

Application :

HelicotecUT[®] is designed to detect the urease activity of *Helicobacter pylori* in gastric mucosal biopsies.

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 immersed in the *HelicotecUT[®]* test gel, the elevated pH level produced by the presence and activity of urease is indicated by a color change of pH indicator in the test gel.



Procedure :

1. Warm the test slide at room temperature for 10 minutes before use.
2. Peel open the adhesive label on the slide. With a clean applicator (e.g., toothpick etc.), transfer the biopsy sample into the yellow gel, make sure the sample is completely embedded in the gel. Re-seal the slide label.
3. Record the biopsy date, time, and patient's information on the label.
4. Incubate the gel slide at 37°C for an hour for rapid results. Alternatively, incubate the test at room temperature for reading during 24 hours.

Observe any color change through the rectangular opening on the back of the test slide.

Reporting Result :

1. Observe whether the gel surrounding the biopsy sample changes color over time at fixed time intervals during 24 hours.
2. If the gel changes color from yellow to pink or red, then the test of *Helicobacter pylori* is positive.
3. If the gel color remains yellow after 24 hours, then the test is negative.

Reaction Temp.	37°C		Room Temp.	
	1 hour	24hours	24 hours	24 hours
Color of Gel	Pink to Red	Yellow	Pink to Red	Yellow
Diagnosis	CONTROL +	CONTROL -	CONTROL +	CONTROL -

Storage Instructions :

Store at 2-8°C. Do not freeze. *HelicotecUT[®]* is stable for up to 18 months at 2-8°C and for 90 days at 25°C.

Expiration Date :

Show on the slide label and outer package.

Notes :

1. *HelicotecUT[®]* is best stored between 2-8°C. Under normal conditions, the gel is stable when it is yellow in color. If the gel has become orange in color, it may produce false positive readings, in which case, it is recommended that the test be repeated for better results.
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, Blincow 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 Camparison of Gastroenterology 1988; 94(5):A410(abstract).

