

One step rapid Card Test for qualitative detection of antibodies to Helicobacter Pylori antibodies in human Serum/Plasma

Store at 2-30°C. DO NOT FREEZE.
For *In-Vitro Diagnostic Use only*

ORDER INFORMATION

Pack Size	REF
10 Tests	HPBC 10
25 Tests	HPBC 25

CLINICAL SIGNIFICANCE

Gastritis and peptic ulcers are one of the most common human diseases. Since the discovery of H. pylori, many reports have suggested that this organism is one of the main causes of ulcer diseases and stomach cancer. The eradication of H. pylori has been associated with elimination of ulcer diseases. The detection of the specific IgG antibodies to H. pylori has been shown to be an accurate method for detection of H. pylori infection in symptomatic patients.

PRINCIPLE

ACCUCARE® ONE STEP H.PYLORI Ab RAPID TEST device has 2 pre coated lines on the surface of the membrane. The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. Anti-IgG and Anti-IgM antibodies coated on the test line respectively. If sample contains antibody, reacts with gold conjugated nanoparticle and flow on the membrane. It will be captured by membrane coated antibodies by developing purple color on test line.

CONTENTS

Test Device
Assay Buffer
Instruction for Use (IFU)
Disposable 10 µl (Dropper) Sampling device

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

LIMITATIONS

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to H.Pylori Bacteria in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The H.Pylori IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to H.Pylori Bacteria in human serum or plasma. The intensity of the test band does not correlate with antibody titer of the specimen.
3. A negative result for an individual subject indicates absence of detectable H.Pylori Bacteria antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with H.Pylori Bacteria.

SPECIMEN COLLECTION & PREPARATION

1. The ACCUCARE® ONE STEP H.PYLORI Ab RAPID TEST can be performed using either Whole Blood or serum or plasma.
2. If you want to use Serum or Plasma than separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
1. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
2. If specimens are to be shipped, it should be packed in compliance with federal regulations for transportation of etiologic agents.

PROCEDURE

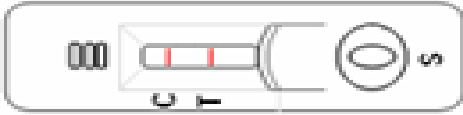
1. Allow test device, Assay buffer and specimen equilibrate to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and flat surface. Carefully dispense 1 drop (10 µl) of Serum/Plasma into the sample well (S) using the sample dropper provided.
4. Add 2 drops (appx. 60 µl) of buffer from the dropper bottle to the sample well (S) of the device and start the timer. Avoid trapping air bubbles in the sample well (S).
5. Read the results at 20 minutes. Do not interpret the results after 20 minutes.

NOTE: When using finger prick or EDTA whole blood the appearance of Control & Test line can take up to 10 minutes to appear and wait till 20 minutes to interpret the results in this case.

INTERPRETATION OF RESULTS

1. POSITIVE

If two color bands appear, one at control line 'C' and other at test line 'T', the specimen is positive for Troponin I.



2. NEGATIVE

If only one color band appear at control line 'C' as the specimen is Negative for Troponin I.















3. INVALID

If no color band appear, at control line 'C' within the stipulated time then result is invalid. Repeat the test using a fresh Test Device.



GLOSSARY OF SYMBOL

	Consult Instruction for Use		Lot Number
	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
	For <i>in vitro</i> Diagnostic use only		Keep Dry
	Tests per Kit		Do Not Use if Damaged

PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP H. Pylori Ab RAPID TEST has been evaluated with positive and negative samples and data are as below:

Specimen	Positive	Negative	Total
Positive	65	10	75
Negative	18	182	200
Total	83	192	275

Related Sensitivity: 86.7 %

Related Specificity: 91.0 %

BIBLIOGRAPHY

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- Hunt, R.H., Mohamed, A.H. (1995) The current role of Helicobacter pylori: eradication in clinical practice. *Scan. J. Gastroenterol.* 30 suppl 208, 47 - 52.
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