



PRODUCT CATALOGUE

Diagnostics tests made easy





Dear friends!

*Let me introduce to you **AMA**, the leading brand in the field of development and manufacturing of innovative test-systems for **Helicobacter pylori** detection. Cooperation with the best medical scientists, researchers and clinical physicians allowed **AMA** to elaborate the up-to-date test-systems with highest diagnostic characteristics, including smart design, ultra-rapid reaction, extended storage period and economy. The tests can be implemented right in the doctor's office in the course of the patient's examination.*

*Through the years of international market experience, **AMA Rapid Urease Test** and **HELIC Ammonia Breath Test** have become increasingly demanded among gastroenterologists, pediatricians, therapists, general practitioners, endoscopists in more than 40 countries all over the world. **AMA RUT** test for gastroscopy procedure and non-invasive **HELIC ABT** for diagnostic selection of patients allow to detect **H. pylori** easily and quickly without the use of a central laboratory.*

*The expertise gained with the **H. pylori** tests paved the way to the new developments of rapid tests for professional use: **AMA Dent** for the detection of red complex bacteria and **AMA Venera** for the detection of **Mycoplasma hominis** and **Ureaplasma spp.***

*Quality guarantee is **AMA's** basic goal. Reliability and safety of the test-systems are confirmed by wide clinical trials, the quality management system is certified according to the ISO 9001:2015 and ISO 13485:2016 standards. **AMA** meets the requirements of the Regulation (EU) 2017/746 (IVDR) and of the in-vitro Diagnostic Directive 98/79/EC for its' products officially registered in the European Community.*

We will be glad to cooperate with you!

Marina Dmitrienko, PhD and SciD in Biotechnology, Dr Habil in Engineering Sciences.

HELIC ABT

The **HELIC Ammonia Breath Test (HELIC ABT)** is a ready-to-use test for qualitative detection of *Helicobacter pylori* urease activity in patients with the suspected infection. The test is based on a change of ammonia level in a patient's mouth cavity air after a portion of unlabelled urea 12C was taken. The test is applied by gastroenterologists, general practitioners, by staff of primary health centers and dispensaries and allows implementing Near Patient Testings (NPT) in any place and situation.

HELIC ABT indicator tube kit

- Indicator tube: plastic tube with the indicator composition inside and both ends sealed;
- Mouthpiece;
- Connecting hose: flexible plastic tube to connect the indicator tube
- Urea load;
- D-Mannitol;
- Instructions for use;
- Registration card with the scale and the QR-code.

Packaging of HELIC ABT indicator tube kit with auxiliary materials	
Individual package dimensions	4x7x16 cm
Net weight	0.05 kg
Amount in transport box 38x28x18 cm, 3.3 kg	50 pcs
Amount in transport box 38x38x29 cm, 5.5 kg	100 pcs

The kit for 50 detections is packed in the 34x16x12 cm cardboard box (net weight 1 kg) and has all the same contents except the hoses.

MATERIALS REQUIRED, BUT NOT PROVIDED:

- Personal computer;
- Still drinking water (~300 ml);
- Medical gloves;
- Scissors.

Cat. Number 0106 (packaging 50 pcs)

Cat. Number 0107 (packaging 1 pcs)

Cat. Number 0109 (packaging 30 pcs)



HELIC ABT Reader

Non-invasive diagnostics of Helicobacter pylori

HELIC ABT Reader allows for an automated air sampling and reading the color of the indicator tube. Thanks to the software and the QR code the testing procedure is conducted step-by-step to avoid human factor errors. **HELIC ABT Reader** doesn't require periodical maintenance as it doesn't have a built-in sensitive element. The single-use indicator tube serves as the sensor.



Package details

Product, 1 pcs.	dimensions, cm	Weight, kg	Amount of items in the box, pcs
HELIC ABT Reader (Electronic block - 1 pcs. Adapter with a nonremovable connecting cord - 1 pcs., USB 2.0 connection cable A-B - 1 pcs., Cassette for placing the sample - 1 pcs., Power cord - 1 pcs., Connecting hose - 10 pcs. CD with HELIC Ammonia Breath Test software - 1 pcs.) or USB Flash drive	(length) 38 cm (height) 29,5 cm (width) 20,5 cm	2,8	1

Cat. Number 0105



*Computer is not included

HELIC ABT suction pump

The electric pump allows for manual air sampling, when the testing procedure is not automated.

Package details

Product, 1 pcs.	dimensions, cm	Weight, kg	Amount of items in the box, pcs
HELIC ABT air pump Adapter with a nonremovable connecting cord - 1 pcs., Power cord - 1 pcs., Connecting hose - 10 pcs.	(length) 26 cm (height) 12 cm (width) 10 cm	1	1

Cat. Number 0108

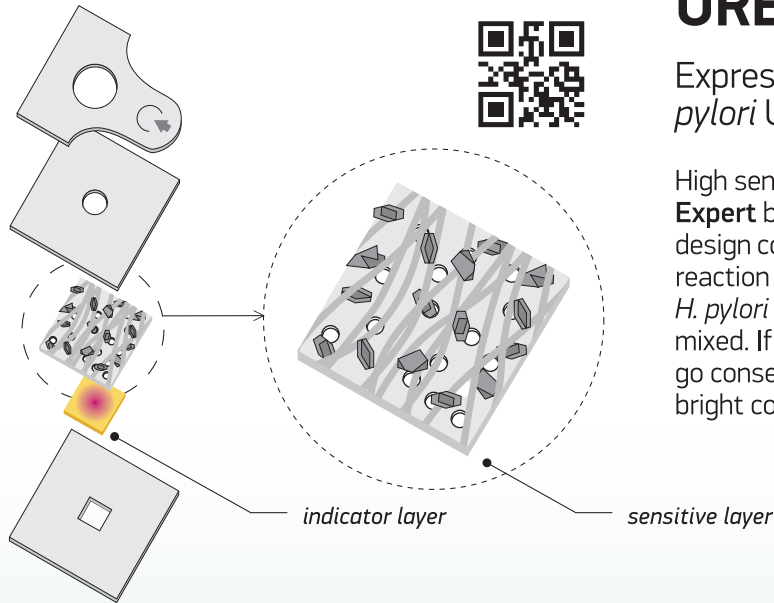


www.helicabt.com

Helicobacter pylori AMA RAPID UREASE TEST — AMA RUT

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

High sensitivity and specificity of **AMA RUT Pro** and **AMA RUT Expert** 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 minutes.



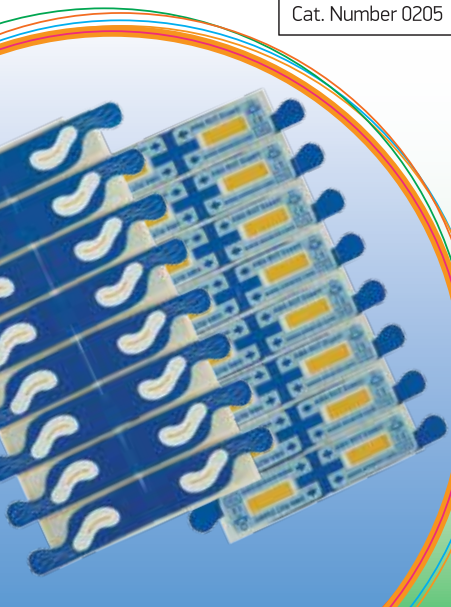
AMA RUT Expert

AMA RUT Pro

The sensitivity threshold of the tests is 10^4 CFU, which conforms to the world's best practices. The diagnostic sensitivity, as shown in the clinical trials, is 98% for **AMA RUT Expert** and 99% for **AMA RUT Pro**. The diagnostic specificity is 100% and 99%, respectively.

Package details

Product name	Quantity of tests, pcs.	Number of blocks in one envelope	Envelope dimensions	Envelope weight, kg
AMA RUT Pro Cat. Number 0206	block of 24	1	(length) 16 cm (width) 11 cm	0,045
AMA RUT Pro Cat. Number 0207	48 in blocks	2	(length) 16 cm (width) 11 cm	0,055
AMA RUT Expert Cat. Number 0205	block of 16 / 48 in blocks	1 / 3	(length) 16 cm (width) 11 cm	0,035 / 0,055



1 AMA RUT Expert
the world's first
Rapid Urease Test
with READER *



AMA RUT Expert with AMA RUT Reader

The test-system consists of a single use test **AMA RUT Expert** and the **AMA RUT Reader**. The Reader makes multiple readings to check if the result of the test has become available. Thus there is no need to wait and follow the color change, the automated readings save time for doctors and nurses.

Focus on the patient: **AMA RUT Expert with AMA RUT Reader** takes routine *H. pylori* detection off the doctor's shoulders.

DESIGN OF THE TEST-SYSTEM

- AMA RUT Reader
- AMA RUT Expert
- Control sample
- USB cable
- AC/DC USB adapter (optional)
- CD/USB flash drive with software and driver (optional)
- Batteries (3 pcs. 3V CR2032)
- Additional slide holder (optional)
- Biopsy pick (optional)

MATERIALS REQUIRED, BUT NOT PROVIDED:

- Forceps;
- Powder-free gloves.

* European patent N° EP3009519B1

AMA RUT Reader

Diagnostics of H. pylori in the course of gastroscopy

Digital reading of **AMA RUT Expert** tests with **AMA RUT Reader** allows to exclude possible doubts in the color change interpretation. The semi-quantitative result is presented on the display of the Reader as HP+++, HP++, HP+ or HP- and can be transferred to a PC.

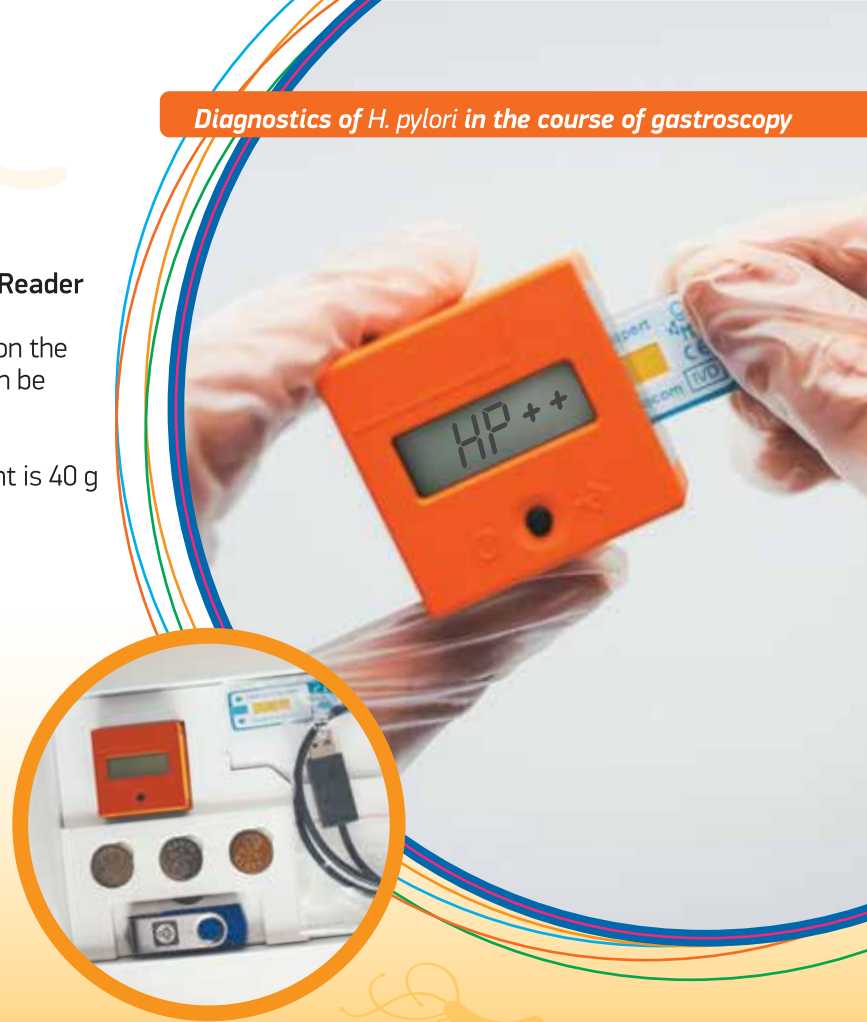
The dimensions of the device are 41x41x40 mm, the weight is 40 g

Package details

Product	Box dimensions, cm	Box weight, grams	Amount of items in the box, pcs
AMA RUT Reader Cat. Number 0204	(length) 21 cm (height) 4,5 cm (width) 13 cm	110	1

Storage and transport

- Store the Reader at -20...+80 °C
- Store the test at +15...+50 °C



Enzymatic express test

Innovative POCT — results within few minutes at the doctor's office

AMA DENT

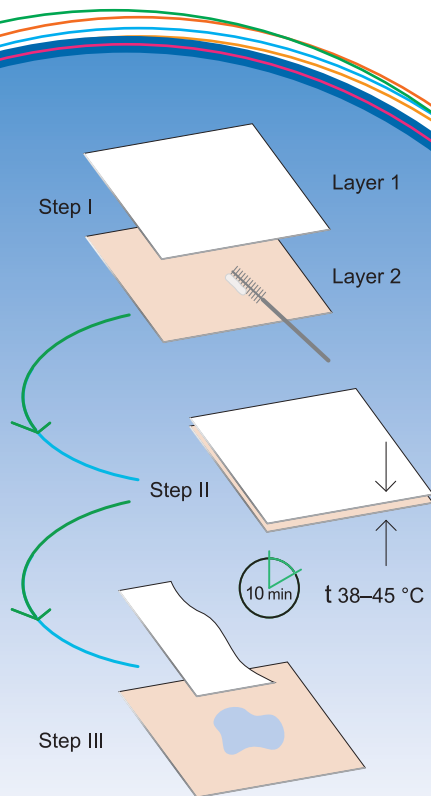
IVD CE



Detect the "red complex" bacteria — associated with inflammatory periodontal diseases

Package details

Product, 1 pcs.	Pack (envelope) dimensions, cm	Weight, grams	Number of test segments in the device, pcs
AMA DENT Cat. Number 0503	(length) 16 cm (width) 11 cm	30	24



Bio sample collected from the interdental space and the back of the tongue scraping is placed on the white substrate layer 1. The test is then folded so that the layer 1 and layer 2 of the reagent strip combined. The temperature range from 38 °C to 45 °C is needed for the test to provide with the results after about 10 minutes. The result is positive when the color of the indicator element has changed from salmon to light-blue.

Porphyromonas gingivalis, *Treponema denticola* and *Tannerella forsythia* are the "red complex" bacteria that have biochemical mechanisms allowing them to colonize and destroy periodontal tissues and cause inflammatory periodontal diseases — the most common dental disorders in the world.

AMA Dent provides with the results minutes after the sample of the dental plaque was placed onto the test. If the bacteria are detected, the positive result is indicated by the color change of the test. Thus, the test justifies the need to undertake antimicrobial treatment in order to prevent inflammatory periodontal disease.

Innovative POC diagnostics

2-in-1 enzymatic express test

AMA VENERA



IVD CE

MYCOPLASMA HOMINIS + UREAPLASMA SPP.

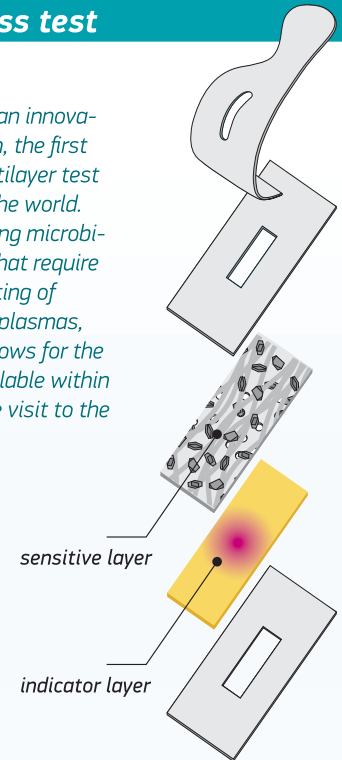
Package details

Product, 1 pcs.	Pack (envelope) dimensions, cm	Weight, grams	Number of test segments in the device, pcs
AMA VENERA Cat. Number 0502	(length) 16 cm (width) 11 cm	30	12

Mycoplasma hominis and *Ureaplasma spp.* bacteria can cause inflammation in the urogenital tract (e.g. non-gonococcal urethritis, prostatitis, bacterial vaginosis) which in turn can lead to fertility problems. With our new **AMA Venera** test, rapid point-of-care detection of *Mycoplasma hominis* and *Ureaplasma spp.* is possible to perform in the doctor's office right after taking the sample. Thanks to the enzymatic activity of these bacteria, they both can be diagnosed with the use of a dry cool test that requires fewer actions to take.

Enzymatic express test

AMA Venera is an innovative test-system, the first "dry" "cool" multilayer test of such kind in the world. Unlike the existing microbiology systems that require 24/48 hours testing of urogenital mycoplasmas, **AMA Venera** allows for the result to be available within the period of the visit to the doctor.





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