

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 to pink/red.

Contents

Each pack contains 4 Tests each consisting of a twin well cartridge containing a substrate tablet in each well and 4 ampoules of buffer.

Method

Open the cartridge lid and fill each well to the marked line with the buffer provided. Close the lid and agitate to dissolve the tablet in each well.

During the endoscopy, take a biopsy specimen and add to well 1. A further specimen can be added to well 2 either from the same or a different region of the stomach. Immediately afterwards re-close the cartridge lid firmly. On the cartridge label, record the patient identification details and the time the specimen was taken.

Pink/red colouration in the reaction well containing a specimen indicates a positive reaction and confirms the presence of *Helicobacter pylori*.

A positive result can be obtained within 30 minutes from patients with an extensive *Helicobacter pylori* infection.

If the result is negative after 30 minutes, make further colour checks at regular intervals as the speed of the colour change is dependent upon the extent of *Helicobacter pylori* present on the specimen.

If no specimen is added to well 2 it can be used as a negative control, in which case;

- If both wells remain yellow the result is negative.
- If the control well remains yellow but in comparison to the control well the test well changes colour to an orange/pink or red colour the result is positive.
- If both the test well and the control well have changed colour the result is invalid

A test can be left up to five days before it is read. As the reconstituted reagents are stable any colour change in the test well during this period is due to *Helicobacter pylori* infection.

Storage

Store between 10°C and 28°C.

Shelf Life

The test reagents should not be used after the expiry date. After reconstituting the tablet, the solution is stable for 5 days at 18 - 25°C and 3 months at 4°C.

Note

If, after the addition of buffer, the reaction well is pink/red before the biopsy specimen is introduced, the test should be discarded.

Used tests should be handled as clinical waste and disposed of in accordance with local rules. It is recommended that gloves are worn when handling such items.

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



Further Advice

Performing a two-site (antrum and gastric corpus) biopsy specimen during endoscope procedures, increases significantly (+16.9%) the accuracy of the test improving, at the same time, the consistency with gold standard methods for Hp infection detection such as histology and microbiological cultures. Two-site rapid urease tests has shown better sensitivity and specificity in comparison with single-site (antrum) test, with a similar accuracy level with culture methods for detection of Hp infection^{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 increased³. In patients on an H₂-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 sensitivity⁴.

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 if the epithelium is eroded or the mucous layer is denuded. Specimen size should be 2 - 3mm.

When first inserted the specimen may have a very slight pink tinge particularly if blood or alkaline bile is present. If urease is present in the tissue then the colour will gradually change from yellow to orange to deep orange and then to magenta colour. An orange solution at 3 hours is almost certainly a positive reaction and will usually turn magenta within 24 hours.

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*. Gastroenterologia 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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