

***H. pylori* Rapid Test (Tartar) Package Insert**

A rapid test for the qualitative detection of *Helicobacter pylori* in human tartar.
For professional *in vitro* diagnostic use only.

【INTENDED USE】

The *H. pylori* Rapid Test (Tartar) is intended for qualitative detection of urease produced by *Helicobacter pylori* in human tartar as an aid in the diagnostic of *Helicobacter pylori* infection.

【SUMMARY】

Helicobacter pylori is one of the most common pathogens entering the digestive tract through the oral cavity, and it is the main pathogenic factor leading to chronic gastritis and peptic ulcer.^{1,2} The detection of urease in human tartar provides the basis for the auxiliary diagnosis of the *Helicobacter pylori* infection. At present, the commonly used clinical detection methods are gastric mucosa biopsy and urea breath test, etc.³ Tests for urease are specific for *H. pylori* because mammalian cells do not produce urease and very few micro-organisms survive in the stomach, except for *H. pylori*.

【PRINCIPLE】

The test paper contains urea and pH indicator. Urease produced by *Helicobacter pylori* can decompose urea and produce ammonia and carbon dioxide, so that the pH value increases, and the indicator in the test paper will change color with the increase of pH value (from yellow to red or purple), then the presence of *Helicobacter pylori* can be detected.

【REAGENTS】

The test contains phenol red and urea pre-coated on the test paper.

【PRECAUTIONS】

- For professional *in vitro* diagnostic use only. Do not use beyond the expiration date.
- Do not reuse. Do not use if package is damaged and consult instructions for use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature may adversely affect results.
- Taking antibiotics to inhibit *Helicobacter pylori* within a few weeks before the test is likely to cause false negative results.

【STORAGE AND STABILITY】

The test can be stored at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- This product is only used to test human tartar samples.
- Taking antibiotics or bismuth salts within the past three weeks will lead to inaccurate results.
- Do not drink, eat or brush teeth before the sample is collected. Exposure of the teeth to acidic or alkaline substances can compromise the test result. Oral acids can cause false negatives, while oral alkalines can cause false positives.
- Maintain an empty stomach before sample collection.
- Using the swab provided with the kit to collect tartar sample:
 - Take out the swab from the foil pouch.
 - Brush away tartar between teeth and at the root of the teeth using the swab.
 - Brush away tartar between 2-3 teeth.

Note: During the sampling process, please be gentle and avoid damaging the gums.

【MATERIALS】

Materials Provided

- Test Cassettes
- Package Insert

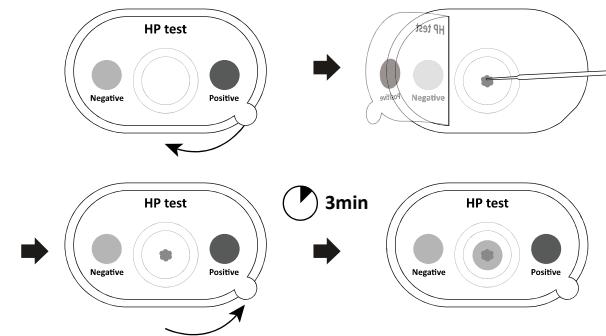
Materials Required But Not Provided

- Swabs

【DIRECTIONS FOR USE】

Allow the test to reach room temperature (15-30°C) prior to testing.

- Place the test on a clean and level surface.
- Peel the label of the *H. pylori* Rapid Test and expose the yellow reactive pad.
- Use the swab to collect and transfer the tartar sample to the reactive pad.
- Re-seal the test.
- Wait for the reactive pad color to change. **Interpret the result within 3 minutes.** Do not interpret the result after 3 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:

The edge of the tartar sample on the reactive pad changes from yellow to red or purple within 1 minute, indicating a **strong positive result**.

The edge of the tartar sample on the reactive pad changes from yellow to red or purple within 1-3 minutes, indicating a **weak positive result**.

NEGATIVE:

The edge of the tartar sample on the reactive pad does not change color within 1-3 minutes, indicating a **negative result**.

***NOTE:** The intensity of the color in the reactive pad will vary depending on the concentration of urease presents in the sample.

INVALID: Before use, each *H. pylori* Rapid Test surface should be yellow. If the reactive pad background is red or purple, the test should not be used.

***NOTE:** If the *H. pylori* Rapid Test only shows a very faint red or purple color, the test should be regarded as inconclusive and needs to be repeated. If in the subsequent retest the *H. pylori* Rapid Test shows a faint red or purple color again, the test result should be regarded as positive, indicating the presence of *Helicobacter pylori* in the mouth. Otherwise, the test result should be considered negative, indicating that *Helicobacter pylori* is not present in the mouth.

【QUALITY CONTROL】

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

- This product is a qualitative test product for clinical reference only. The *H. pylori* Rapid Test results should be used in combination with the patient's clinical examination and other laboratory data, and cannot be used as the sole basis for diagnosis.
- Some samples may show a negative result due to the very low concentration of urease. It is recommended to confirm results with gastric mucosa biopsy or urea breath test.
- Exposure of the teeth to acidic or alkaline substances can compromise the test result.

【POSITIVE JUDGMENT VALUE OR REFERENCE INTERVAL】

When urease concentration is above 12.5 U/mL, the detection result shows positive, and the contact sample area of the reactive pad turns red or purple.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The *H. pylori* Rapid Test (Tartar) has been compared with a leading commercial *H. pylori* test.

Method	Results	Commercial test		Total Results
		Positive	Negative	
		48	1	
<i>H. pylori</i> Rapid Test (Tartar)	Negative	2	149	151
Total Results		50	150	200

Relative Sensitivity: 96.0% (95%CI*: 86.3%~99.5%);

Relative Specificity: 99.3% (95%CI*: 96.3%~99.9%);

Overall Accuracy: 98.5% (95%CI*: 95.7%~99.7%).

*Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 5 replicates of these specimens: negative, low positive and middle positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 5 independent assays on the same specimens: negative, low positive and middle positive specimens. Three different lots of the *H. pylori* Rapid Test (Tartar) have been tested using these specimens. The specimens were correctly identified >99% of the time.

【BIBLIOGRAPHY】

- Xi Ying, Clinical analysis of *Helicobacter pylori* detection using bacterial culture and urease test, Clinical Medicine Research and Practice, 2016.
- Xue Wang, Advances in diagnostic methods for *Helicobacter pylori* infection, Journal of Clinical Pediatrics, 2020.
- Wang Haini, Application value analysis of two test methods in clinical examination of *Helicobacter pylori*, China Health Standards Management, 2015.

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