NanoEnTek

IVD

BioTracer™ H.pylori Rapid Card

※ Product code : 10412 (30Tests/Kit)

▶ INTENDED PURPOSE

BioTracer™ H.pylori Rapid Card is intended for the detection of antibodies to H. pylori in human serum, plasma or whole blood.

▶ EXPLANATION OF THE TEST

Helicobacter pylori (H.pylori) is a Gram-negative, microaerophilic bacterium found in the stomach. Over 80 percent of individuals infected with the H.pylori are asymptomatic and it has been postulated that it may play an important role in the natural stomach ecology. This bacterium also is etiologically involved in gastric ulcer, duodenal ulcer, gastric adenocarcinoma and primary gastric B-cell lymphoma. The organism is very common, infected at least half of the world's population. H. pylori infection is typically acquired in childhood. Once acquired, infection persists chronically, probably continuing in the stomach throughout life. The damage to gastric structure and function of stomach is constant and direct. Approximately one in six of H. pylori infection develops peptic ulcer disease and a small portion of H. pylori infection leads to gastric cancer. **BioTracer™ H.pylori Rapid Card** is a chromatographic immunoassay kit for rapid qualitative determination for H.pylori infection using human blood specimen. **BioTracer™ H.pylori Rapid Card** is a rapid test for the qualitative detection of antibodies of all isotypes(IgG, IgM, IgA, etc) spectific to H.pylori in human serum, plasma or whole blood.

▶ PRINCIPLE OF THE METHOD

BioTracer™ H.pylori Rapid Card is based on the principle of an immunochromatography in vitro test for the qualitative determination of antibodies to H. pylori in human serum, plasma or whole blood. When the sample and sample diluent are added to the sample pad, they move to the conjugate pad and resuspend the H.pylori antigen conjugated gold complex that is dried on the conjugate pad. The mixtures move along the membrane by capillary action and react with the H.pylori antigen that are immobilized on the test reaction zone. If antibodies against H.pylori are present enough in the sample, a colored band in the test reaction zone will be appeared. If there are no antibodies against H.pylori or not sufficient in the sample, the area will remain colorless. The sample continues to move to the control reaction zone and forms a red or purple color, indicating the test is working properly and the result is valid.

▶ CONTENTS

1. Test device
2. Dropper
3. Package insert

▶ SPECIMEN COLLECTION AND PREPARATION

1. Whole blood specimen collection
   1) Whole blood is collected in syringe or evacuated tube containing the anticoagulant.
   2) Whole blood specimens should be tested immediately after collection. In the case of storing at 2-8℃, it should be tested within 24 hours.
2. Plasma / Serum specimen collection
   1) Plasma or serum specimens should be tested immediately after collection.
   2) Do not leave the specimens at room temperature for prolonged period. Specimens may be stored at 2-8℃ for up to 3 days. For long term storage, specimens should be kept below -20℃.

※ Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

▶ TEST PROCEDURE

Allow the specimens and sealed pouch containing the test devices to room temperature prior to use.

1. Remove the test device from the sealed pouch, and place it on a clean and flat surface.
2. Apply 3 drops (120-150 μL) of serum, plasma or whole blood into the sample well (S) of the test device.
3. Read the test result at 10 minutes. Do not read the test result after 10 minutes.

※ Caution: Perform the test immediately after removing the test device from the foil pouch.

▶ READING AND INTERPRETATION OF RESULT

1. Control (C) band means that the test is working properly.
2. Test (T) band indicates the test result.

NEGATIVE:
The presence of only (C) band indicates a negative result.
POSITIVE:
The presence of Test band (T) with Control (C) band indicates a positive result(refer to back page).

INVALID:
If control (C) band is not appeared in the result window after performing test, the result is considered invalid.

※ The directions may not have been followed correctly or the test device may have been deteriorated. It is recommended that the specimens be re-tested with the new device.

▶ FOLLOW-UP ACTION

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.

▶ READING AND INTERPRETATION OF RESULT

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.

▶ LIMITATIONS OF THE METHOD

A negative result does not preclude the possibility of infection with H.pylori. Other clinically available tests are required if questionable results are obtained.

▶ PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity

The sensitivity for H.pylori was more than 99.9% (30/30). The specificity was 97% (65/67).

		BioTracer™ H.pylori Rapid Card		Total
		Positive	Negative	
ELISA	Positive	30	0	30
	Negative	2	65	67
Total		32	65	97

2. Reproducibility

1) Within run performance test was determined by one analyst with ten times for 3 different positive and 1 negative control specimens. There were no variation within the test devices.
2) Between run performance test was determined by three analyst with 3 different lots for 3 different positive and 1 negative control specimens. There were no variation between different analyst.

3. Interference test

No interference was found with bilirubin (10 mg/dL), hemoglobin (20mg/dL) or triglycerides (600 mg/dL) on the sensitivity and specificity of the **BioTracer™ H.pylori Rapid Card.**

▶ WARNING AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterward.
4. Do not use test kit if the packing is damaged or the seal is broken.
5. Avoid splashing or aerosol formation while handling specimens.
6. Clean up spilled specimens thoroughly using an appropriate disinfectant.
7. Decontaminate and dispose of all specimens, tested kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.

▶ STORAGE AND SHELF LIFE

BioTracer™ H.pylori Rapid Card should be stored at 1~30℃ (34~86°F). The test device is sensitive to humidity as well as to heat. Do not use it beyond the expiration date, 18 months from manufacturing date.

▶ LITERATURE REFERENCE

1. Marshall, B.J. and Warren, J.R. Unidentified curved bacilli in the stomach of patients with gastric and peptic ulceration. Lancer I: 1984: 1311-1314.
2. Graham K.S and Graham D.Y. 1999. Contemporary Diagnosis and Management of H. pylori-Associated Gastrointestinal Diseases, Handbooks in Health Care Co., Newtown, PA., 1999: 39-67.
3. Howden C.W. Clinical expressions of Helicobacter pylori infection. Am J Med; 1996; 100: 27S-33S.

Date issued : 2016.04
61527-16-04-04

Manufactured by
NanoEnTek Inc.
851-14, Seohae-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, 18531, Korea
Tel : +82-2-6220-7942 / Fax : +82-2-6220-7999
ivdst@nanoentek.com
www.nanoentek.com

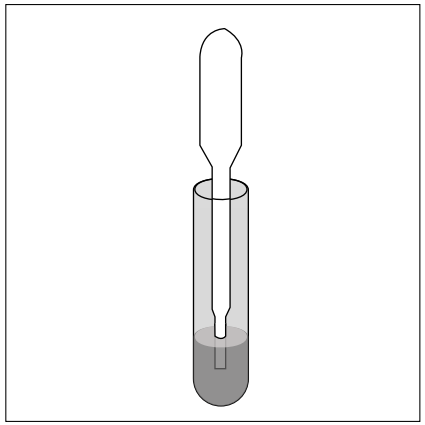
CE

EC REP

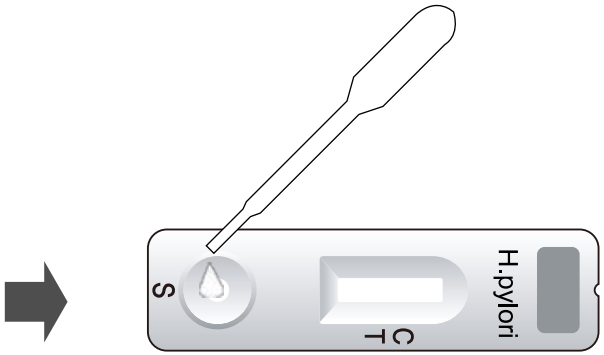
MT Promedt Consulting GmbH
Altenhofstrasse 80, 66386
St. Ingbert, Germany

BioTracer™ H.pylori Rapid Card

▶ TEST PROCEDURE AND INTERPRETATION OF RESULT



1. Take blood using disposable dropper

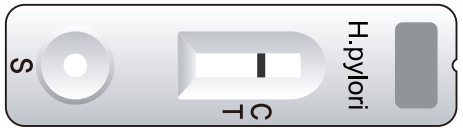


2. Apply 3 drops of human blood specimens to sample well using disposable dropper

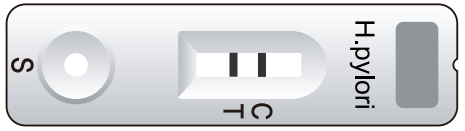
3. Read at 10 minutes

10 min

Negative



Positive



Invalid