HELISTOOL

Helicobacter pylori Stool Ag CARD TEST

Rapid test in card format for detecting
Helicobacter pylori antigen in stool specimen

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INTRODUCTION

This Ag Stool Card Test is a immunochromatographic based screening assay to detect Helicobacter pylori antigen in stool samples.
Helicobacter pylori (formerly known as Campylobacter pylori) is a spiral-shaped, gram-negative bacteria with a typical flagellum, infecting gastric mucosa. It causes several gastro-enteric diseases such as non-ulcerous dyspepsia, gastric and duodenal ulcer, active gastritis and rarely stomach adenocarcinoma. Therefore, it is classified as carcinogen agent type I.
Many H. pylori strains have been isolated today. Among them, the strain expressing CagA antigen is evaluated as strongly immunogenic. It is widely reported in many literature articles that, in infected patients showing antibodies against CagA gene product, the risk of gastric cancer is up to five times higher than the reference group infected with a CagA negative bacterial strain.
Several invasive and non-invasive approaches are available to detect this infection state. Many problems associated with invasive methodologies changed the direction of the diagnosis to non-invasive tests such as Breath Test, classical ELISA and immunoblotting assays together with the rapid test that is explained in detailed below.

PRINCIPLE OF THE TEST

HELISTOOL Ag Stool Card Test is a rapid, precise and easy to perform non-invasive lateral flow assay. This test makes use of specific antibodies against H. pylori antigen adsorbed onto a reactive membrane. If H. pylori is present in stool specimen, the specific antigen is bounded by the second antibody which is conjugated with colloidal gold particles. A generic antibody, fixed onto the reactive membrane, in shape of the band, is able to capture the second conjugated antibody, assuring the correctness of the test performance. Stool is used as the sample in this test.

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KIT CONTENT

Card:	A membrane with specific antibodies against H. pylori including also a second monoclonal antibody conjugated with colloidal gold.
Extraction Tube (With Buffer):	Include hipotonic solution.
Plastic pipette	For collecting liquid samples.
Instruction For Use	

MATERIALS REQUIRED BUT NOT SUPPLIED WITH KIT

- Timer.
- Specimen collection containers

STABILITY OF THE KIT

The kit should be stored at +6^{0}C - +35^{0}C. In these conditions, the kit is stable up to the expiry date signed on the label of the kit.

COLLECTION AND STABILITY OF THE SAMPLES

The specimen should be transported in an airtight container and stored at +2 ^{0}C - +8^{0}C until tested. The specimen should be tested as soon possible, but may be held up to 48 hours at +2^{0}C - +8^{0}C prior to testing. If testing cannot be performed within this time frame, specimens should be frozen immediately on receipt and stored frozen (-20^{0}C or below) until tested. Specimens may be frozen and thawed twice.

NOTE: Stool in transport media, on swabs, or mixed with preservatives is not appropriate for testing.

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1- Liquid or Semi-Solid Stools

Use a separate plastic pipette (included in the kit) for each sampling. Dispense 6-7 drops of stool into the extraction tube. Mix the tube carefully, then vortex 15 seconds. If vortex is not available, shake the tube manually for 1- 2 minutes. Special care is needed when pipetting semi-solid stool. False negative or invalid results can be observed due to restricted or overloaded sample flow.

2- Solid Stool Specimens

Unscrew the top of the extraction tube. Collect the stool sample with the tip of the collection device by dipping in three different places of the same stool specimen. Verify to collect a small portion (approximately 6 mm diameter) of stool by the tip of the collection device. Put the collection device back into the plastic test tube. Shake the extraction tube in order to get a homogeneous solution. Wait at least 3 minutes. Continue shaking until obtaining a dark yellow-brown solution.

The sample should be thoroughly mixed with a vortex or manually before testing. Special attention is needed to transfer the exact amount of stool in to the extraction tube. The transfer of insufficient amount of stool, or failure to obtain a homogenous solution may result in false-negative test results. The addition of excessive amount of stool may cause invalid results due to restricted sample flow.

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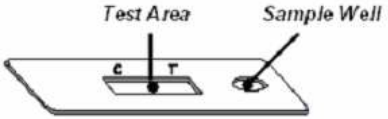
TEST PROCEDURE

1. Remove the test card from the protective pouch. Identify the plastic cassette with the patient's data.
2. Gently shake the extraction tube containing the sample under investigation.
3. Brake the tip of the extraction tube and squeeze 3-4 drops of the extracted mixture into the sample well "S" of the card.
4. Read the result 5 -10 minutes after the sample addition.



INTERPRETATION OF THE RESULTS

Negative Result
If in the test area only one pink-red band appears in the control region "C" (control band), the result is to be considered as negative. This is the control line assuring the correctness of the test.

Positive Result
In addition to the control band "C", if a pink-red band appears in "T" region of the test area, the result is to be considered as positive. The intensity of the band colour in the test region is proportional to the antigen concentration in the sample.

Invalid Result
If no band appears in the test area or the band appears just in the "T" region, then the result is to be considered as invalid and it is recommended to repeat the test.

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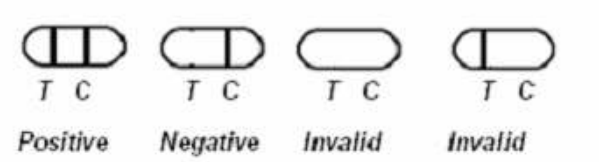

WARNINGS AND PRECAUTIONS

For in vitro diagnostic use only.
Stool specimen can be potentially infectious. Safety measures for handling and storing the collected specimen must be fixed by the operators.
As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test.
But should only be made by the physician after all clinical and laboratory findings have been evaluated.
The kit must be used by clinical test trained staff only.

PERFORMANCE CHARACTERISTICS OF THE TEST

In this study the known positive and negative samples that are previously detected with ELISA test was compared. At the end of this study 14 positive stool samples (which are previously confirmed as positive by ELISA test) have been all confirmed positive with HELISTOOL H.pylori Stool Ag Card Test (clinical sensitivity 100%). 12 negative stool samples (which are previously confirmed as negative by ELISA test) have been all confirmed negative with HELISTOOL H.pylori Stool Ag Card Test (clinical specificity 100%).

Sensitivity

The sensitivity of the test have been performed and found as a 0,05 µg H.pylori Ag/mL extraction buffer.

Specifity

No cross-reactions have been found with bacteria normally present in the gastro-intestinal tract and those ones generally infecting the same area such as; Enterococcus, Klebsiella, Proteus, Candida, Campilobacter, Shigella, Salmonella as well as yeast strains and viruses.

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