Intended Use:

*Helicotec*UT®Plus is designed to detect the urease activity of *Helicobacter pylori* in gastric mucosal biopsies.

Principle:

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 transferred onto the *Helicotec*UT®Plus test kit, the elevated pH level produced by the presence and the activity of urease is indicated by a color change of pH indicator in the test paper.

$$\text{UREA} + 2\,H_2O + H^+ \xrightarrow{\text{UREASE}} HCO_3^- + 2NH_4^+$$

Procedure:

1. Peel back the adhesive label on the test slide.
2. Transfer 2-3 biopsy specimens onto the test paper with the applicator included in the test kit.
3. Re-seal and press the adhesive label over the test paper to squeeze the tissue fluid out of the biopsy specimens.
4. Record the biopsy date, time, and the patient's information on the label.
5. Monitor the test slide and observe any color change over the period of an hour.

Interpretation of Result:

1. Observe whether the outer ring of the test paper changes color in an hour.

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2. If the outer ring of the test paper changes color to pink or red, the test of *Helicobacter pylori* is positive. If it remains yellow in color after an hour, then the test is negative.

Reaction Time	1 hour	1 hour
Color of The Ring	Pink to Red	Yellow
Diagnosis	CONTROL +	CONTROL -

Main Active Ingredients:

Urea, Phenol Red, Buffers

Storage and Stability:

Store at room temperature in a cool and dry place. *Helicotec*UT®Plus is stable for up to 30 months.

Expiration Date:

Please refer to the slide label and the outer package.

Notes:

1. In most cases, positive result will appear in 5 to 30 minutes, while weakly positive result may take up to an hour to develop.
2. Patients should not take any antibiotics or bismuth salts for at least three weeks, nor ingest proton pump inhibitors in two weeks prior to the biopsy. These agents effectively scatter the *H. pylori*, making them more difficult to detect, potentially leading to false negative reading.
3. It is recommended that biopsy specimens be taken from both the antrum and the greater curvature of the stomach. *H. pylori* thrives in healthy tissue rather

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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 specimens 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 performed by physicians or medical technicians.

References:

1. Marshall BJ, McGechie 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 Campylobacter pylori. Gastroenterology 1988; 94(5):A410(abstract).

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