SBio *H. pylori* Test

Rapid Test for detection of antibodies to *H.pylori* in human serum or plasma

REF	90507010
Σ	10 T

CE

Temperature Limitation	Manufacturer	PIPETTE — Disposable Plastic Sample Applicator	EC REP — Authorised Representative in the European Community
Use by (Last day of stated month)	Consult Instructions for use	DEVICE — Device	BUF — Assay Buffer
Date of Manufacture	REF — Catalogue Number	Σ — Contains sufficient for <n> tests	Do not reuse
LOT — Batch Number/ Lot Number	IVD — *In vitro* Diagnostic Medical Device	This side up	*H.pylori* - Ab — Rapid test for antibodies to *H.pylori* in human serum

Xn

NaN$_3$ 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.

INTENDED USE

SBio *H. pylori* Test is a rapid, double antigen sandwich immno-assay for the detection of antibodies to *Helicobacter pylori* in human 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.

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

PRINCIPLE

SBio *H. pylori* Test is based on the principle of immunochromatography. An unique two-site immunoassay on a nitrocellulose membrane. The conjugate pad is impregnated with two components – recombinant *Helicobacter pylori* antigen conjugated to colloidal gold and rabbit IgG 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 IgG 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 IgG colloidal gold conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the anti rabbit antisera coated on the membrane at the control region (C) forming a pink / purple coloured band. The control band formation is based on the 'Rabbit / anti-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 SBio *H. pylori* Test 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 IgG; Recombinant *Helicobacter pylori* antigen (capture) and anti rabbit antisera at the respective regions.
   2. Desiccant pouch.
   3. Disposable Sample dispensing droppers.

B. Package insert.

OPTIONAL MATERIAL REQUIRED

Calibrated micropipette capable of delivering 50µl sample accurately.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 4-30ºC till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE.

NOTE

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 dispensing dropper.
5. Handle all specimens as if potentially infectious.
6. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
7. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.

SPECIMEN COLLECTION AND PREPARATION

1. SBio *H. pylori* Test uses human serum/plasma as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved technique.
3. 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 2-8°C for up to 24 hours before testing. Clotted, hemolysed, lipaemic or contaminated serum/plasma should not be used for performing the test.
4. Refrigerated specimen must be brought to room temperature prior to testing.

TESTING PROCEDURE

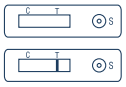
1. Bring the SBio *H. pylori* Test kit components to room temperature before testing.
2. Open the pouch by tearing along the "notch" and retrieve the device, sample dropper and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the device 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. Do not use turbid, lipaemic and hemolysed serum/ plasma.

6. With the help of the sample dispensing dropper provided dispense **Two drops (50µl)** of serum or plasma in the sample port (S). Alternatively, 50µl of serum or plasma specimen may be delivered in the sample port (S) using a micropipette.
7. Read test result at the end of **15 minutes** as follows:

INTERPRETATION OF RESULTS

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 15 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 SBio *H. pylori* Test was evaluated using panel of 65 samples with commercially available *H. Pylori* antibody (IgM & IgG) detection ELISA.

Sample Characteristics	TOTAL	SBio *H. pylori* Test	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 SBio *H. pylori* Test- 92.3%
Specificity of SBio *H. pylori* Test - 90.5%

LIMITATIONS OF THE TEST

1. The deliberate slow reaction kinetics of SBio *H. pylori* Test is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.
2. Most positive results develop within 15 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. SBio *H. pylori* Test 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.

BIBLIOGRAPHY

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