

UREASE LIQUID TEST

Detection of Helicobacter Pylori urease activity on gastric biopsies

TEST SUMMARY

Helicobacter pylori is a bacterium that survives in the acidic environment of the stomach damaging cells and triggering an inflammatory reaction that leads to chronic disease, chronic superficial or atrophic gastritis. Infection is also the main etiological factor of peptic, duodenal and gastric ulcer.

PRINCIPLE OF THE TEST

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 sample the reagent colour turns from yellow to bright magenta.

SAMPLES

Gastric biopsies.

Patients should not have taking antibiotics or bismuth salts during the three week 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.

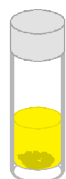
Read the colour of tube against a tube without biopsy. To make easier this comparison is possible put the vial against white ground (ex. Paper, white coat, ecc.)

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 is however recommended to re-read the results after 3 hours to verify the presence of minimum concentrations of *Helicobacter Pylori* in the sample.



NEGATIVO



POSITIVO

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 TEST LTA, whereas the second was processed by histologic methods.

Results obtained after 30 minutes are summarized in the following table.

	HISTOLOGY		
	POSITIVE	NEGATIVE	TOTAL
UREASE LTA POSITIVE	29	0	29
UREASE LTA 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 LTA.
- 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.
- Only for IVD use

WASTE DISPOSAL

Product is intended for professional laboratories. Waste products must be handled

as per relevant security cards and local regulations.

PACKAGING

CODE VK03200 (50 TESTS)
Test plastic tube 50

CODE VK03250 (300 TESTS)
Test plastic tube 300

REFERENCES

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SYMBOLS

- Only for IVD use
- Lot of manufacturing
- Code number
- Storage temperature interval
- Expiration date
- Warning, read enclosed documents
- Read the directions
- Biological risk

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