LOMINA
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Lomina Calprotectin 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-CPT--Pro/1B or 1P	La-CPT--Pro/2B	La-CPT--Pro/25B	La-CPT--Pro/50B
IVD test strip in plastic cassette [pcs]	1	2	25	50
Sample tube with stabilization fluid (buffer) with integrated dropper [pcs]	1	2	25	50
IFU [pcs]	1	1	1	1

[INTRODUCTION]

Calprotectin is a 24 kDa dimer of the calcium-binding proteins S100A8 and S100A9. This complex accounts for up to 60% of the soluble protein content in the neutrophil cytosol. Calprotectin enters the intestinal lumen via leukocyte secretion, active secretion, cell disruption and cell death. As a result, an elevated level of calprotectin is present and can be detected in the stool. Thus, elevated calprotectin levels indicate migration of neutrophils into the intestinal mucosa, which occurs during intestinal inflammation. Calprotectin present in stool is used to detect intestinal inflammation and can serve as a marker of inflammatory bowel disease. Calprotectin is useful as a marker because it is resistant to enzymatic degradation and can be easily measured in stool.

[INTENDED USE]

The Lomina Calprotectin Test is a rapid chromatographic immunoassay for the qualitative detection of calprotectin in human stool samples that can be useful for the diagnosis of inflammatory gastrointestinal diseases.

[TEST PRINCIPLE]

The Lomina Calprotectin Test is a qualitative lateral flow membrane immunoassay for the detection of Calprotectin in stool. The membrane is pre-coated with an anti-calprotectin 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-calcprotectin on the membrane to form a coloured 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. Sample tube with 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 all the information in this manual before performing the test.
- For professional use only.
- Do not eat, drink or smoke in the area where samples or kits are handled.
- Do not use the foil packaging if it is damaged or has been opened.
- Strictly observe the specified time for evaluation of 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]

1. Store in a dry place at a temperature of 2-30 °C, avoid areas with excessive humidity.
2. Do not mix components of different batches.
3. The contents of the kit are stable until the expiry date marked on the outer packaging and containers.
4. Prolonged exposure to heat and moisture renders the reagent unusable.

[SAMPLE PREPARATION AND COLLECTION]

- The stool sample must be collected in a clean, dry, watertight container that does not contain any detergents, preservatives or transport media.
- Bring the reagent to room temperature before use.

[SAMPLE QUALITY REQUIREMENTS]

1. Collection of stool samples:

- Take a sufficient amount of stool (1-2 ml or 1-2 g) to obtain maximum antigens (if present). For best results, test within 6 hours of collection. The specimen collected may 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 sampling tube and then randomly poke the sampling applicator into the stool sample in at least 3 different places 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 a vertical position, aspirate the stool samples, and 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.

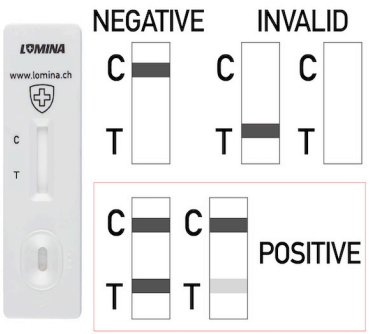
[INSTRUCTIONS FOR USE]

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:
   - The stool sample should be collected in clean collection containers.
   - Use a stool collection container to avoid contamination of the specimen and ensure that the specimen or part of the container containing the specimen does not come into contact with any contaminating objects, including toilet cleaners.
3. Stool sample processing:
   - Solid stool: unscrew the cap of the sample tube (specimen collection tube) and then randomly poke the specimen collection applicator into the stool sample in at least 3 different locations. Do not load the stool sample.
   - Liquid stool: Hold the cap of the sample tube with the integrated dropper in a vertical position and then transfer 2 drops (approximately 80 µl) back into the sample tube with the stabilization solution (buffer).
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, perform the 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 (80 µl) of the collected sample into the sample port (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the sample port (S).
7. Evaluate the results after 5 minutes. Do not read the results after 10 minutes.

[INTERPRETATION OF TEST RESULTS]

1. After applying the sample, start the stopwatch, wait 10 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.
2. 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:



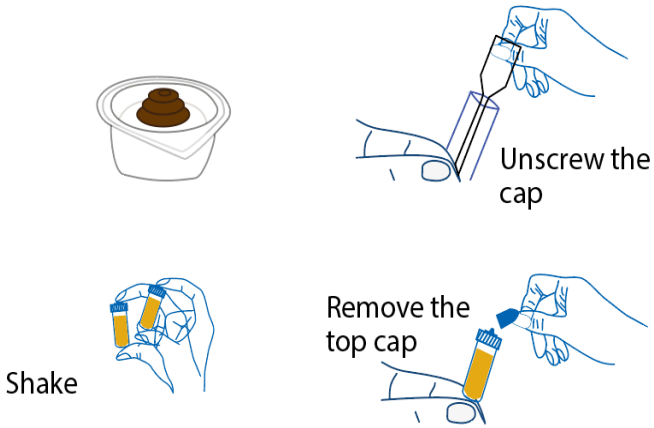
POSITIVE:* Two coloured lines appear. One colour line should be in the control area (C) and the other colour line should be in the test area (T).*NOTE: The intensity of the colour in the test area (T) will vary depending on the concentration of antibodies present in the sample. Therefore, any shade of 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 Calprotectin Test is intended for in vitro diagnostic use only.
2. 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.

[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.



[ANALYTICAL ACCURACY]

Within batch (Intra-Assay): Within batch analytical precision was determined by 15 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 15 replicates in 3 different batches on the same three samples: negative, weakly positive and strongly positive. Samples were correctly identified > 99% of the time.

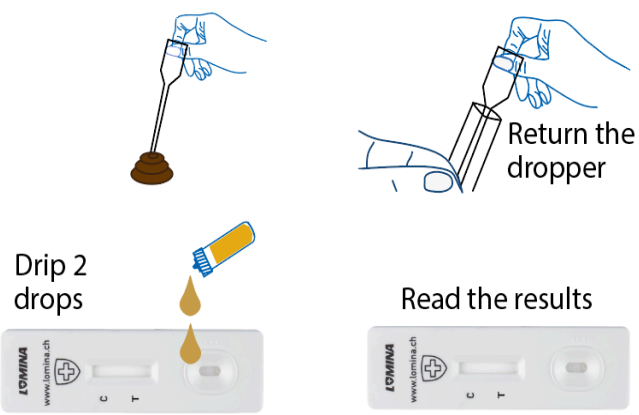
[SENSITIVITY/SPECIFICITY]

Method		Commercially Available Calprotectin Test		Total
Lomina Calprotectin Test	Results	Positive	Negative	
	Positive	133	2	135
	Negative	3	198	201
Total		136	200	336

Sensitivity: 97,8% (95% CI: 93,7%-99,5%)
Specificity: 99,0% (95% CI: 96,4%-99,9%)
Accuracy: 98,5% (95% CI: 96,6%-99,5%)

[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.
- Do not mix different batches (LOTs) of tests and reagents!
- Read the instructions for use (IFU) carefully before testing and follow the procedures in the manual carefully.
- 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. Once the reaction is complete, do not evaluate the result later than 10 minutes. In other words, the result is invalid 10 minutes after loading the test solution.
- The Lomina Calprotectin Test is intended for in vitro diagnostic use by healthcare professionals and should only be used for the qualitative detection of the presence of calprotectin in a sample.
- 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				

MANUFACTURER:
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CE
REF La-CPT-Pro

IVD 2°C 30°C

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Version: La-CPT-Pro/ CZ-IFU-1.1