RAPYDTEST®

FOR THE DETECTION OF H.PYLORI AG IN FAECES

APACOR

H.pylori Ag
RAPYDTEST®

Intended Use

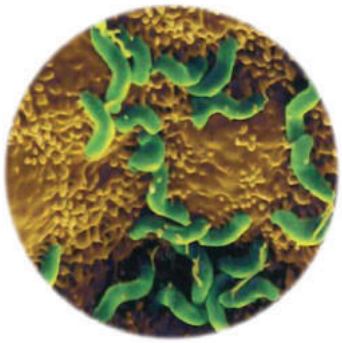
The H.pylori Ag Rapydtest® is a lateral flow chromatographic immunoassay for the qualitative detection of H.pylori antigen in human faecal specimen. It is intended to be used by professionals as a screening test and as an aid in the diagnosis of infection with H.pylori.

Performance Characteristics

Clinical Performance

324 faecal samples collected from subjects with symptomatic gastrointestinal disorders and non-gastrointestinal symptoms were tested with the H. pylori Ag Rapydtest® and with the UBT as reference test.

A comparison of the results for all subjects is shown in the table below.



	H.pylori Ag Rapydtest®		
UBT	POSITIVE	NEGATIVE	TOTAL
POSITIVE	118	7	125
NEGATIVE	0	199	199
TOTAL	118	206	324

Relative Sensitivity: 94.4%

Relative Specificity: 100.0%

Overall Agreement: 97.8%

BACTERIOLOGY

SINGLE USE IN VITRO DIAGNOSTIC DEVICE

H.pylori Ag
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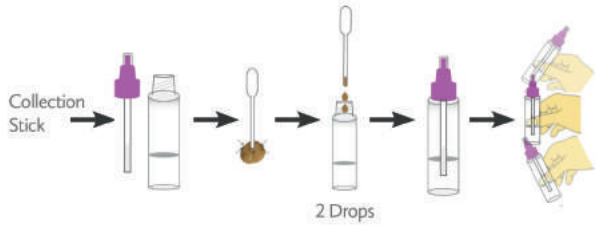
Reagents and Materials Provided

1. Individually sealed foil pouches containing:
   a. One cassette test device.
   b. One desiccant.
2. Sample extraction tubes, each containing 2ml of extraction buffer.
3. Plastic droppers for transferring watery stool.
4. One package insert (instruction for use).

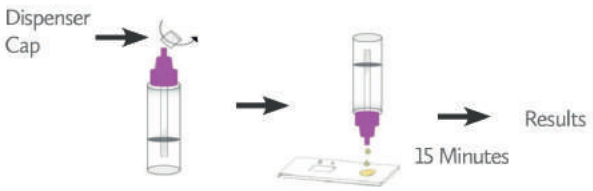
Specimen Collection and Handling

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Procedure for Stool Sample Collection



Test Procedure



Do not read results after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

Interpretation of Assay Result

1. Negative Result:
   If only the C band is developed, the test indicates that no detectable H.pylori antigen is present in the specimen.
   The result is negative.

2. Positive Result:
   If both C and T bands are developed, the test indicates the presence of H.pylori antigen in the specimen.
   The result is positive.

3. Invalid:
   If no C band is developed, the assay is invalid regardless of any colour development on the T band as indicated below. Repeat the assay with a new test device. Excess faecal specimen can lead to invalid test results; if this is the cause, re-sample and re-test (see instructions for collection of specimen).

References

1. Marshall BJ, et al, pyloric camplylobacter infection and gastroduodenal disease. Med.J. Aust. 1985, 142: 439-444
2. Lambert IR, Lin SK, and Aranda-Michel. J, helocobacter pylori Scan. J. Gasteroenterol. 1995, 30 suppl 208: 33-46
3. Vans DJ, Evans DG, et at A sensitive and specific seriologic test for detection of campylobacter pylori infection. Gastroenerology. 1989, 96:1004
4. Shimoyama T, Kato C, et al. Applicability of a monoclonal antibody- based stool antigen test to evaluate the results of Helicobacter pylori eradication therapy. 2009, May 62(3): 225
5. Krausse R, Muller G, Doniec M. Evaluation of a rapid new stool antigen test for diagnosis of Helicobacter pylori infection in adult 1008, 46(6): 2062
6. Altman E, Fernanez H. et al Analysis of Helicobacter pylori isolates from Chile: Occurrence of selective type I Lewis b antigen expression in lipopolysaccharide. 2008, 57(pt 5): 585

PRODUCT	PACK SIZE	CODE
H.pylori Ag Rapydtest®	25	1632

Products can be ordered direct from Apacor or from an appointed distributor
Visit our website for all the latest information www.apacor.com or email on: orders@apacor.com

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