H. pylori stool Card  
REF: CLZC82002

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

INTRODUCTION

H. pylori Stool Card is a screening immunochromatographic assay to detect Helicobacter pylori antigen in stool samples.

Helicobacter pylori (also known as Campylobacter pylori) is a spiral-shaped with a typical flagellum, Gram-negative bacteria, infecting gastric mucosa. It causes several gastro-enteric diseases such as non-ulcerous dyspepsia, gastric and duodenal ulcer, active gastritis and can even increase the risk of stomach adenocarcinoma, so as to be classified as carcinogen agent type I.

Many H. pylori strains have been isolated: among them, the strain expressing CagA antigen is strongly immunogenic and, according to this, it is of utmost clinical importance because it is associated to the cytotoxic factor. 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.

The presence of the gene itself determines the persistence of the infection, the ulceration and the protein associated, VacA toxin is frequently the main cause of inflammations in the gastric mucosa. This antigen is associated to others, such as CagII, CagC, seems to act as starting agent of a sudden inflammatory response which can provoke ulceration (peptic ulcer), allergic episodes, and a decrease of the therapy efficacy.

At present several invasive and non-invasive approaches are available to detect this infection state. Invasive methodologies requires endoscopy of the gastric mucosa with a histologic, cultural and urease investigation, which are cost-effective and requiring long times to come to a correct final diagnosis. Alternatively, non-invasive methods are available such as Breath Test, which is extremely complicated and not highly selective, or classical ELISA and immunoblotting assays.

PRINCIPLE OF THE TEST

H. pylori Stool Card is a non-invasive lateral flow assay, rapid, precise and easy to perform.

This test makes use of monoclonal specific antibody against H. pylori antigen adsorbed onto a reactive membrane. If H. pylori is present in stool specimen, the specific antigen is bound by the antibody which is conjugated with latex. A generic antibody, fixed onto the reactive membrane, in shape of the band, is able to capture the conjugated antibody, assuring the correctness of the test performance.

SPECIMEN

Stool. Stability 2 days at +4°C.

COMPOSITION OF REAGENTS

Card: membrane with monoclonal specific antibody against H. pylori including the same monoclonal antibody conjugated with latex.

Extraction buffer: isotonic solution.

Reagents can be stored at +6°C - +35°C.

PROCEDURE

1. Remove the test card from the protective pouch. Identify the plastic cassette with the patients data.
2. Gently shake the test tube containing the sample under investigation.
3. Brake the tip of the test tube and squeeze 2-3 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 RESULTS

Negative

In the reading window only 1 red band appears in the control region “C”. This is the control line assuring the correctness of test performing.

Positive

In addition to the control red band, a clearly distinguishable red band appears in the test region “T”. The intensity of the band colour in the test region is proportionally to the antigen concentration in the sample.

Invalid

No band appears in the control region. The test is to be considered as in conclusive and it is recommended to

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WARNINGS AND PRECAUTIONS

• For in vitro diagnostic use only.
• For professionally use only.
• Stool specimen can be potentially infectious. Safety measures for handling as well as 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 components of this I.V.D. are tested always each other without verify the compatibility with components produced by other manufacturers. It is not excluded that these components can be used with components of same chemical composition but produced by other manufacturers, but there is not an experimental evidence of this compatibility.
• The kit must be used by clinical test trained staff only.

SENSITIVITY
The sensitivity limit of test (cut-off) is ≥ 0.05 µg Helicobacter pylori antigen/ml extraction buffer.

LINEARITY RANGE
The linearity range has been determined using standard Aalto Code BM6079, and is in the range 0.05 µg - 2.5 µg of Helicobacter pylori antigen/ml extraction buffer.

PROZONE EFFECT
Prozone effect was not observed up to 2.5 mg of Helicobacter pylori antigen/ml extraction buffer.

CROSS-REACTIVITY
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, Campylobacter, Shigella, Salmonella as well as yeasts strains and virus.
Leukocytes, whole blood, mucin, stearic and palmitic acid were found not to have any effect if present in stool specimens.

CLINICAL TRIALS
The kit was validated comparing the results obtained with H.pylori Stool Card versus those ones obtained with an ELISA test (Meridian).
Sensitivity and specificity of kit have been determined on 160 stool samples, 60 resulted positive with the ELISA test e 100 resulted negative with the ELISA test. The results are:
sensitivity = 91.66 % (55 samples confirmed positive versus 60 positive with ELISA test);
specificity = 94.00 % (94 samples confirmed negative versus 100 negative with ELISA test);
accuracy = 93.12 %.

X. BIBLIOGRAPHY
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XX. CERTIFICATES

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