■ *INTENDED USE*

The *H. pylori* Ag Test is a lateral flow immunochromatographic assay for the qualitative detection of *Helicobacter pylori* antigen (HP Ag) in dog's or cat's feces specimen.

Assay Time: 5-10 minutes

Specimen: feces

■ *PRINCIPLE*

The *H. pylori* Ag Test is based on sandwich lateral flow immunochromatographic assay. The test device has a testing window for the observation of assay running and result reading. The testing window has an invisible T (test) zone and a C (control) zone before running the assay. When the treated sample was applied into the sample well on the device, the liquid will laterally flow through the surface of the test strip and react with the pre-coated monoclonal antibodies. If there is *H. pylori* antigen in the specimen, a visible T line will appear. The C line should always appear after a sample is applied, which indicates a valid result. By this means, the device can accurately indicate the presence of Helicobacter pylori antigen in the specimen.

■ *REAGENTS AND MATERIALS*

- 10 test pouches, with cards and disposable droppers
- 10 vials of assay buffer (1000μL each)
- 10 bags of swab stick
- 1 package insert

■ *STORAGE AND STABILITY*

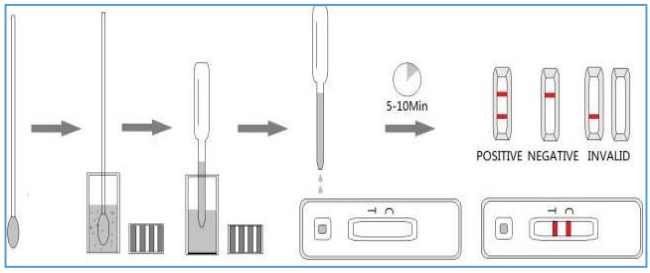
The kit can be stored at room temperature (2-30°C). The test kit is stable through the expiration date (18 months) marked on the package label. DO NOT FREEZE. Do not store the test kit in direct sunlight.

■ *TEST PROCEDURE*

- Collect dog's or cat's fresh feces with the swab stick from dog or cat's anus or from the ground.
- Insert the swab into the provided assay buffer tube. Agitates it to get efficient sample extraction.
- Take out the test card from the foil pouch and place it horizontally.
- Suck the treated sample extraction from the assay buffer tube and place 4 drops into the sample well "S" of the test device.

Note: If the liquid will not flow through the surface of the test strip in 30 seconds, please add another drop of the treated sample extraction.

- Interpret the result in 5-10 minutes. Result after 10 minutes is considered as invalid.



■ *INTERPRETATION OF RESULTS*

- Positive (+): The presence of both "C" line and zone "T" line, no matter T line is clear or vague.
- Negative (-): Only clear C line appear. No T line.
- Invalid: No colored line appears in C zone. No matter if T line appears.

■ *PRECAUTIONS*

- All reagents must be at room temperature before running the assay.
- Do not remove test cassette from its pouch until immediately before use.
- Do not use the test beyond its expiration date.
- The components in this kit have been quality control tested as standard batch unit. Do not mix components from different lot numbers.
- All specimens are of potential infection. It must be strictly treated according to the rules and regulations by local states.

■ *LIMITATION*

The *H. pylori* Ag Test is designed for in vitro veterinary diagnosis use only. All result should be considered with other clinical information available with veterinarian. It is suggested to apply a further confirmative method such as PCR when positive result was observed.

Manufacturer:
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