CAMBRIDGE Life Sciences

Endosc-Hp® TEST

Intended Use
The test detects the Urease enzyme of *Helicobacter pylori* present in gastric mucosal biopsies.

Principle
The Endosc-Hp® Test consists of a twin well cartridge containing urea, phenol red and buffer salts in tablet form and an ampoule of buffer. If the Urease enzyme of *Helicobacter pylori* is present in a biopsy specimen, the rise in pH associated with the hydrolysis of urea causes a change in colour from yellow through orange to magenta.

Contents
Each pack contains 4 tests.

Each test consists of a twin well cartridge containing a substrate tablet in each well and an ampoule of buffer.

Method
1. Open the cartridge lid and using the fill level lines as an approximate guide, add the buffer provided to each well.
2. During the endoscopy, take a biopsy specimen and add to one of the wells . A second biopsy specimen either from the same or a different region of the stomach can be added to the same well. Immediately afterwards re-close the cartridge lid firmly.
3. Record the patient identification details and the time the specimen was taken on the cartridge label.

Interpretation of Results

- If both wells remain yellow the result is negative.
- Any colour change from yellow through orange to magenta in the well containing the biopsy specimen is a positive result.

Read Time
Any colour change through orange to magenta at <u>any time</u> after the addition of the specimen indicates a positive result. This colour change may occur within minutes for highly inoculated specimens.

Any tests that remain negative at 30 minutes should be confirmed as such at 24 hours.

Quality Control
Once the tablets are reconstituted they are stable for up to 5 days.

If, after the addition of buffer, either of the wells is pink or magenta <u>before</u> the biopsy specimen is introduced, the test should be discarded.

Storage
Store between 10°C and 28°C.

Shelf Life
The kits are stable for 24 months from date of manufacture. The test reagents should not be used after the expiry date which is printed on the pack.

Note
Used tests should be handled as clinical waste and disposed of in accordance with local rules.

For professional use only. For *in-vitro* diagnostics only

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Further Advice
One or more biopsies may be taken from the sump of the antrum, along the greater curve and the fundus. Biopsy an area of normal looking tissue rather than an area affected by erosions or ulceration. This is because *Helicobacter pylori* may be present in smaller numbers where the epithelium is eroded or the mucous layer is denuded. Specimen size should be 2 - 3mm.

The performance claims made for Endosc-Hp® are based upon a single biopsy specimen however performing a two-site (antrum and gastric corpus) biopsy specimen during endoscope procedures, increases significantly (+16.9%) the accuracy of the test. Two-site rapid Urease tests has shown better sensitivity and specificity in comparison with single-site (antrum) test[1, 2].

Patients should not have taken antibiotics or bismuth salts for at least three weeks prior to endoscopy. Suppression of *Helicobacter pylori* by these agents makes the organism difficult to detect by any means, and re-growth of *Helicobacter pylori* may be patchy leading to false negative results in the first few weeks after treatment.

During treatment with a proton pump inhibitor (PPI), the distribution of *Helicobacter pylori* within the stomach probably changes so that the density in the antrum is reduced and that in the corpus is relatively increased[3]. In patients on an H_2-receptor antagonist or PPI, it is recommended that biopsies for Endosc Hp testing be taken from both the antrum and fundus of the stomach to increase sensitivity[4]. If it is of interest from an epidemiological viewpoint the antral and fundic specimens can be added to separate wells.

When first inserted the specimen may have a very slight pink tinge particularly if blood or alkaline bile is present, this rapidly washes off the specimen and disperses in the solution and does not interfere with the reading.

The substrate tablets do not have to be fully dissolved before the specimen is added as long as the liquid in the wells is of a yellow colour.

References

1. Bona SG, Coci L and Daghetta L. Accuratezza e rilevanza clinica di un doppio rapido all'ureasi la diagnosi di infezione da *Helicobacter pylori* . Gastroenterogia clinica 2001; 30: 173 -176.

2. Lim LL, Ho KY, Ho B and Salto-Tellez M. Effect of biopsies on sensitivity and specificity of ultra-rapid urease test for detection of *Helicobacter pylori* infection: A prospective evaluation. World J Gastroenterol 2004; 10 (13): 1907 -1910.

3. Graham DY, Genta R, Evans DG, et al. *Helicobacter pylori* does not migrate from the antrum to the corpus in response to omeprazole. Am J Gastroenterology 1996; 91: 2120 - 4.

4. Weston AP, Campbell DR, Hassanein RS, et al. Prospective, multivariate evaluation of CLOtest performance. Am J Gastroenterology 1997; 92: 1310 - 5.

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