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IVD

REF 0206-0207

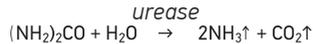
INFORMATION LEAFLET

AMA RUT Pro



INTENDED USE AND PRINCIPLE OF OPERATION

The intended use is specific rapid *Helicobacter pylori* detection by establishing the presence of urease activity in a biopsy specimen taken from either adult or child patients during the gastroscopy procedure. *Helicobacter pylori* produces the enzyme urease, which breaks down urea to ammonia. The detection of the enzymatic activity is based on the following biochemical reactions:



The principle of operation of AMA RUT Pro is based on the color change of the indicator after the biopsy specimen placed on the reactive element of the test. In the event of urease activity in the biopsy specimen, a red or magenta spot appears on the back side of the test. The sensitivity threshold is 2.6×10^4 CFU *Helicobacter pylori*.

Biological test samples could be:

- A biopsy specimen taken from any part of the stomach;
- A biopsy specimen taken from the duodenal cap.

LIMITATIONS

Not recommended

- testing at an ambient temperature below +17 °C and above +35 °C;
- eating legumes a day before testing;
- drinking carbonated beverages 2-3 hours before testing.

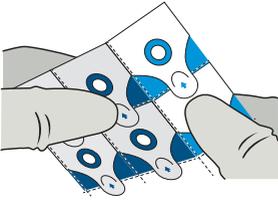
All these factors can affect the reliability of test results, in addition, false results may occur if:

- the concentration of bacteria of *Helicobacter pylori* in the sample taken during the biopsy is below the sensitivity threshold of the test;
- the sample does not contain *Helicobacter pylori* due to the uneven distribution of bacteria in the gastric mucosa (in 1-5 % of patients, the bacteria is present in the body/corner of the stomach, and not in the antral part, and conversely);
- if the sample contains bacillary forms of *Helicobacter pylori* cells below 10 % of the total number of cells;
- the biopsy stick or forceps contaminated before testing;
- taking antibiotics that inhibit *Helicobacter pylori* 4-6 weeks before the test;
- PPIs or H2 receptor antagonists, analgetics, antisecretory agents, anti-inflammation agents, bismuth compounds have an anti-*Helicobacter pylori* activity and decrease the load of *Helicobacter pylori* leading to false negative results, an interval of 2 weeks is required.

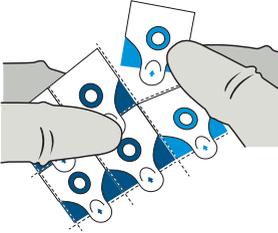
The test results must be interpreted by the physician based on the patient's clinical presentation. If there is a discrepancy with other diagnostic parameters it is recommended to make additional tests using other methods.

TEST PROCEDURE

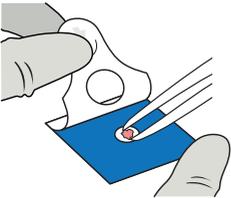
Please refer to the “AMA RUT Pro” Instructions for use.



1) Bend the block along the perforation lines.



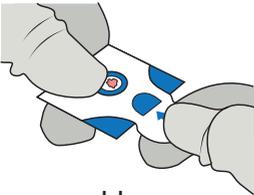
2) Separate one segment for examination.



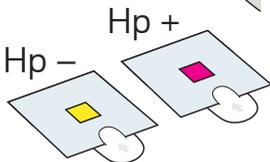
3) Open the protective cover, but do not pull hard not to tear it off, place the biopsy specimen on the white reactive element, and not beyond.



4) After placing the biopsy, gently smooth the protective cover with your finger around the perimeter of the test.



5) Fix the cover along the cut line. Fixation is necessary to preserve the reaction products in the express test cell.



6) Evaluate the test result from the back after 5 minutes.