitative detection of human fecal occult blood.

### [ TEST PRINCIPLE ]

Lomina Fecal Occult Blood (FOB) Test is a qualitative lateral flow membrane immunoassay for the detection of human fecal occult blood. The membrane is pre-coated with anti-hemoglobin antibody in the test area of the strip. A mixture of stool and reagent migrates across the membrane where an immunochemical reaction occurs during capillary migration and reacts with the anti-hemoglobin 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 coloured 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. Stabilization fluid (buffer) with integrated dropper
4. Instructions for use

### [ NOT INCLUDED IN THE PACKAGE ]

- Stopwatch/clock for measuring the duration of the test
- Sample container

### [ ATTENTION ! ]

- Please read and follow all information in this manual before performing the test.
- The Lomina Fecal Occult Blood (FOB) Test is intended for in vitro diagnostic use by healthcare professionals and should only be used for the qualitative detection of the presence of fecal occult blood in a specimen.
- Do not eat, drink or smoke in the area where samples or kits are handled.
- Store in a dry place at 2-30 °C, avoiding areas with excessive humidity.
- If the foil packaging is damaged or has been opened, do not use it.
- Strictly observe the specified time for evaluation of the test.
- 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.
- Do not mix different batches (LOT) of tests and reagents!

### [ 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 expiry date marked on the packaging.
3. Prolonged exposure to heat and moisture renders the reagent unusable.

### [ SAMPLE PREPARATION AND COLLECTION ]

- Samples should not be taken during or within three days of menstruation, or if the patient has bleeding haemorrhoids or blood in the urine.
- Alcohol, aspirin and other drugs taken in excess can cause irritation of the digestive tract, which can lead to occult bleeding. These substances should be discontinued at

least 48 hours prior to testing.

- No dietary restrictions are necessary before using the Lomina Fecal Occult Blood (FOB) Test.

### [ SAMPLE QUALITY REQUIREMENTS ]

#### 1. Stool sampling:

- Collect enough faeces (1-2 ml or 1-2 g) to obtain maximum antigens (if present). For best results, test within 6 hours of collection. The collected sample can be stored for 3 days at 2-8°C if not tested within 6 hours. For long-term storage, samples should be stored at temperatures below -20 °C.

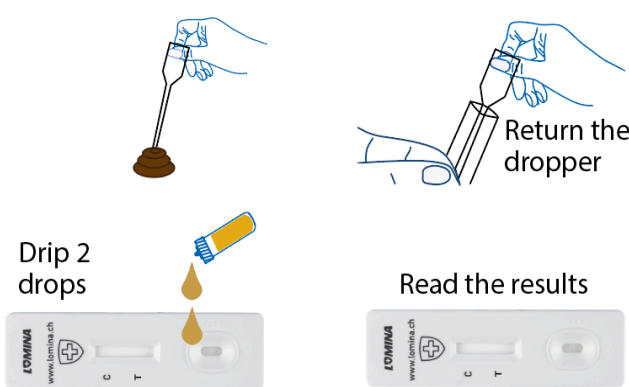
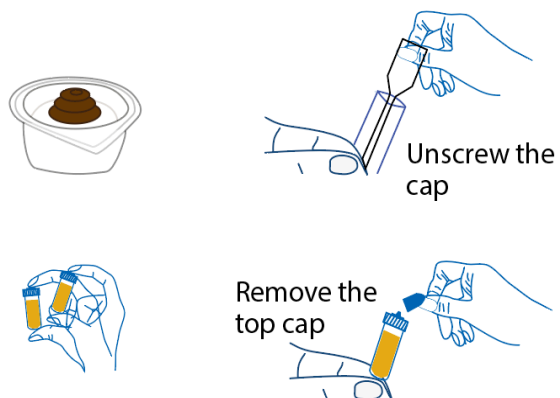
#### 2. Processing of stool samples:

- For solid samples: unscrew the cap of the collection tube, then randomly poke the collection applicator into the stool sample at at least 3 different locations to obtain approximately 50 mg of stool (equivalent to 1/4 of a pea). Do not inject the stool sample.
- For liquid samples: Hold the dropper in an upright position, aspirate the stool sample, then transfer 2 drops (approximately 80 µl) into the sample tube containing the extraction buffer. Tighten the cap of the sample tube and then shake the sample tube vigorously to mix the sample and extraction buffer. Allow the tube to stand for 2 minutes without handling.

### [ INSTRUCTIONS FOR USE ]

Before performing the test, stool samples should be collected according to the instructions below.

1. Wash your hands with soap and rinse them with clean water.
2. Stool sampling:
  - Stool samples should be collected in clean collection containers.
  - Use the specimen collection container in a way that prevents contamination of the specimen, and ensure that the container containing the specimen does not come into contact with any contaminating objects, including toilet cleaners.
3. Processing faecal samples:
  - Unscrew the cap of the specimen collection tube and then randomly stick the specimen collection applicator into the faecal specimen in at least 3 different places. Do not inject the stool sample.
4. Screw and tighten the cap on the sample tube and then shake the sample tube vigorously to mix the sample and stabilization fluid (buffer).

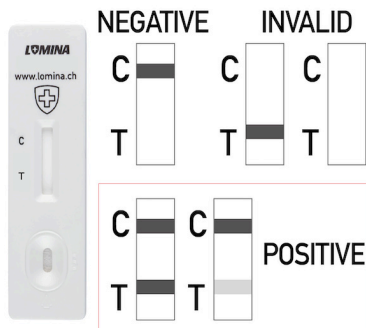


5. Warm the bag to room temperature before opening. Remove the test cassette from the foil bag and use it as soon as possible. For best results, test immediately after opening the foil pouch.
6. Open the cap of the sample tube and break off the tip. Invert the sample tube and transfer 2 full drops of the collected sample into the sample slot (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the sample port (S)
7. Read the results after 5 minutes. After 10 minutes, do not evaluate the results.

#### [ INTERPRETATION OF TEST RESULTS ]

- After applying the sample, start the stopwatch, wait 5 minutes without handling the cassette and then evaluate the result in the „T“ section of the test cassette. The streak may appear within a few seconds for strong concentrations, weaker concentrations will pull the streak out a little later.
- The result is evaluated by the presence of a visible streak 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 coloured lines will appear. One color line should be in the control area (C) and the other color line should be in the test area (T).\*NOTE: The intensity of the color in the test area (T) will vary depending on the concentration of FOBs present in the sample. Therefore, any shade of color 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 Fecal Occult Blood (FOB) Test is intended for in vitro diagnostic use only.
2. Lomina FOB test only indicates the presence of fecal occult blood; the presence of blood in the stool does not necessarily indicate bleeding in the colon.
3. As with all diagnostic tests, all results should be interpreted in conjunction with other clinical information available to the physician. If the test result is negative and clinical symptoms persist, further testing using other clinical methods is recommended.

#### [ CROSS-REACTIVITY ]

The Lomina CA125 Test has been tested for the following substances: Bovine hemoglobin, Chicken haemoglobin, Pork haemoglobin, Horse haemoglobin, Rabbit haemoglobin, Turkey haemoglobin, Goat haemoglobin. The results showed no cross-reactivity.

#### [ INTERFERENCE FACTORS ]

No interference with the following substances has been detected: Ascorbic acid 20 mg/dl, Oxalic acid 60 mg/dl, Bilirubin 100 mg/dl, Glucose 2000 mg/dl, Caffeine 40 mg/dl, Uric acid 60 mg/dl, Aspirin 20 mg/dl, Urea 2000 mg/dl, Albumin 2000 mg/dl.

#### [ SENSITIVITY/SPECIFICITY ]

Method	Commercially Available FOB Test		Total	
	Results	Positive		Negative
Lomina FOB Test	Positive	63	3	66
	Negative	1	397	398
Total		64	400	464

Sensitivity: 98,4% (95% CI: 91,6%-100%)  
 Specificity: 99,3% (95% CI: 97,8%-99,9%)  
 Accuracy: 99,1% (95% CI: 97,8%-99,8%)

#### [ CAUTION! ]

- 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.
- Read the instructions for use (IFU) carefully before testing and follow the procedures in the manual.
- Apply the sample to the test card very slowly and observe the exact number of drops of sample and reagent!
- The reaction time of the test is 5 minutes. When 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 intensity of the color or the thickness of the positive band cannot be considered „quantitative or semi-quantitative“.

#### [ SYMBOL INDEX ]

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

**MANUFACTURER:**  
 LOMINA SUPERBIO a.s.  
 Na Radosti 184/59, Praha 5,  
 155 21, CZECH REPUBLIC  
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La-FOB-Pro

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 Version: La-FOB-Pro/ EN-IFU-1.0