

# Endosc-*Hp*<sup>®</sup> TEST

## *Helicobacter pylori* Urease Test

- **Accurate** - specifically designed to detect the urease enzyme of *Helicobacter pylori*
- **Flexible** - twin wells allow two specimens per patient, second well can be used as a control.
- **Practical** - room temperature storage.
- **No wasted reagents** - once reconstituted the solution is stable for 5 days at 18-25°C.
- **Quick** - result usually within 30 minutes, any colour change from **yellow** through **orange** to **magenta** indicates a positive reaction.

### • **Background**

*Helicobacter pylori* is a bacterium that is found in the gastric mucous layer or adherent to the epithelial lining of the stomach. *Helicobacter pylori* causes more than 90% of duodenal ulcers and up to 80% of gastric ulcers.\*

Most persons who are infected with *Helicobacter pylori* never suffer any symptoms related to the infection; however, *Helicobacter pylori* causes chronic active, chronic persistent, and atrophic gastritis in adults and children.

Since it is known that most ulcers are caused by *Helicobacter pylori*, appropriate antibiotic regimens can successfully eradicate the infection in most patients, with complete resolution of the mucosal inflammation and a minimal chance for recurrence of ulcers.

\*Source: CDC Centers for Disease Control and Prevention, Fact Sheet for Health Care Providers "*Helicobacter pylori*" Updated July 1998

### • **Indication**

The Endosc-*Hp*<sup>®</sup> test detects the urease enzyme of *Helicobacter pylori* present in gastric mucosal biopsies.

### • **Summary and explanation of test**

The Endosc-*Hp*<sup>®</sup> test consists of a twin well cartridge containing urea, phenol red and buffer salts in a 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.



- **Safety data sheet & Instructions for Use available on-line at:**  
<http://www.clsdiagnostics.com/downloads/>

# Helicobacter pylori Urease Test

Catalogue No. U1021



## • Stability and Quality Control

The Endosc-*Hp*<sup>®</sup> test does not require cold storage. The Endosc-*Hp*<sup>®</sup> test has been designed for storage between 10°C and 28°C. After reconstituting the tablet, the solution is stable for 5 days at room temperature. If the test was reconstituted and not used, there is no wastage.

Shelf life is 24 months from date of manufacture. Expiry date is printed on the packaging.

The test also has an in-built quality control, if the solution becomes pink before the specimen is added the test should not be used.

## • Evaluation

In 1998, a study, established in the Gastroenterology Unit of Leeds General Infirmary under the guidance of Dr Paul Moayyedi, Consultant Physician and Ms Berenice Quinlan, staff Nurse in the Dyspepsia Clinic, compared the performance of the Endosc-*Hp*<sup>®</sup> test with CLOtest<sup>™</sup> and Histology.

To receive a copy of this study, please contact us at [info@clsdiagnostics.com](mailto:info@clsdiagnostics.com)

## • Correlation

100 patients were tested using the Endosc-*Hp*<sup>®</sup> test and CLOtest<sup>™</sup> and all except 5 samples were also tested for histology (Geimsa stain).\*\* 46 patients were female and 54 were male with an age range of 78 to 22 years. The tests were performed according to the manufacturer's instructions. Three biopsies were taken for the Endosc-*Hp*<sup>®</sup> test, CLOtest<sup>™</sup> and for histology from the antrum. No record was taken whether these patients were on antibiotics, triple therapy or bismuth or whether they had been within the 3 weeks prior to the endoscopy.

\*\*Source: Endosc-*Hp*<sup>®</sup> test Evaluation study by the Gastroenterology Unit from Leeds General Infirmary, 1998.

	Endosc- <i>Hp</i> <sup>®</sup> Test		
CLOtest <sup>™</sup>	Positive	Negative	Total
Positive	34	2	36
Negative	1	63	64
<b>Total</b>	<b>35</b>	<b>65</b>	<b>100</b>
<b>Sensitivity:</b>	94.4%		
<b>Specificity:</b>	98.4%		
<b>Positive Predictive Value:</b>	97.1%		
<b>Negative Predictive Value:</b>	96.9%		
<b>Efficiency:</b>	97.0%		

Cambridge Life Sciences Ltd.  
14 St. Thomas' Place, Cambridgeshire Business Park,  
Ely, Cambs, CB7 4EX, UK  
Telephone: +44 (0)1353 645200 Fax: +44 (0)1353 645250  
E-mail: [sales@clsdiagnostics.com](mailto:sales@clsdiagnostics.com)  
<http://www.clsdiagnostics.com/>



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