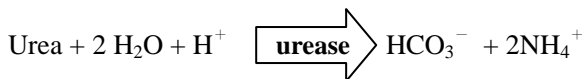


**Application :**

*HelicotecUT® Plus* is designed to detect the urease activity of *Helicobacter pylori* in gastric mucosal biopsies in an hour.

**Product Description :**

*H. pylori* produce large amounts of the enzyme urease which exhibits the ability to hydrolyze urea into ammonium ion and bicarbonate. When a tissue specimen from a patient is put onto the *HelicotecUT® Plus* test kit, the elevated pH level produced by the presence and activity of urease is indicated by a color change of pH indicator in the test paper.



**Procedure :**

1. Peel back the adhesive label on the test slide.
2. Transfer the biopsy sample onto the test paper with a clean applicator (e.g., toothpick etc.).
3. Re-seal and press the label over the test paper to squeeze fluid out of the biopsy sample.
4. Record the biopsy date, time, and the patient's information.
5. Monitor the test slide over the period of an hour.

*Observe any color change through the opening on the back of the test slide. For more details, see the table in the following section.*

**Reporting Results :**

1. Observe whether the outer ring of test paper changes color over an hour. Strongly positive results may become visible within 5 minutes.
2. If the outer ring of the paper changes color to pink or red, test of *Helicobacter pylori* is positive.
3. If it remains yellow in color after an hour, then the test is negative

Reaction Time	5 min	30 min	1 hour	1 hour
Color of Ring	Pink to Red	Pink to Red	Pink to Red	Yellow
Diagnosis	<b>CONTROL +</b>	<b>CONTROL +</b>	<b>CONTROL +</b>	<b>CONTROL -</b>

**Storage Instruction :**

Store at room temperature in a cool and dry place.  
*HelicotecUT® Plus* is stable for up to 24 months.

**Expiration Date :**

Show on the slide label and outer package.

**Notes :**

1. In most cases, positive results will appear in 5 to 30 minutes, while weakly positive results will take up to an hour to develop.
2. Patients should not take any antibiotics or bismuth salts for at least three weeks prior to the biopsy. These agents effectively scatter the *H. pylori*, making them more difficult to detect, potentially leading to false negative readings.
3. It is recommended that biopsy samples be taken in both the antrum and the greater curvature of the stomach. *H. pylori* thrive in healthy tissue rather than in areas already damaged by ulceration.
4. For patients who have suffered a recurrence or who have been treated prior to this test, biopsy samples should be taken farther above the typical locations.
5. Standard biopsy forceps will provide a specimen of sufficient size. (~2-3 mm)
- 6. This test is for *in vitro* diagnostics only, and should be administered by a physician or medical technician.**

**Reference:**

1. Marshall BJ, McGeachie DB, Rogers PAR, Glancy RG. Pyloric Campylobacter Infection and gastroduodenal disease. *Med J* Aug 1985; 149:439-44
2. Mobley HL, Cortesa MJ, Rosenthal LE, Jones BD. Characterization of urease from *Campylobacter pylori*. *J. Clin Microbiol* 1988; 25(5):831-836.
3. Marshall BJ, Warren JR, Francis GJ, Langton SR, Goodwin CS, Blinow E. Rapid urease test in the management of *Campylobacter pyloridis*-associated gastritis. *Am J Gastroenterol* 1987; 82(3):200-210.
4. Dye KD, Marshall MJ, Frierson HF, Barrett LJ, Guerrant RL, McCallum RW. Is CLOtest alone adequate to diagnose *Campylobacter pylori*. *Am J Gastroenterol* 1988; 83:1032(abstract).
5. Schnell GA, Schubert TT, Bames WG, Rupani MK. Comparison of urease, H&E, and culture tests for *Campylobacter pylori*. *Am J Gastroenterol* 1988; 94(5):A410(abstract).

