

AMA Co Ltd



*Helicobacter pylori*  
**AMA RAPID UREASE TEST 1**  
**(AMA RUT 1)**

Express-test for the Detection of *Helicobacter pylori*  
Urease Activity in Biopsy Specimen

For *in vitro* diagnostic use  
Store at 15-50 °C Upon Receipt

**INSTRUCTIONS FOR USE**

EDITION 01, February, 2013



Authorized Representative  
in Europe  
Emergo Europe  
Molenstraat 15, 2513 BH  
The Hague, The Netherlands



Manufacturer  
Association of Medicine and  
Analytics Company Limited  
17 line of Vasilievsky Island, 4-6,  
199034, Saint-Petersburg, Russia



# Instruction for Use AMA RUT 1

## 1. Intended Use and Principle of Operation

The device is intended for specific rapid *Helicobacter pylori* detection by establishing the presence of urease activity in a biopsy specimen. The test is administered by endoscopy surgeons during the gastroscopy with a biopsy taken from either adult or child patients.

The principle of operation of AMA RUT 1 is based on the color change of the indicator disk after the biopsy specimen has been placed on its surface. In the event of urease activity in the biopsy specimen, a colored spot with shades of blue will appear on the surface of the indicator disk.

The biomaterial tested could be:

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

The size of the biopsy specimen should be no less than 2 mm (at any dimension).

## 2. Design of the Device

The device is a rectangular-shaped polymer carrying base with a transparent hole in which the indicator disk is imbedded and hermetically sealed by a transparent protective cover.



## 3. Warnings and precautions

For *in vitro* diagnostic use. CAUTION: Handle biopsy specimens as potentially biohazardous material.

All biopsy specimens should be regarded as potentially contaminated and treated as if they were infectious. Please refer to the local or national regulations.

Always use protective gloves when handling patient samples. Read all instructions prior to performing the test. Do not use device beyond the expiry date. Discard the used devices to biohazardous waste according to the local and national regulations.

## 4. Materials required, but not provided

- Forceps
- Timer
- Powder-free gloves

## 5. Preparation Before the Test

Put on the gloves.

Remove the protective cover to access the indicator disk.

Put the carrying base with disk on a white flat surface.

## 6. Test Procedure

- Using dry clean forceps place the biopsy specimen on the indicator disk and start timing.

**Warning!** The biopsy specimen should be placed directly on the indicator disk and should not extend beyond its borders.



- Cover the biopsy specimen with the previously removed protective cover.
- If positive, a color spot will appear within 3 minutes. After 3 minutes, one may establish the presence or absence of a color spot on the back side of the indicator disk.

- If detection is difficult, remove both the protective cover and the biopsy specimen from the indicator disc to establish the presence or absence of a color spot under the biopsy specimen.

## 7. Evaluation of Test Results

The presence of a color spot on one side of the indicator disk indicates urease activity in the biopsy specimen. The greater the urease activity is, the larger the colored spot and the stronger the blue or violet color will be.

- If within 3 minutes there is a color spot on the indicator disk, the result is positive (HP+).
- If within 3 minutes there is not a color spot on the indicator disk, the result is negative (HP-).

**Warning! Any changes that occur after the 3 minute period must not be taken in consideration.**

№	At the moment of placing the biopsy	3 minutes after placing the biopsy			Result
		Front side	Back side	Front side, the biopsy has been removed	
1.					High urease activity HP+
2.					Low urease activity HP+
3.					Absence of urease activity HP-

**Note! The biopsy specimen is applicable for further histology or culture detections.**

## 8. Limitations

False negative results may occur if:

- *H. pylori* inhibiting antibiotics have been taken 2-4 weeks prior to the examination.
- acid inhibiting drugs (PPI or H2-blockers) have been taken prior to the examination.

As with any diagnostic procedure the AMA RUT 1 results must be interpreted in the light of the patient's clinical presentation and any other information available to the physician.

## 9. Storage, stability and transportation terms

Store test

- in the manufacturer's packaging,
- in a dark, dry place with the temperature from +15°C to +50°C,
- in a place protected from mechanical actions (friction, pressure, strokes).
- Keep the device away from the ammonia vapor, moisture and direct sunlight.

When stored at this temperature the device is stable for 24 months.

Transport by any kind of transportation with the temperature from -50 °C to +60 °C, sealed. The transport period must not exceed 1 month.

## 10. Warranty

The Manufacturer shall remedy all defects discovered in any Product (the "Defective Product") that result from unsuitable materials or negligent workmanship and which prevent the mechanical functioning or intended use of the Products including, but not limited to, the functions specified in the Manufacturer's specifications for the Products.

Any warranty will, however, be deemed as void if fault is found to have been caused by maltreatment, misuse, accidental damage, incorrect storage or use of the product for operations outside their specified limitation or outside their specifications, contrary to the instructions given in the instruction manual.

The period of this warranty is 24 months from the date of manufacture.

## 11. Ordering information

- Distributor in Lithuania: Gapro Medica, Closed JSC, Siesikų g. 15-2, LT-07170 Vilnius, Lithuania.  
Tel: (370) 601 70034; e-mail: [info@gapromedica.com](mailto:info@gapromedica.com); web: [www.gapromedica.com](http://www.gapromedica.com)
- Distributor in Italy, France, Switzerland, Belgium, Spain, The Netherlands, Luxembourg: «Spectra 2000» Srl, Via Santa Margherita di Belice, 16, 00133 Roma, Italy. Tel: +39-06-20630997 Fax: +39-06-20685490  
Cell: +39-3356279810 Web: <http://www.spectra2000.it/>
- Manufacturer: AMA Co Ltd, 17 line of Vasilievsky Island, 4-6, 199034, St-Petersburg, Russia. Tel: (007) 812 321-7501  
Fax: (007) 812 380-7699. E-mail: [ama@sp.ru](mailto:ama@sp.ru) Web: [www.amamed.ru](http://www.amamed.ru)
- Authorized Representative in Europe (Regulatory affairs only): Emergo Europe, Molenstraat 15, 2513 BH The Hague, The Netherlands. Tel: (31) (0) 70 345-8570 Fax: (31) (0) 70 346-7299

## 12. References

1. U.S. department of Health and Human SERVICES (Dethesda, MD., USA) publication Biosafety in Microbiological and Biochemical Laboratories, 1999, 4th ed. (CDC/NIH) and No. (CDC) 88-8395 on reports of laboratory safety procedures on different diseases.

## Explanation of the symbols, used in labels



«Association of Medicine and Analytics» Company Limited  
17 line of Vasilievsky Island, 4-6, 199034, Saint-Petersburg, Russia



Emergo Europe  
Molenstraat 15, 2513 BH The Hague, The Netherlands



Use by



Batch code



Date of manufacture



Contents sufficient for n tests



Do not reuse



Consult instructions for use



In vitro diagnostic medical device



+15...+60 °C Temperature limitation. Storage at +15...+50°C and use at +15...+60°C