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HelicoCheck™

Rapid test for detection of antibodies to *H. pylori* (Device)

INTENDED USE

HelicoCheck™ is a rapid, double antigen sandwich immno-assay for the detection of antibodies to *Helicobacter pylori* in human **whole blood, serum or plasma**.

SUMMARY

Helicobacter pylori (*H. pylori*) is a gram-negative bacterium that has been associated with a variety of gastrointestinal diseases such as chronic gastritis, duodenal and gastric ulcers. *H. pylori* infection occurs when an individual swallows the bacteria in food, fluid from contaminated utensils. The rate of infection increases with age, so it occurs more often in older people. The infection tends to be more common where sanitation is poor or living quarters are cramped. In many cases, the infection does not produce symptoms.

HelicoCheck™, a rapid test for detection of IgG and/or IgM antibodies to *Helicobacter pylori* in human whole blood/ serum/ plasma, helps diagnose the infection in patients with clinical symptoms relating to the gastrointestinal tract and serves as an adjunct to endoscopy.

PRINCIPLE

HelicoCheck™ utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. The conjugate pad is impregnated with two components – recombinant *Helicobacter pylori* antigen conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the *Helicobacter pylori* antigen-colloidal gold conjugate complexes with the *Helicobacter pylori* specific antibodies present in the test specimen and travels on the membrane due to capillary action along with the rabbit globulin - colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is immobilized by recombinant *Helicobacter pylori* antigen coated on the membrane, leading to formation of a pink/purple coloured band. The absence of this band in the test region (T) indicates a negative result. The rabbit globulin- colloidal gold conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region (C) forming a pink / purple coloured band. The control band formation is based on the 'Rabbit / Agglutinating sera for Rabbit globulin' system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signal independent of the analyte concentration. This control band acts as a procedural control and serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

A. Each **HelicoCheck™** kit contains individual pouches each containing a,
   1. DEVICE : Membrane test assembly impregnated with colloidal gold conjugated to recombinant *Helicobacter pylori* antigen (tracer) and rabbit globulin; Recombinant *Helicobacter pylori* antigen (capture) and Agglutinating sera for rabbit globulin at the respective regions.
   2. Desiccant pouch.
   3. PIPETTE : Disposable Plastic Sample Applicator.

B. BUF : Sample running buffer in a dropper bottle.

C. Package Insert.

REF	501070010	501070025
Σ	10T	25T

OPTIONAL MATERIAL REQUIRED

Calibrated micropipette capable of delivering 25µl sample accurately.

STORAGE AND STABILITY

The sealed pouches in the test kit & the kit components may be stored between 4ºC to 30ºC till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE. After first opening of the sample running buffer bottle it can be stored between 4ºC to 30ºC for the remaining duration of its shelflife.

NOTES

1. Read package insert carefully before performing the test.
2. For *In vitro* diagnostic use only. NOT FOR MEDICINAL USE. For professional use only.
3. Do not use beyond expiry date.
4. Do not re-use the device and sample applicator.

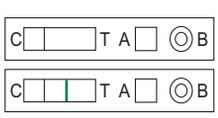
5. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.
6. Handle all specimens as if potentially infectious.
7. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
8. Do not intermix the reagents from different lots.
9. Sample running buffer contains Sodium Azide (0.1%),avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.

SPECIMEN COLLECTION AND PREPARATION

1. **HelicoCheck™** uses human whole blood/serum/plasma as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. For using **whole blood as specimen:** EDTA or Heparin or Oxalate can be used as suitable anti-coagulant.
4. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible, then the specimen may be stored at 2 ºC to 8 ºC for upto 24 hours before testing. Do not freeze the specimen.
5. Refrigerated specimen must be brought to room temperature prior to testing.
6. Clotted, hemolysed, lipaemic or contaminated specimens should not be used for performing the test.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the **HelicoCheck™** kit components to room temperature before testing.
2. Open the pouch by tearing along the "notch" and retrieve the device, sample applicator and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the device and use another device. ***Once opened, the device must be used immediately.***
3. Label the test device with patient's identity.
4. Place the testing device on a flat horizontal surface.
5. Using the sample applicator provided in the pouch, dispense **one drop** of whole blood or serum or plasma in the sample port 'A'. Alternatively, 25µl of whole blood or serum or plasma specimen may be delivered in the sample port 'A' using a micropipette.
6. Add **five drops** of sample running buffer in buffer port 'B'.
7. Read test result at the end of **20 minutes** as follows:

	**Negative Result** The presence of only one pink/purple coloured band in the control region (C) indicates the absence of antibodies to *Helicobacter pylori* in the test specimen.
	**Positive Result** In addition to the band in the control region (C), appearance of pink/purple coloured band in the test region (T), indicates the presence of *Helicobacter pylori* specific IgG and / or IgM antibodies in the test specimen.
	**Invalid Result** The test should be considered invalid if no bands appear on the device after 20 minutes. The test should also be considered invalid if only test band appear and no control band appears. The test should be re- run with a new device as per the test procedure accurately.

PERFORMANCE CHARACTERISTICS

Performance of **HelicoCheck™** was evaluated using panel of 65 samples with commercially available *H. pylori* antibody (IgM & IgG) detection ELISA.

Sample Characteristics	TOTAL	HelicoCheck™	ELISA
No. of sample tested	65	65	65
No. of Positive	25	24	25
No. of Negative	40	38	40

Base on above evaluation:
Sensitivity of **HelicoCheck™** - 96%
Specificity of **HelicoCheck™** - 95%

LIMITATIONS OF THE TEST

1. The deliberate slow reaction kinetics of **HelicoCheck™** is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.
2. Most positive results develop within 20 minutes. However, certain specimen may take a longer time to flow. Therefore, negatives should be confirmed only at 30 minutes. Do not read results after 30 minutes.
3. A positive result suggests the presence of IgG and/or IgM antibodies to *H. pylori* it does not distinguish between active infection and past exposure to *H. pylori* and does not necessarily indicate the presence of gastrointestinal disease.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings of gastritis and/or peptic ulcers have been evaluated.
5. **HelicoCheck™** should be used as a screening test in clinically suspected cases only, and its results should be confirmed by other supplemental method before taking clinical decisions.
6. In children below one year of age maternal IgG antibodies to *H. pylori* may be present.
7. Serological tests may be positive up to three years after eradication of infection.
8. False negative test results may be obtained in immunocompromised, immunosuppressed as well as elderly patients.
9. Antibodies to *H. pylori* titers in serum and severity of *H. pylori* induced gastritis may not always correlated.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. *Helicobacter pylori* Infection and the Development of Gastric Cancer, Naomi Uemura, et. al., The New England Journal of Medicine, Vol. 345, No. 11, September 13, 2001, p: 784-789.
2. Fecal and Oral shedding of *Helicobacter pylori* from Healthy Infected Adults, Julie Parsonnet, et.al., JAMA 1999;282(23):2240-2245.
3. Data on file: Zephyr Biomedicals.

SYMBOL KEYS

Temperature Limitation	Manufacturer	EC REP Authorised Representative in the European Community	DEVICE Device
Use by	Consult Instructions for use	PIPETTE Disposable Plastic Sample Applicator	Xn NaN_R22, S23-46-61 Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
Date of Manufacture	REF Catalogue Number	BUF Sample Running Buffer	
LOT Batch Number / Lot Number	IVD *In vitro* Diagnostic Medical Device	This side up	
Σ Contains sufficient for <n> tests	Do not reuse	Do not use if package is damaged	

Manufactured by:

Zephyr Biomedicals

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EC REP

CMC Medical Devices & Drugs S.L., Spain.

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