

INTEX[®] - *Helicobacter pylori* Test

Instructions for use

Rapid test for the detection of *Helicobacter pylori* in human serum or whole blood

1. INTRODUCTION

The INTEX[®] - *Helicobacter pylori* Test is a rapid, visual test for the qualitative detection of specific antibodies to *Helicobacter pylori* in human serum, plasma or whole blood. This kit is intended as an aid in the diagnosis of *H. pylori* infection in patients with gastrointestinal symptoms. The test does not discriminate between IgG and IgM antibodies and is thus suitable for detecting fresh primary infections as well as longer lasting infections or reinfections. For *in vitro* diagnostic use only.

Gastritis and peptic ulcers are one of 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 fully understood yet, 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 the specific antibodies to *H. pylori* has been shown to be an accurate method for detection of *H. pylori* infection in symptomatic patients. *H. pylori* may colonize in some asymptomatic persons. A sero-logical test may be used either as an adjunct to endoscopy or as an alternative measure in symptomatic patients.

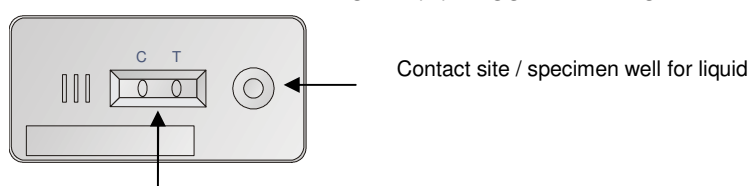
2. TEST PRINCIPLE

The INTEX[®] - *Helicobacter pylori* Test is intended for use in the detection of antibodies specific to *H. pylori* in serum. Proper use of the test permits detection of *H. pylori* infection in symptomatic patients. This information can be used by the physician and the patient for ulcer disease management.

The INTEX[®] - *Helicobacter pylori* Test has been designed to detect the *H. pylori* infection through visual interpretation of color development in the test device, which is a sandwich immunoassay. The membrane was precoated with *H. pylori* antigens on the test line region (T). During the test the diluted patient serum is allowed to react with a colored conjugate (*H.pylori* antigens-dye conjugate) which was submitted on the pad inside the test cassette. The mixture then moves on the membrane chromatographically by a capillary action. If *H. pylori* specific antibodies are present in a sample, a colored line with a specific antibody-antigen-colored conjugate complex will form at the test line region of the membrane.

On the other hand, a color line will always appear at the control region (C) using another antigen-antibody reaction. This control line serves as a procedural indicator for the proper function of the device. It shows that the test procedure has been correct and membrane wicking has occurred.

A distinct color development in the test line region (T) indicates a positive result and absence of a color line in the test line region (T) suggests a negative result.



Reaction zone with the test- (T) and the control- (C) zone (with ellipses marked).

3. MATERIALS AND REAGENTS PROVIDED

- 10 or 20 Single pouched test devices
- 1 Dilution buffer (containing less than 0.09% NaN₃)
- 10 or 20 Capillary pipettes for 10 µl
- 10 or 20 Lancettes
- 1 Instruction sheet

4. MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

5. STORAGE AND STABILITY

The INTEX[®]-*Helicobacter pylori* Test kit is to be stored at refrigeration (2-8°C) or room temperature (up to 30°C) in the sealed pouch for the duration of the shelf life.

6. PRECAUTIONS

- *For professional in vitro diagnostic use only!*
- *Do not use the kit beyond expiration date.*
- *Read the instructions carefully before performing the test.*
- *Do not use if pouch was damaged, because the test is humidity-sensitive.*
- *Do not open the foil pouch until you are ready to perform the test.*
- *Do not use twice!*
- *Do not eat, drink or smoke in the area where the specimen or devices are handled.*
- *All patient samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.*
- *Do not pipette reagent by mouth!*
- *Do not spill solution into the reaction zone!*
- *Do not touch the reaction zone of the device to avoid contamination!*
- *Do not interchange or mix reagents from different lots.*
- *Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.*
- *Store and transport the test device always at 2-30 °C (36°-86 °F)*
- *Humidity and high temperature can adversely affect results.*

7. SPECIMEN COLLECTION, PREPARATION AND STORAGE

- The INTEX[®]-*Helicobacter pylori* Test (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens. There are no limitations concerning the usage of any anticoagulants.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

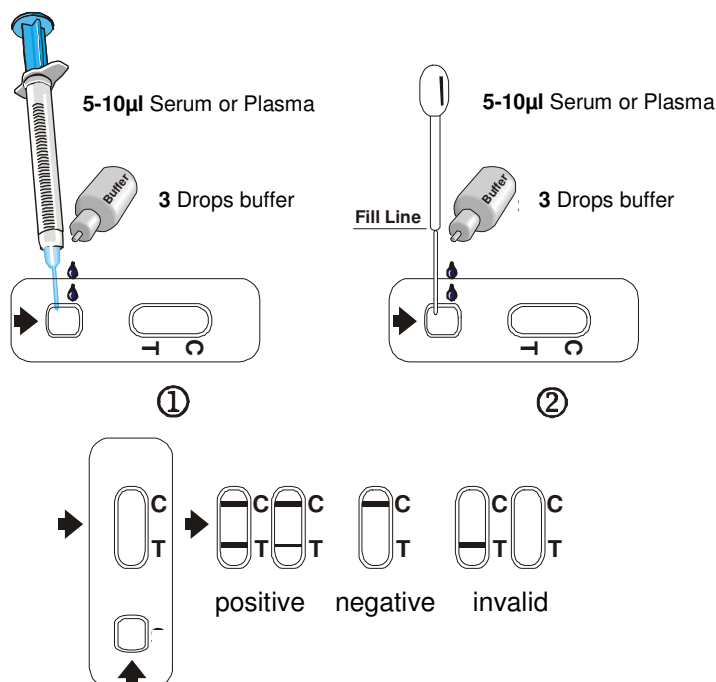
INTEX[®] Diagnostika

- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- 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.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

8. TEST PROCEDURE

Test device, buffer and patient's samples, should be brought to room temperature (20-30 °C) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test device from its protective pouch (bring the device to room temperature before opening the pouch to avoid condensation of moisture on the membrane). Label the device with patient or control identification.
2. Add app. 20 µl serum, plasma or whole blood sample (1 drop using the pipette supplied with the test) into the sample well first and then add 2-3 drops of dilution buffer. Avoid dropping any solution in the observation window
3. Start the timer!
4. Read the result within **5 minutes** after the addition of sample. Do not read results after 10 minutes.



9. INTERPRETATION OF RESULTS

Negative result: Only one red colored line appears on the control line (C) region. No apparent red-colored line is visible on the test line region (T).



Positive result: In addition to the control line, a distinct red colored line also appears on the test line region. Note: The color intensities of the lines might vary!



Invalid result: If no control line appears in the C-region the test is not conclusive and must be interpreted as invalid. The absence of the control line might indicate an error. Please repeat the test with a new test card paying special attention to the instructions. If the problem persists contact your manufacturer.



10. QUALITY CONTROL

An internal procedural control is included in the test. A reddish control line appearing in the Control region (C-region) of the membrane indicates proper performance of the test.

Good laboratory practise (GMP) recommends the use of external controls for the indication of the proper function of the test set.

11. 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).

12. LIMITATIONS

- This test is to be used for the qualitative detection of antibody to *H. pylori*.
- This kit should be used for symptomatic individuals with gastrointestinal disorders. Diagnosis of gastritis and/or peptic ulcers should be made by confirmation with other clinical findings.
- A positive result suggests the presence of antibodies to *H. pylori* and does not allow one to distinguish between active infection and colonization by *H. pylori*. It does not necessarily indicate that a gastrointestinal disease is present.
- A negative result does not rule out infection by *H. Pylori*, because the antibody to *H. pylori* may be absent or may not be present in sufficient quantities to be detected.
- Specimens from patients infected with *C. jejuni* may produce a low level of cross-reactivity in this test.

13. SPECIFICITY

The INTEX[®]-*Helicobacter pylori* Test should not give positive results with antibodies against similar respectively closely related bacteria like *Campylobacter coli* (ATCC 33559), *Campylobacter fetus* (ATTC 27374), and *Escherichia coli*. Serum samples from patients infected with *C. jejuni* (*Campylobacter jejuni* (ATCC 33560)) may produce a low level of cross-reactivity in this test.

14. PERFORMANCE CHARACTERISTICS

The relative sensitivity and the relative specificity of the INTEX[®]-*Helicobacter pylori* Test were determined against the Biopsy/Histology/RUT showing following values:

INTEX[®] -*Helicobacter pylori* Test vs Biopsy/Histology/RUT

		INTEX [®] - <i>Helicobacter pylori</i> Test		Total results
		positive	negative	
Biopsy/ Histology/ RUT	positive	246	18	264
	negative	10	343	353
Total results		256	361	617

Relative Sensitivity: 93.2% (89.5%-95.9%)*

Relative Specificity: 97.2% (94.9%-98.6%)*









Overall Agreement: 95.5% (93.5%-97.0%)*



*95% Confidence Interval

15. LITERATURE

1. Anderson, L.P.; Nielsen, H., (1993). Peptic ulcer: an infectious disease? Ann. Med. 25: 563-568.
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3. Hunt, R.H.; Mohamed, A.H. (1995). The current role of *Helicobacter pylori*: eradication in clinical practice. Scand. J. Gastroenterol. 30 suppl 208: 47-52.
4. Lambert, J.R. et al. (1995). *Helicobacter pylori*, Scand. J. Gastroenterol. 30 suppl. 208: 33-46.
5. Tytgat, G.N.J.; Rauws, E.A.J. (1989). The role of *Campylobacter pylori* in gastroduodenal diseases: A "believer's" point of view, Gastroenterol. Clin. Biol., 13: 118-121B.
6. Vaira, D.; Holton, J. (1989). Serum immunoglobulin G antibody levels for *Campylobacter pylori* diagnosis, Gastroenterology 97: 1069-1071.
7. Warren, J.R.; Marshall, B. (1983). Unidentified curved bacillus on gastric epithelium in active chronic gastritis (letters), Lancet 1: 1273-1275.

16. SYMBOLS

	Article number		For single use only
	Lot number		Expiry date
	Storage		Content
	Only for in vitro diagnostics		Instructions for use

INTEX [®] - <i>Helicobacter pylori</i> Test		
	10 Test cassettes	SK81010
	20 Test cassettes	SK81020



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Diagnostika

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