LOMINA
WWW.LOMINA.CH IVD CE

Lomina H.pylori Antigen Test

Instructions for Use (IFU)

[PRODUCT NAME]

Lomina H.pylori Antigen Test

[PACKING SPECIFICATION]

Varianty	1 piece in a package - box or pouch	2 pieces in a package - box	5 piece in a package - box	25 pieces in a package - box	50 pieces in a package - box
Catalogue Nr. (REF)	La-HpyAg-Pro/1B or 1P	La-HpyAg-Pro/2B	La-HpyAg-Pro/5B	La-HpyAg-Pro/25B	La-HpyAg-Pro/50B
IVD test strip in a plastic cassette [pcs]	1	2	2	25	50
Tube with extraction buffer [pcs]	1	2	2	25	50
Swab for specimen collection [pcs]	1	2	2	25	50
25 µL dropper [pcs]	1	2	2	25	50
Instructions for Use (IFU) [ks]	1	1	1	1	1

[INTRODUCTION]

H.pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis. Both invasive and non-invasive methods are used to diagnose H.pylori infection in patients with symptoms of gastrointestinal disease. Specimen-dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining. A very common approach to the diagnosis of H.pylori infection is the serological identification of specific antibodies in infected patients. The main limitation of serology test is the inability to distinguish current and past infections. Antibody may be present in the patient's serum long after eradication of the organisms. HpSA (H. pylori Stool Antigen) testing is gaining popularity for diagnosis of H. pylori infection and also for monitoring the efficacy of the treatment of H. pylori infection. Studies have found that more than 90% of patients with duodenal ulcer and 80% of patients with gastric ulcer are infected with H.pylori.

[INTENDED USE]

The Lomina H.pylori Antigen Test is a rapid chromatographic immunoassay for the qualitative detection of H.pylori antigens in human stool. The test provides results within 10 minutes. The test uses antibodies specific for H. pylori antigens to selectively detect H. pylori antigens in human stool samples.

[TEST PRINCIPLE]

The H. pylori Antigen Rapid Test is a qualitative, lateral flow immunoassay for the detection of H. pylori antigens in human feces specimens. In this test, the membrane is pre coated with anti H. pylori antibodies on the test line region of the test. During testing, the specimen reacts with the particle coated with anti H. pylori antibodies. The mixture migrates upward on the membrane by capillary action to react with anti H. pylori antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. If the specimen contains H. pylori Antigen, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain H. pylori Antigen, a colored line will not appear in this region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

[CONTENT OF PRESENTATION]

1. IVD test strip in a plastic cassette
2. Humidity absorbing pad.
3. Tube with extraction buffer
4. 25 µL dropper
5. Swab for specimen collection
6. Instruction for use

[NOT INCLUDED IN THE PACKAGE]

- Sample container
- Stopwatch/clock for measuring test duration

[ATTENTION !]

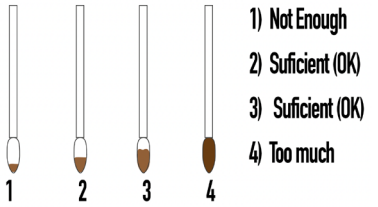
- Please read all information in this package insert before performing the test.
- Do not eat, drink or smoke in the area where samples or kits are handled.
- Store in a dry place at a temperature of 2-30 °C, avoid areas with excessive moisture.
- If the foil packaging is damaged or has been opened, do not use it.
- The Lomina H.pylori Antigen Test is for professional use only and should only be used for the qualitative detection of the presence of H.pylori antigen in a sample.
- Strictly observe the indicated time for evaluation of the results.
- Use the test only once.
- 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.
- 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. Components of different batches must not be mixed.
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.
5. Do not freeze.

[OPERATING STEPS]

1. Stool samples should be taken before the test according to the instructions below.
2. Wash your hands with soap and rinse with clean water.



- Stool sampling:
- Using a swab, collect enough stool (1-2 ml or 1-2 g) in a clean, dry container to obtain the maximum amount of 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.

3. Processing of stool samples:

- For solid samples: unscrew the cap of the specimen collection tube and then randomly poke the specimen collection applicator into the stool sample at least 3 different locations to obtain approximately 50 mg of stool (equivalent to 1/4 of a pea). Place the stool sample in the reagent vial.
- For liquid samples: Hold the dropper in a vertical position, aspirate the stool sample, and then transfer 3-4 drops (approximately 80 µl) into the reagent (buffer) vial.

4. Tighten the cap on the sample reagent (buffer) vial and then shake the vial vigorously to mix the sample and extraction buffer. Allow the tube to stand for 2 minutes.
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 reagent vial and use the dropper to transfer 3-4 drops (approximately 80 µl) of the collected sample into the sample well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the sample well (S).
7. Evaluate the results after 10 minutes. Do not evaluate the results after 20 minutes.

[INTERPRETATION OF TEST 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 10 minutes without moving the card, and then read the result in the test section „T". The strip may appear within seconds for strong infections, weaker infections will pull the strip a little later.

(A) Positive: Two lines appear. This result means that there is the presence of the H.pylori antigen in feces and that you should consult a physician.

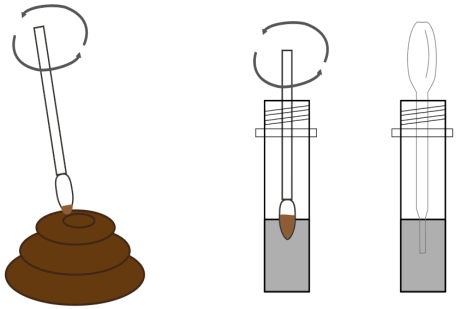
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of H.pylori antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

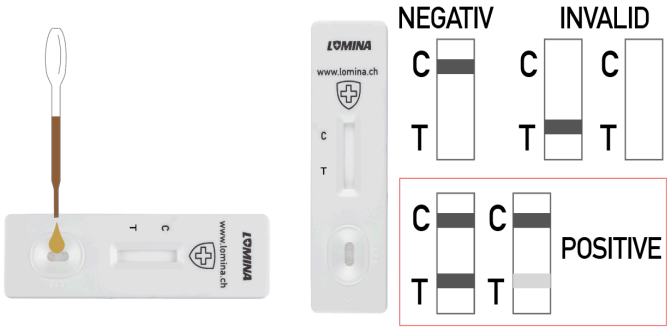
(B) Negative test: One colored line appears in the control line region (C). This result means that the presence of the H.pylori antigen in feces was not detectable.

(C) Invalid test: Control line fails to appear insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

[LIMITATIONS OF INSPECTION METHODS]

1. The H.pylori Antigen Test Cassette (Feces) is for in vitro diagnostic use only. The test should be used for the detection of H.pylori antigens in feces specimens only. Neither the quantitative value nor the rate of increase in H.pylori antigens concentration can be determined by this qualitative test.
2. The H.pylori Antigen Test Cassette (Feces) will only indicate the presence of H.pylori in the specimen and should not be used as the sole criteria for H.pylori to be etiological agent for peptic or duodenal ulcer.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of H.pylori infection.
5. Following certain antibiotic treatments, the concentration of H.pylori antigens may decrease to the concentration





below the minimum detection level of the test. Therefore, diagnosis should be made with caution during antibiotic treatment.

[INTERFERENCE FACTORS]

No interference reaction with the following substances has been detected: Ascoribic 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.

[CROSS-REACTIVITY]

No significant cross-over with the listed viruses/bacteria: Acinetobacterspp, Acinetobactercalcoaceticius, Adenovirus, Branhamella catarrhalis, Candida albicans, Chlamydia trachomatis, E. coli, Enterococcus faecalis, Enterococcus faecium, Gardnerella vaginalis, Group A Streptococcus, Group B Streptococcus, Group C Streptococcus, Hemophilus influenzae, Klebsiella pneumonia, Neisseria meningitides, Proteus mirabilis, Proteus vulgaris, Preudomonas aeruginosa, Rotavirus, Salmonella choleraesius, Staphylococcus aureus.

[SENSITIVITY/SPECIFICITY]

		Endoscopic method		
		POSITIVE	NEGATIVE	Total
Lomina H.pylori Antigen Test	POSITIVE	168	3	171
	NEGATIVE	2	189	191
	Total	170	192	362

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

[HOOK EFFECT]

There is no hook dose effect for the Lomina H.pylori Antigen Test.

[ATTENTION]

- 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 improperly collected, transported or handled - in other words, if these instructions for use are not followed.
- The reaction time of the test is 10 minutes. Once the reaction is complete, do not read the result later than 20 minutes later. In other words, the result is invalid 20 minutes after the test solution has been loaded.
- The intensity of the color or the thickness of the positive strip cannot be considered „quantitative or semi-quantitative".

[SYMBOL INDEX]

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Consult Instructions For Use		Manufacturer

MANUFACTURER:
LOMINA SUPERBIO a.s.
Na Radosti 184/59, Praha 5,
155 21, CZECH REPUBLIC
www.lomina.ch ivd@lomina.ch

CE

REF La-HpyAg-Pro

IVD 2°C 30°C

Date of last revision: 2022/06/29
Version: La-HpyAg-Pro/ EN-IFU-0.6