

INTEX® -*Helicobacter pylori* Stuhltest

Instructions for use

Rapid test for the detection of *Helicobacter Pylori* antigen in stool specimen

1. INTRODUCTION

The INTEX® *Helicobacter pylori* Stuhltest is an immunochromatographic screening assay for the qualitative detection of *Helicobacter pylori* antigen in stool samples.

Helicobacter pylori (also formerly known as *Campylobacter pylori*) is a spiral-shaped, Gram-negative bacterium with typical flagella. It is capable of infecting the gastric mucosa. It causes several gastro-enteric diseases such as non-ulcerous dyspepsia, gastric and duodenal ulcer, active gastritis and might even increase the risk of stomach adenocarcinoma, so that it has been classified as carcinogenic agent type I.

Various *H. pylori* strains have been isolated that differ in their virulence. Strains exhibiting a high virulence are generally characterized by the possession of the vacuolating cytotoxin (Vac A) and the so called cytotoxin associated genes *cag* pathogenicity island. These factors seem to be necessary for an effective infiltration of the gastric mucosa and seem to be associated with the persistence of the infection. They also contribute to sudden inflammatory responses, ulceration (gastric and duodenal ulcer), allergic episodes, and decrease of therapy efficacy.

Especially the CagA protein that is strongly immunogenic and is secreted into the gastric cells by a special mechanism is of special clinical importance. It has been widely reported in many literature articles that infected patients showing antibodies against the CagA gene product have a five times increased risk of developing gastric cancer if compared to a reference group infected with a CagA negative bacterial strain.

At present several invasive and non-invasive approaches are available to detect the infection state. Invasive methodologies require endoscopy of the gastric mucosa with a histological, cultural and urease investigation, which are expensive and require a long time to come to a correct final diagnosis.

Alternatively, non-invasive methods are available such as Breath Tests with isotope labelled urea, which are complicated and cost-intensive, or classical ELISA or immunoblotting assays.

The INTEX® *Helicobacter pylori* Stuhltest is an immunological rapid assay that takes advantage of a highly specific antibody/antigen reaction to detect *H. pylori* antigen in stool samples.

2. TEST PRINCIPLE

The INTEX® *Helicobacter pylori* Stuhltest is a non-invasive lateral flow assay. It is precise, easy to perform and rapid, generating the test result within several minutes.

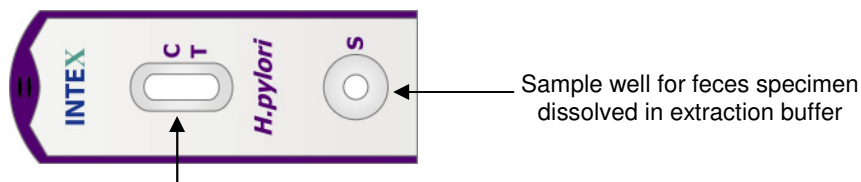
The test makes use of specific monoclonal antibodies against *H. pylori* antigen. One of the antibodies has been adsorbed onto the membrane as a line. The second antibody has been conjugated with colloidal gold particles to provide a reddish color label. If *H. pylori* antigen is present in the stool sample it forms a complex with the color labelled antibody. When the liquid passes the membrane this complex will be captured by the antibody fixed onto the membrane. A red line appears. Therefore a red line in the T-region indicates a positive test result.

In addition the test contains an internal procedural control represented by a control line that appears in the C-region of the assay. In contrast to the test result line in the T-region, the control

line is formed independent of the presence of *H. pylori* antigen. The formation of the control line shows that the test procedure has been correct and membrane wicking has occurred. The control line must show in every valid assay.

3. SET-UP OF THE TEST DEVICE

The plastic case of the test cassette encloses the test strip. At the right side of the picture you can see the round sample well into which the specimen is dropped. The test result window is in the middle of the cassette. You can see the white membrane where the line(s) will appear after the addition of the sample that show if the analyte is present in the sample or not. In the picture the test result line region T and the control line region C are marked with ellipses.



Test result window with the test result line region (T-region) and the control line region (C-region) marked with ellipses.

4. MATERIALS AND REAGENTS PROVIDED

- 10 individually wrapped test cards
- 10 Sample Collection Tubes with buffer
- 10 Stool specimen collection units for the collection of fecal samples.
- 1 Instruction sheet

5. MATERIALS REQUIRED BUT NOT PROVIDED

- Absorbent tissue paper to prevent solution from splashing.
- Timer

6. STORAGE AND STABILITY

The INTEX[®] *Helicobacter pylori* Stuhltest kit (test cards and collection tubes with buffer) should be stored refrigerated (2-8°C) or at room temperature (up to 30°C). The test cards must remain in the sealed pouch until used because they are susceptible to humidity. Under these storage conditions the test is stable for the duration of the shelf-life.

7. PRECAUTIONS

- *For in-vitro diagnostic use only*
- *For professional use only*
- *Use each test device only once.*
- *Do not eat, drink or smoke in the area where the specimens or kits are handled.*
- *Do not use test if pouch is damaged.*
- *Do not use test kit after expiration date.*
- *Do not mix Sample Collection Tubes from different lots.*
- *Do not open the protective pouch until ready to perform the assay.*
- *Do not spill solution into the reaction zone*
- *Do not touch the result window of the card to avoid contaminations.*
- *Avoid cross-contamination of samples by using a new specimen collection containers/stool specimen collection units and sample collection tubes for each sample.*

- *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 use more than the required amount of liquid.*
- *Bring all reagents to room temperature (15-30 °C) before use.*
- *Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.*
- *The buffer contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of buffer over the sink always flush with copious quantities of water to prevent azide build up.*
- *Store and transport the test device always at 2-30 °C (36°-86 °F)*
- *Humidity and high temperature can adversely affect results.*
- *Patients should closely follow the specimen collection procedures.*

8. SPECIMEN COLLECTION, PREPARATION AND STORAGE

Please ensure that patients will pay attention to the following instructions for the collection of the stool samples.

- 1) Collect a random sample of feces in a clean dry container or a special stool specimen collection unit.
- 2) Unscrew and remove the collection tube applicator stick. Be careful not to spill or spatter solution from container.
- 3) Collect random sample by using the applicator stick. Take sample from various surfaces of the feces specimen.
- 4) Re-insert the applicator stick into the tube and screw the cap tightly. Be careful not to break the tip of the Sample Collection Tube.
- 5) The specimen is now ready to be tested, stored, or transported. The specimen should be tested as soon possible, but may be held up to 2 days prior to testing if necessary. The sample should be kept in an airtight container e.g. a plastic bag. It is recommended to store it at 2-8 °C (refrigerator) until tested. Short time exposure to temperatures up to 30 °C e.g. during transportation do normally not affect the specimen. However, exposure times to high temperatures should be kept as short as possible.

9. TEST PROCEDURE

- 1) The sealed test card and the patient's sample dissolved in the buffer should be brought to room temperature (15-30 °C) prior to testing. Do not open refrigerated test cards to prevent the condensation of moisture on the test membrane.
- 2) Remove the test device from its pouch when ready to perform the test. Label the device with patient or control identification.
- 3) Shake the collection tube thoroughly to ensure proper mixing of the fecal sample with the extraction solution.
- 4) Using a piece of tissue paper, break the tip of the collection tube using a twisting motion. Hold the collection tube vertically and dispense 3 drops (app. 120 µL) of solution into the sample well of the test device. Start the timer.
- 5) Read the result after 10 minutes. Strong positive results may be read sooner. The test result should not be read later than 20 minutes after the addition of the sample.

IMPORTANT: You must not read the test results after **20 Minuten** any more.

10. TEST RESULTS

Quality Control / Internal Procedural 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.



NOTE: When testing control material dissolved in buffer the background of the assay is usually clear within 5 minutes. However, when fecal samples are tested, the background may appear slightly yellowish due to the original color of the fecal samples. This is acceptable as long as it does not interfere with the interpretation of test result. The test is invalid if the background fails to clear and obscures the reading of the result.

11. INTERPRETATION OF THE TEST RESULTS

For the interpretation of the test result the line(s) that has(ve) appeared in the test result window are visually interpreted.

Positive Test Result

Two red colored lines appear in the test result window. In addition to the the red control line in the C-region a distinct red test result line appears at the T-region. The color intensities of the lines might vary. This result shows that *H. pylori* antigen is present in the stool sample.



Negative Test Result

A single red control line appears in the C-region of the test result window. No line is visible in the T-region. This indicates that no *H. pylori* antigen has been detected in the sample.



Invalid Test 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 in the test procedure or that the ingredients of the assay have deteriorated. Please repeat the test with a new test card paying special attention to the instructions. If the problem persists contact your manufacturer.



12. LIMITATIONS

- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
- Antibiotics, proton pump inhibitors and bismuth preparations inhibit *H. pylori*. Negative test results obtained during or shortly after a therapy might be false negative. In this case it is useful to repeat the *H. pylori* test 2 weeks after the end of the therapy.









13. EXPECTED VALUES

Epidemiological studies show that infections with *H. pylori* are of worldwide occurrence. The exact route of infection between individuals is presently unknown. The values indicate that the incidence of infection rises about 1-2% with each year of life so that infection rates of 50% or higher are not uncommon for elderly people being 60 years or older. A high percentage of people colonized with *H. pylori* do not develop any clinical symptoms.

14. LITERATURE

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4. Weiss, Judith; Mecca, James; da Silva, Elvira; Gassner, Dieter (1994): Comparison of PCR and other Diagnostic Techniques for Detection of Helicobacter Pylori Infection in Dyspeptic Patients, Journal of Clinical Microbiology Vol.32, No.7, p.1663-1668, (1994).

15. SYMBOLS

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

INTEX[®] -Helicobacter pylori Stuhltest		
	10 Test cassettes	SKA81510



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Diagnostika

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