H. pylori Saliva Test

One-Step Test for Determination of
H. pylori bacteria in Human Saliva

Instruction Manual
Catalog No. 41121

For In Vitro Diagnostic Use
For professional use only

Store at 2 -30°C. **Do Not Freeze**

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Intended Use
The *H. pylori* saliva test is a one step immunochromatographic assay for the rapid detection of *H.pylori* antigen in human saliva.

For in vitro diagnostics use only.

Introduction

Physicians currently diagnose *H. pylori* infections with endoscopy, blood tests and breath tests. Endoscopy, the gold standard is invasive, expensive and can miss *H. pylori* infections if a biopsy sample from one part of the stomach does not contain the bacteria. Blood tests detect antibodies to *H. pylori*, but these antibodies can persist for up to a year after the bacteria are eradicated, making it impossible for physicians using blood tests to quickly determine if a patient's treatment succeeded. Breath tests capitalize on the fact that *H. pylori* contains abundant urease and can rapidly metabolized urea, releasing CO_2 and NH_3. To perform the test, physicians have their patient swallow a capsule full of urea labeled with the radioactive isotope C^{13}. If the patient has an *H. pylori* infection, the bacteria will metabolize the urea and soon the patient's expired CO_2 will have a higher than normal concentration of the radioactive carbon isotope. To collect the labeled CO_2, the patient breathes into a mylar balloon.
The laboratory can quantitate the number of C^{13} counts with a liquid scintillation counter. Breath tests have their disadvantages in that the equipment is very expensive and not available in some cities as well as can miss *H. Pylori* in oral cavity and esophagus.

The *H. pylori* saliva test is an immunochromatographic assay, which utilizes unique antibodies to selectively identify *H. pylori* in saliva for oral infection.

Materials Provided

The *H. pylori* saliva test kit contains the following items to perform the assay;
1. *H. pylori* saliva test device.
2. Running buffer in a dropper bottle
3. Instructions for use.

PRECAUTIONS
The *H. pylori* saliva test devices should be stored at room temperature 2-30ºC. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it after the expiration date.

WARNINGS

1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Do not use the test kit if the pouch is damaged or the seal is broken.

Assay Procedure

No food or drink should be taken at least one hour prior to performing the test.

1. Remove the test device from the foil pouch.
2. Remove the plastic cover from the stick
3. Hold the stick in the patient's mouth for 2 minutes- (can be held on or under the tongue).
4. Remove the test stick from mouth, and add two to three drops of buffer solution on the stick.
5. As the test kit begins to work, the purple color will move across the Result Window in the center of the test disk.
6. Interpret test results at 5 to 15 minutes. Do not interpret test result after 20 minutes.

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30ºC. If your room temperature is significantly lower than 15ºC, then the interpretation time should be increased by 5 min.

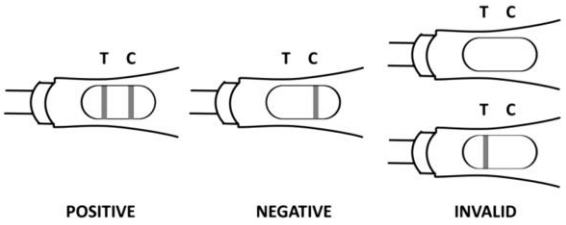
Interpretation of the test

POSITIVE RESULT: The presence of two color lines, Test line ("T") and Control "C" line within the result window regardless of which band appears first indicates a positive result. Note: Generally, the higher the analyte level in the specimen, the stronger the "T" band color will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the "T" band will be very faint.

NEGATIVE RESULT: The presence of "C" line only within the Result Window indicates a negative result.

INVALID RESULT: the absence of "C" line within the result window indicates an invalid result. The

directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested



Note 1: please make sure that the device is positioned according to the drawing

Note 2: A positive result will not change once you have established your answer at 20 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 20 minutes.

Limitation of the test

The test is limited to the detection of Urease with *H. Pylori* infections in saliva. Although the test is very accurate in detecting urease, a low incidence of false results can occur. Other clinically available tests are required if negative or questionable results are obtained. 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.

Performance Characteristics

Sensitivity and specificity

The ***H. pylori Saliva Test*** has been evaluated in symptomatic patients. Urea Breath Test (UBT) was used as the reference method. Specimens were considered positive if the UBT indicated a positive result. Specimens were considered negative if UBT indicated a negative result. The results show that the ***H. pylori Saliva Test*** has a high sensitivity and specificity relative to UBT results.

H. pylori Saliva Test	**UBT**		
	Positive	Negative	Total
POSITIVE	**19**	**2**	**21**
NEGATIVE	**0**	**39**	**39**
TOTAL	**19**	**41**	**60**

Sensitivity: 19/19 = 100%
Specificity: 39/41 = 95%
Accuracy: 58/60 = 96%

Interference

An in-house study was conducted with 3 separate lots of the *H. pylori* saliva Test to determine the Specificity of the test. Compounds tested include: Serum with triglyceride concentrations up to 500 mg/ml, Serum with Bilirubin concentrations up to 10 mg/100ml, Hemolyzed specimens with hemoglobin concentrations up to 10 mg/ml, Prostatic acid phosphatase with concentrations up to 1000 mIU/ml and Albumin with concentrations up to 20 mg/ml. All of the above were analyzed and did not show interference or cross reactivity with the test.

CE

EC REP

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	Temperature Limitation
	Consult instructions for use
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
EC REP	Authorized European Representative

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