UREA INSTANT TEST

For professional *in Vitro* diagnostic use only.

Detection of Helicobacter Pylori urease activity on gastric biopsies

TEST SUMMARY

Helicobacter Pylori is a bacterium that produces urease. The test uses this characteristic in order to determinate the presence of Helicobacter Pylori on gastric biopsies. The urease breaks the urea (present in the reagent) in ammonia and carbon dioxide. The ammonia produced increases the PH of reagent and they change colour. In positive samples the reagent colour turns from yellow to bright magenta.

SAMPLES

Gastric biopsies.
Patients should not have taking antibiotics or bismuth salts during the three weeks preceding the endoscopy.
It is recommended that biopsy specimens be processed immediately after collection.

REAGENTS

Test tube: Urea, red phenol, stabilisers.

REAGENT PREPARATION AND STORAGE

Reagent is ready to use. It will remain stable until the expiration date stated on the label, when stored at 4-25°C.
A light amber coloured does not prejudice the analysis result. DO NOT FREEZE.

MATERIAL REQUIRED BUT NOT SUPPLIED

The test doesn't necessitate any materials out of the Kit.

PRECAUTIONS

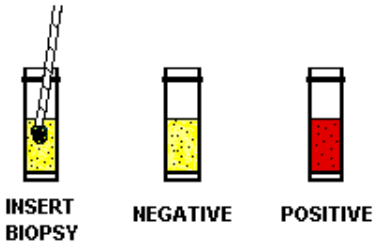
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

PROCEDURE

Insert a biopsy in the test tube, close the tube and mix. Check that the sample is completely immersed in the reagent.
Read the colour of tube against a tube without biopsy. To make easier this comparation is possible put the vial against white ground (ex. Paper, white coat, ecc.)

RESULTS INTERPRETATION

The test is a kinetic determination. The sample with an highest concentration of Helicobacter Pylori changes colour in a short time as to lower one.
The positive sample turns colour from yellow to magenta within 30 minutes.
It's advisable to reread after 3 hours results that can show minima concentrations of Helicobacter Pylori in the sample.



TEST PERFORMANCE

A total of 80 subjects were examined. Biopsies were collected according to guide lines and each biopsy was divided in two parts. The first part was tested with UREASE INSTANT TEST(Mascia Brunelli-MB), whereas the second was processed by histologic methods. Results obtained after 30 minutes are summarized in the following table.

	HISTOLOGY		
	POSITIVE	NEGATIVE	TOTAL
UREASE MB POSITIVE	29	0	29
UREASE MB NEGATIVE	6	45	51
TOTAL	35	45	80

From the table can be obtained the following results between 2 methods after 30 minutes:

Sensitivity: 82%
Specificity: 100%

In 6 "false negative" samples the histological reading showed "rare H. Pylori".
Among these 6 patients :

- 2 were positive to reading after 3 hours with Urease MB.
- 2 were patients in PPI therapy and 1 was a patient recently subjected to antibiotic-therapy: negative to reading also after 24 hours.
- 1 patient without particularity, negative to reading after 24 hours.

Excluding samples not suitable because from patients in therapy, we obtain the following results between the two methods to read after 3 hours:
Sensitivity: 96.8%
Specificity: 100%

NOTES

- Incomplete eradication of Helicobacter pylori can give negative results.
- If the test tube, (before sample insert) is already magenta, do not use for testing.
- The test should be handling with particular attention in order to avoid contamination and false positive result.
- Any contamination could cause false positive results.

WASTE DISPOSAL

Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

REFERENCES

Goodwin CS, Mendall MM, Northfield TC – *Helicobacter pylori* infection. Lancet 1997; 349-265-9.
International Agency for Research on Cancer. Schistosomes, liver flukes and *Helicobacter pylori*. In:IARC Monograph on the Evaluation of Carcinogenic Risk to Human (vol.61). Lyon: IARC, 1994; 177-240.
Pajares-Garcia J.M., Ital. J. Gastroenterol. Hepatol. (1998), 30 Suppl 3: S320 – 3.
Dixon, M. F.; Genta, R. ; Yardley, J.H.; Correa, P. International Workshop on the Histopathology of Gastritis, Houston 1994. Am. J. Surg. Pathol. (1996 oct), 20(10): 1161-81.

	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT (50 tests) **COD. NCURE900**

Tests plastic tube	50 items
Instruction for use	1item

EDMA CODE 11 70 70 90 00 CE IVD