

Helicobacter pylori Ab cassette

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REF	4260240 H. pylori cassette 40 tests
For professional <i>in vitro</i> diagnostic use only	

HELICOBACTER PYLORI

A rapid test for the qualitative detection of antibodies to Helicobacter pylori (H. pylori) in human serum, plasma or whole blood.

ONE STEP

PRINCIPLE

The Linear *Helicobacter pylori* Ab cassette is a rapid visual immunoassay for the qualitative presumptive detection of specific IgA, IgM and IgG antibodies to *Helicobacter pylori* in human whole blood, serum, or plasma specimens. This kit is intended for use as an aid in the diagnosis of *H. pylori* infection.

The *Helicobacter pylori* Ab cassette detects *Helicobacter pylori* antibodies through visual interpretation of color development on the internal strip. *H. pylori* antigens are immobilized on the test region of the membrane. During testing, the specimen reacts with *H. pylori* antigen conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are sufficient antibodies to *Helicobacter pylori* in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result.

REAGENT COMPOSITION

H. pylori test device, contains protein A and anti-human IgA / IgG / IgM antigen coated on the membrane.

PACKAGING CONTENTS

REF	4260240 40 H. pylori test device 40 Disposable specimen droppers Sample diluent
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STORAGE AND STABILITY

 Store at 2-30°C. The test device is stable through the expiry date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiry date. Do not use if pouch was damaged, because the test is humidity-sensitive.

SPECIMEN COLLECTION AND PREPARATION

- **Serum or plasma** should be separated as soon as possible to avoid hemolysis. Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, kept below -20°C. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- **Whole blood** collected by venipuncture should be stored at 2-8°C if the test is to be run within 24 hours of collection. Do not freeze. Anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage. Whole blood collected by finger stick should be tested immediately.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.
- Bring specimens to room temperature prior to testing.

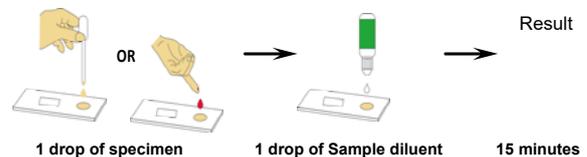
MATERIALS REQUIRED

- Timer
- Specimen collection container
- General laboratory equipment.

PROCEDURE

Allow the test device, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test from its sealed pouch. Label the device with patient or control identification. For best results the assay should be performed within one hour.
2. Place the test device on a clean, flat surface.
3. Transfer **1 drop** of specimen (approximately 30-45 µL) to the specimen well (S) of the device with the provided disposable pipette, then add **1 drop of Sample diluent** and start the timer.



4. Set up timer. As the test begins to work, color will migrate across the result area in the center of the device.
5. Wait for the colored band(s) to appear. The result should be read at **15 minutes**. Positive results may be visible in as soon as 1 minute.
6. Do not interpret the result after **20 minutes**.

To avoid confusion, discard the test device after interpreting the result.

RESULTS



POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.



NOTE:

The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit. It is recommended that positive and negative controls should be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Handle the negative and positive controls in the same manner as patient specimens.

CLINICAL SIGNIFICANCE

Gastritis and peptic ulcers are among the most common human diseases. Since the discovery of *H. pylori* (Warren & Marshall, 1983), many reports have suggested that this organism is one of the major causes of ulcer diseases (Anderson & Nielsen, 1983; Hunt & Mohamed, 1995; Lambert et al, 1995). Although the exact role of *H. pylori* is not yet fully understood, eradication of *H. pylori* has been associated with the elimination of ulcer diseases. The human serological responses to infection with *H. pylori* have been demonstrated (Varia & Holton, 1989; Evans et al, 1989). The detection of IgG antibodies specific to *H. pylori* has been shown to be an accurate method for detecting *H. pylori* infection in symptomatic patients. *H. pylori* may colonize some asymptomatic people. A serological test may be used either as an adjunct to endoscopy or as an alternative measure in symptomatic patients.

EXPECTED VALUES

The majority of individuals exposed to *H. pylori* possess antibodies against *H. pylori*. It is reported that *H. pylori* is universally distributed and as estimated value 50% of the world's populations are colonized by *H. pylori* (Lambert et al., 1995). The presence of *H. pylori* antibodies is a function of age, race, geography and clinical condition. A relatively large proportion of patients who have positive levels of antibodies are without any symptoms, even through they are colonized with the *H. pylori*. Therefore, antibody levels do not necessarily correlate with the severity of clinical symptoms (Tytgat & Rauws, 1989).

ANALYTICAL PERFORMANCE

A total of 200 specimens from the non-*H. pylori* infected patients and 75 specimens from the patients under anti-*H. pylori* treatment were tested by the Linear *Helicobacter pylori* Ab cassette. Comparison for all subjects is shown in the following table.

H. pylori Patients	Linear <i>Helicobacter pylori</i> Ab cassette		Total
	Positive	Negative	
Positive	65	10	75
Negative	18	182	200
Total	83	180	275

Relative Sensitivity: 86.7%, Relative Specificity: 91%, Overall Agreement: 89.8%

PRECAUTIONS

- This insert must be read completely before performing the test. Failure to follow the insert may lead to inaccurate test results.
- Do not open the sealed pouch unless ready to conduct the assay.
- Do not use expired devices.
- Bring all reagents to room temperature (15°C-30°C) before use.

- Do not use components from any other type of test kit as a substitute for the components in this kit.
- Do not use hemolyzed blood specimens for testing.
- Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
- Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
- Handle the negative and positive controls in the same manner as patient specimens.
- The test result should be read 15 minutes after a specimen is applied to the sample well. Reading the result after 20 minutes may give erroneous results.
- Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.

NOTES

1. LINEAR *Helicobacter pylori* Ab is limited to the qualitative detection of IgG, IgM and IgA to *H. pylori* in human serum, plasma or whole blood. The intensity of the test line does not have a linear correlation with the antibody titer in the specimen.
2. A negative result for an individual subject indicates absence of detectable antibodies to *H. pylori*. However, a negative test result does not preclude the possibility of exposure to or infection with *H. pylori*.
3. A negative result can occur if the quantity of antibodies to *H. pylori* present in the specimen is below the detection limits of the assay or if the antibodies that are detected are not present during the stage of disease in which a sample is collected.
4. Infection may progress rapidly. If the symptom persists, while the result from LINEAR *Helicobacter pylori* Ab is negative or non-reactive, it is recommended to re-test the patient a few days later or test with an alternative test method.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
6. Results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

1. Marshall, B.J. et al. 1985. Med. J. Australia. 149:439-44.
2. Soll, A.H. 1990. New England J. Med. 322:909-916.
3. Parsonnet, J. et al. 1991. New England J. Med. 325:1127-31.
4. Ansong, R. et al. 1991. J. Clin. Micro. 29:51-53.
5. Pronovost, A.P. et al. 1994. J. Clin. Microbiol. 32:46-50.
6. Megraud, F. et al. 1989. 27:1870-3, 1989.
7. Marshall, B.J. et al. 1988. Lancet. Dec. 1437-42

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