H. Pylori Saliva Antigen for Self Testing

Revised (6-5-2019)

IVD	In vitro diagnostic device
REF	R102-114 HPS
	Read instruction before use

INTENDED USE

The one step H. Pylori-Saliva (HPS) test is a simple one step immunochromatographic assay for the rapid, qualitative detection of Urease released by H. Pylori in saliva.

EXPLANATION OF THE TEST

Physicians currently diagnose H. Pylori infections with endoscopy, blood tests and C^{13} or C^{14} 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 C14. 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 be quantitative the number of C14 counts with a liquid scintillation counter. Breath tests have their disadvantages in that can miss H. Pylori in oral cavity and esophagus.

The one step HPS test is an immunochromatographic assay, which utilizes a unique antibodies to selectively identify H. Pylori Urease in saliva.

MATERIALS PROVIDED

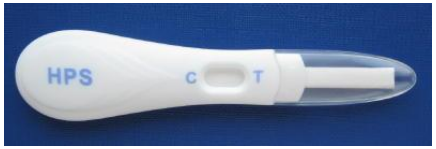
The HPS test kit contains the following items to perform the assay;
1. HPS test stick.
2. Buffer and drop
3. Instructions for use.

PRECAUTIONS

The One Step HPS test devices should be stored at room temperature 4-30°C (40-86°F). 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 beyond the expiration date.

WARNINGS

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 afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.
8. Biotin can interfere and cause incorrect test results for subjects who have elevated levels of biotin in their specimen.



PROCEDURE OF THE TEST

No food or drink should be taken at least one hour prior run the test.
1. Remove the test stick from the foil pouch.
2. Holding the test stick in mouth for 2 minutes.
3. After removed stick from mouth, then add 2 to 3 drops of buffer solution on stick.
4. As the test kit begins to work, you will see purple color move across the Result Window in the center of the test disk.
5. Interpret test results at 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 30 °C. If your room temperature is significantly lower than 15 °C, then the interpretation time should be properly increased.

INTERPRETATION OF THE TEST

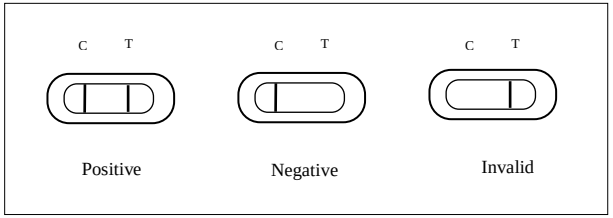
1. As the test kit begins to work, a color band will appear in the control section of the Result Window to show that the test is working properly. This band is the Control Band (C).
2. The right section of the result window indicates the test results. If another color band appears in the test section of the Result Window, this band is the Test Band (T).

POSITIVE RESULT: The presence of two color bands ("T" band and "C" band) 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. Note: any faint "T" band should be considered a positive result as indicated in the color chart.

NEGATIVE RESULT: The presence of only one purple color band within the Result Window indicates a negative result.

INVALID RESULT: If after performing the test no band is visible within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested

Note: A positive result will not change once you have established your answer at 15 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 20 minutes.



LIMITATIONS 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
Analytical Sensitivity/ Limit of Detection

The One Step H. Pylori-Saliva Test showed high sensitivity for H. Pylori infection included stomach and oral cavity, sensitivity is at 96% with H. Pylori Blood antibody test.

SPECIFICITY

An in-house study is conducted with 3 separate lots of the One Step H. Pylori Saliva Test to determine the Specificity of One Step H. Pylori Saliva test. Other organisms commonly found in the Oral flora are tested for interference test. Potentially interfering organism such as Staphylococcus epidermidis (ATCC # 9491 at 1x 105 CFU/ml), Lactobacillus (ATCC # 314 at 1x 105 CFU/ml), Enterococcus faecalis (ATCC # 828 at 1 x 105 CFU/ml) and Streptococcus salivarius (ATCC # 7073 at 1 x 105 CFU/ml) were supplemented to negative specimen and specimens spiked with ATCC H. Pylori #43504 at 1.0 x 103 CFU/ml (cutoff sensitivity for Ameritek H. Pylori Test). These samples were tested using the Ameritek H. Pylori test by a replicate of 10. A sample was classified negative, when no purple color band was visible for the H. Pylori test line but the purple color "C" control line being visible within 20 minutes. A sample was classified positive, when both the control and test line were visible within 20 minutes. All of the above were analyzed and did not show interference or cross reactivity with the test.

SENSITIVITY

By lab study shows the sensitivity level of HPS is 10 ng/ml of Urease by a replicated of 50.

REFERENCES

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