INSTRUCTION MANUAL

REF 6110

April 01, 2014

Helicobacter Antigen Quick

- 25 determinations -

CE

IVD *In vitro* diagnostic device

Rapid immunochromatographic test for the detection of Helicobacter pylori antigen in fecal specimens

REF	Catalogue number	LOT	Batch code
	Consult accompanying documents		Manufactured by
	Temperature limitation		Use by
	Consult operating instruction		Biological risk

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INTENDED USE

Helicobacter Antigen Quick is used for the qualitative determination of Helicobacter pylori antigen in fecal specimens.

Helicobacter pylori is a spiral-shaped bacterium colonizing human stomach and duodenum. The bacterium has adapted to the acidic environment of the stomach. The enzyme urease transforms urea into ammonia and carbon dioxide neutralizing the acid and enabling Helicobacter to survive in this milieu. It is established as the causative agent of gastritis, peptic ulcers and gastric carcinoma since it was firstly described in 1984 by Marshall and Warren (1). Helicobacter pylori cause more than 90% of duodenal ulcers and 80% of gastric ulcers. Infection is usually acquired in early childhood. Rate of infection in Europe is about 30-40%, worldwide about 50%. The infection is on a decline in the developed countries due to therapeutic regimes and improved hygiene to prevent re-infections. This situation is opposite in many of the developing countries (2).

Direct detection of antigen in stool samples by rapid one-step assay is an inexpensive, easy to handle sensitive test with no need of invasive examination and specialized instrumentaion.

(1) Marshall BJ, Warren RM. Unidentified curved bacilli in the stomach of patients with gastritis and peptic ulceration. Lancet 1984, 16, 1311-5
(2) Niyaz A. 23 years of the discovery of Helicobacter pylori: Is the debate over? Ann Clin Microbiol Antimicrob. 2005; 4, 17

PRINCIPLE OF THE TEST

Helicobacter Antigen Quick is a fast one-step immunochromatographic assay for the detection of Helicobacter pylori antigen in faecal samples.
The membrane is pre-coated with monoclonal antibodies to Helicobacter pylori on the test band region. During testing, the antigen in the sample is allowed to react with the colored conjugate (anti-Helicobacter pylori monoclonal antibodies - red microspheres) which was pre-dried on the test. The complex formed of Helicobacter pylori antigen and conjugate then migrates upward on the membrane by capillarity. In case of a positive result the specific antibodies present on the membrane will capture the colored conjugate forming a RED band.
The access conjugate continues to migrate across the membrane to the immobilized antibodies placed in the control band region forming a green colored band. The presence of this GREEN band serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained and 3) as an internal control for the reagents.

PATIENT SAMPLES

Specimen collection and storage

Stool samples should be collected in clean containers and the assay should be done right after collection. Do not use watery or diarrhoeal samples. The samples can be stored at 2-8 ºC for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at –20ºC. In this case, the samples have to be totally thawed and brought to room temperature before testing. Repeated freezing and thawing of samples should be avoided.

Preparation before use

Allow frozen or refrigerated fecal samples to reach room temperature prior to assay. Take care to agitate samples gently in order to ensure homogeneity.
Shake the test tube well in order to assure good sample dispersion before immersion of the test strip.

TEST COMPONENTS for 25 determinations

A Ab 25	**Test strips**, 25 test strips coated with monoclonal antibodies to Helicobacter pylori and conjugate	1 container vacuum sealed with desiccant
B DIL	**Sample diluent**	3 x 10 ml ready for use dropper bottles

Materials required but not provided

- specimen collection container
- swabs
- micropipettes
- tubes or vials
- disposable gloves
- timer

Size and storage

Helicobacter Antigen Quick has been designed for 25 determinations.

The expiry date of each component is reported on its respective label that of the complete kit on the box labels.

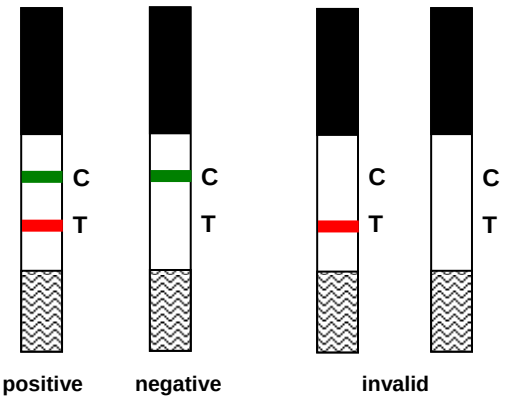
Upon receipt, all components of the Helicobacter Antigen Quick have to be kept at 2 - 8 °C, preferably in the original kit box.

After opening all kit components are stable for at least 3 months, provided proper storage.

ASSAY PROCEDURE

1. Allow the test strips and samples to reach room temperature (15-30°C) prior to iesting. Do not open the package until ready to perform the assay.
2. Place 1 ml (approximately 20 drops) of the sample diluent in a test tube.
3. Add approximately a sample portion of 5 mm diameter with a swab and shake gently in order to unstick and facilitate the sample dispersion.
4. Shake the test tube well in order to assure good sample dispersion. Let the tube rest for at least 5 min for sedimentation.
5. Using a pipette, extract some liquid from the topside and dispense in a small tube er vial, enough to get a deepness of 1 cm or less.
6. Immerse the test strip in the liquid prepared in step 5. Do not exceed the line shown on the strip.
7. Read the result **5 minutes** after the immersion of the strip.

EVALUATION OF RESULTS



NEGATIVE: Only one GREEN band (control line) appears in the white central zone of the test (control region).

POSITIVE: In addition to the GREEN control band, a distinguishable RED band (result line) also appears in the white central zone of the test (result region).

INVALID: A total absence of the control band (GREEN) regardless of the appearance or not of the result line (RED). Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test performance using a new test. If the problem persists, discontinue using the test kit and contact you local distributor.

Test validity

Internal procedural controls are included in the test. A green line appearing in the control region is an internal control. It confirms sufficient specimen volume and correct procedural technique.

Limitations of the method

The test must be carried out within 2 hours of removing a test strip from the container.

An excess of stool sample could cause wrong results (brown bands appear).

Particles in the sample dispersion could lead to a loss in capillarity in the test system and cause invalid results. Only use clear supernatant.

The intensity of the Red band in the result region (T) varies depending on the concentration of antigens present in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be detemined by this qualitative test.

A negative test result not necessarily excludes a Helcobacter pylori infection. Inhomogeneous antigen distribution in the sample can cause false negative results.

Any clinical diagnosis should not be based on the results of in vitro diagnostic methods alone. Physicians are supposed to consider all clinical and laboratory findings possible to state a diagnosis.

ANALYTICAL PERFORMANCE

Sensitivity

The minimum detectable unit of Helicobacter pylori is of 4-8 ng/ml.

Clinical evaluation

Detecting clinically evaluated Helicobacter pylori samples using the Helicobater Antigen Quick a concordance level of 95% was found.

Diagnostic specificity

The use of monoclonal antibodies in the elaboration of the assay assures a high degree of specificity for antigens of Helicobacter pylori. The monoclonal antibodies used recognize epitopes present in the antigen found in stool of patients as well as in preparations from bacteria cultures in vitro. Sonicated Helicobacter pylori extract from different commercial samples react positive with Helicobacter Antigen Quick.

SAFETY PRECAUTIONS

- **This kit is for in vitro use only**. Follow the working instructions carefully. GA GENERIC ASSAYS GmbH and its authorized distributors shall not be liable for damages indirectly or consequentially brought about by changing or modifying the procedure indicated. The kit should be performed by trained technical staff only.
- The expiration dates stated on the respective labels are to be observed.
- Do not use or mix reagents from different lots. Do not use reagents from other manufacturers.
- All reagents should be kept at 2 - 8 °C before use in the original shipping container.
- Some of the reagents contain small amounts of Sodium azide (0.095%) as preservative. They must not be swallowed or allowed to come into contact with skin or mucosa.
- Sample materials must be handled as infectious material. Wear disposable gloves while handling clinical specimens. Dispose clinical specimens in accordance with local legislation.
- Since the kit contains potentially hazardous materials, the following precautions should be observed:
  - Do not smoke, eat or drink while handling kit material,
  - Always use protective gloves,
  - Never pipette material by mouth,
  - Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.
- In any case GLP should be applied with all general and individual regulations to the use of this kit.