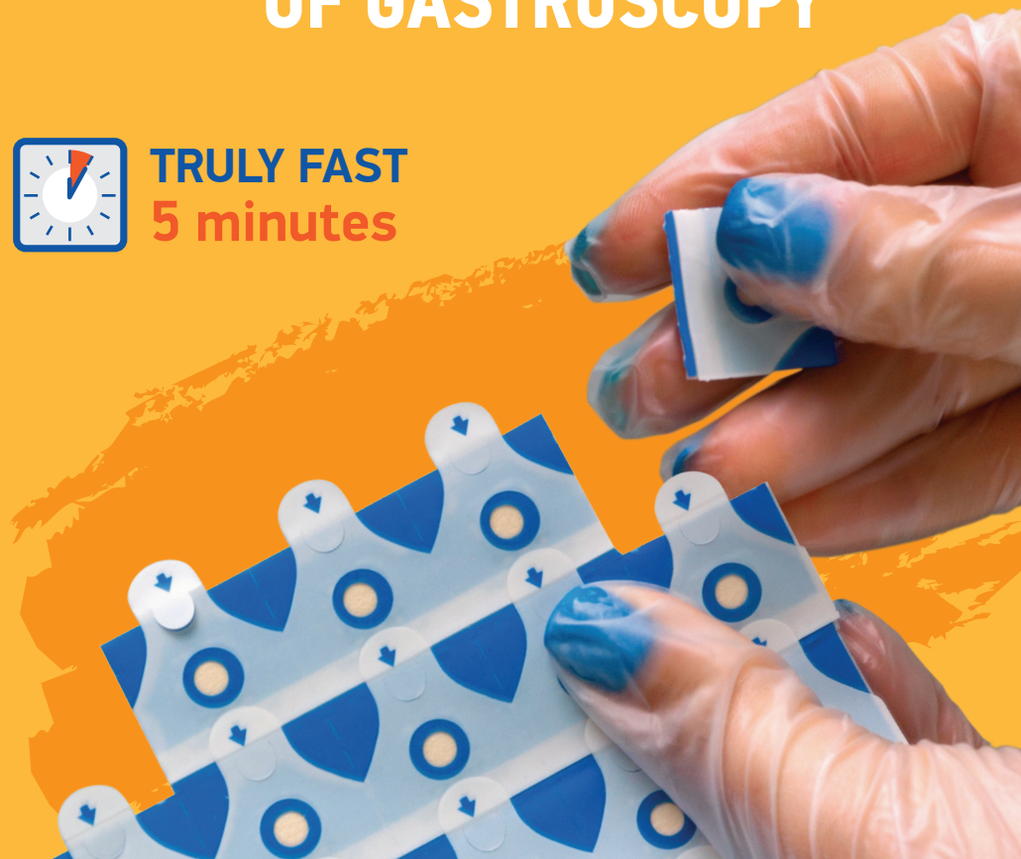
AMA Co Ltd

AMA RUT Pro

THE UP-TO-DATE TEST FOR *H.PYLORI* DETECTION IN THE COURSE OF GASTROSCOPY

TRULY FAST
5 minutes



AMA RUT Pro is a dry cool rapid urease test, so it requires no buffer and is ready to use without incubation.

The test boasts an extended shelf-life of 24 months and requires no special conditions for storage, the temperature range is +4 to +42°C.

The quality management system of AMA Co Ltd is ISO 9001:2015 and ISO 13485:2016 certified.

WO2020139142 patent pending. The design of AMA RUT Pro is patent protected in Russia and internationally; "AMA" and "AMA RUT" are registered trademarks of AMA Co Ltd.

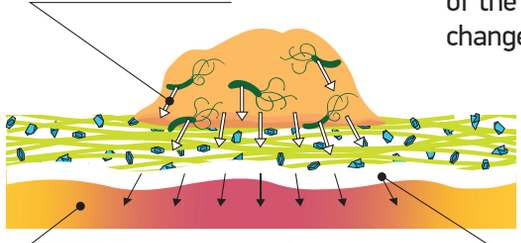
www.amarut.pro

WHAT MAKES THE NEW AMA RAPID UREASE TEST A PROFESSIONAL TEST?

The high sensitivity and specificity of AMA RUT Pro become possible thanks to its' innovative multilayer design comprising a special membrane. It separates the enzymatic reaction layer from the indicator layer, so that the reaction with *H. pylori* urease and the following indicator reaction were not mixed. If the biopsy sample is *H. pylori* positive, the two reactions go consequently in the different layers of the test, resulting in a bright color change within just 5 minutes.

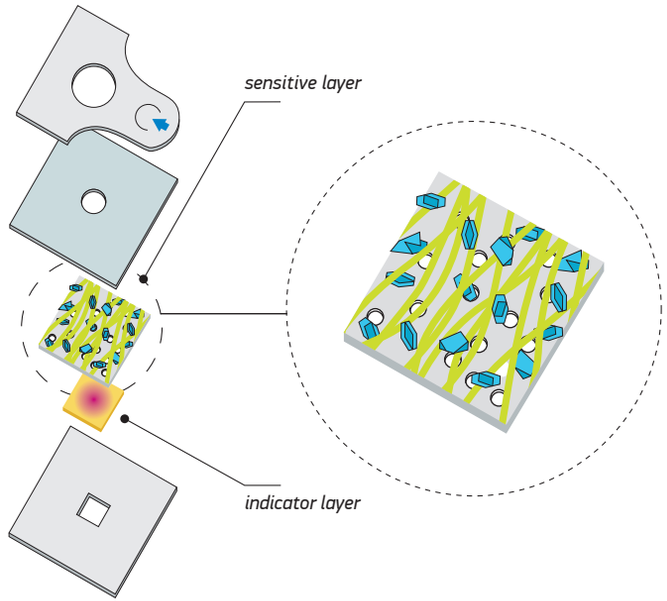
STRUCTURE OF THE TEST

sensitive layer:
reaction of H. pylori urease enzyme and urea, with the formation of ammonia ***(first reaction)***



indicator layer reaction: ammonia increases the pH ***(second reaction)****, which leads to the target color change*

only the ammonia formed during ***the first reaction*** *penetrates to the next layer*



WHY IS IT CRUCIAL TO SEPARATE THE TWO REACTIONS?

- Maximum specificity is reached — the test reacts only to the target urease, not to any interfering substances that may come with the biopsy (such as bile, blood or lidocaine). It is only the urease, if present in the biopsy, that launches the reaction on the substrate layer, and the gaseous products of the reaction pass through the membrane to launch the second, indicator reaction.

With this separation, the test shows a positive result only in the presence of *H. pylori* urease, as confirmed by the microbiology trials held in the Pasteur Institute. The diagnostic specificity of the test reaches 99%, as proved by clinical trials.

Higher sensitivity is achieved: thanks to the membrane separation, the components and reagents are chosen so that the two reactions could run to the full extent and as quick as possible. The sensitivity threshold of the test is 10^4 CFU, which conforms to the world's best practices. The diagnostic sensitivity, as shown in clinical trials, is 99 %.