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 10 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 basement with 10 segments, in which indicator disks are imbedded and hermetically sealed by a transparent protective cover. The device is designed for carrying out 10 tests. As one segment has been opened, other segments remain hermetically sealed and can be further used or stored.

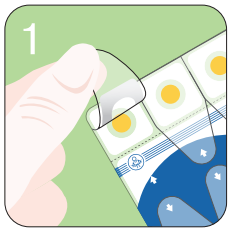
3. WARNINGS AND PRECAUTIONS

For **in vitro** diagnostic use only.
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 the instruction prior to performing the test. Do not use device beyond the expiry date. Discard the used segments of the devices to biohazardous waste according to the local and national regulations.

4. MATERIALS REQUIRED, BUT NOT PROVIDED

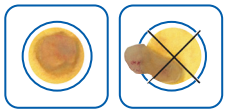
- Forceps
- Timer
- Powder-free gloves

5. TEST PROCEDURE

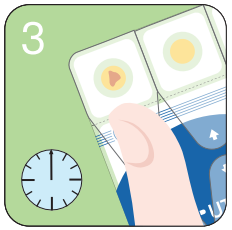


Put on the gloves.
Remove the protective cover in the line of perforation to access the indicator disk.
Put the basement on a white flat surface.

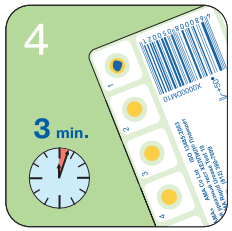
Using dry clean forceps place the biopsy specimen on the indicator disk. Start timing.



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.



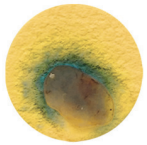
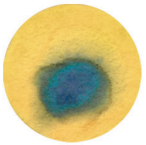
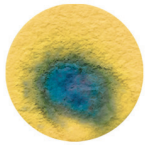
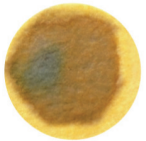
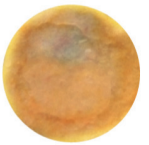
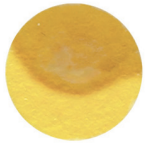
After 3 minutes, one may establish the presence or absence of a color spot on the back side of the indicator disk.
If detection is difficult, remove both the protective cover and the biopsy specimen from the indicator disk to establish the presence or absence of a color spot under the biopsy specimen.

6. EVALUATION OF THE TEST RESULTS

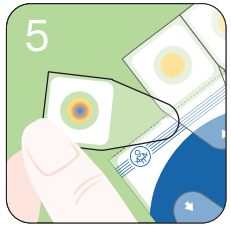
The presence of a color spot on the indicator disk indicates urease activity in the biopsy specimen. The greater the urease activity is, the larger the colored spot and the stronger the blue or violet color will be.

- 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 hystology or culture detections.



After the test you need to separate the used segment of the device in the line of perforation and discard it in accordance with the item “WARNINGS AND PRECAUTIONS”

7. 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 10 results must be interpreted in the light of the patient’s clinical presentation and any other information available to the physician.

8. 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.