VITASSAY

H. pylori

Rapid test for the qualitative detection of Helicobacter pylori in human stool samples.

IUE-7355020 Ed00 May 2016

CE IVD EN

Vitassay

For professional *in vitro* diagnostic use only.

INTENDED USE

Vitassay H. pylori is a rapid one step immunochromatographic assay for the qualitative detection of Helicobacter pylori (H. pylori) in human stool samples.

Simple, non-invasive and a highly sensitive screening assay to make a presumptive diagnosis of Helicobacter pylori infection.

INTRODUCTION

Helicobacter pylori is a spiral shaped pathogenic bacterium found on the human gastric mucosa.

Infection is generally asymptomatic, with the majority of those persons infected not developing clinical disease. However, because H. pylori has been recognized as a major cause of gastritis and is associated with duodenal ulcer disease, gastric ulcer disease, gastric lymphoma, and gastric cancer in humans, it is a public health problem in both developed and developing countries.

PRINCIPLE

Vitassay H. pylori is a qualitative immunochromatographic assay to make a presumptive diagnosis of Helicobacter pylori infection in human stool samples.

The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against Helicobacter pylori.

During the process, the sample reacts with the antibodies against H. pylori, forming conjugates. The mixture moves upward on the membrane by capillary action. If the sample is positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible. Although the sample is positive or negative, the mixture continues to move across the membranes and the green control line always appears.

The presence of this green line (in the control zone (C)) indicates that sufficient volume is added; proper flow is obtained and serves as an internal control for the reagents.

PRECAUTIONS

- For professional *in vitro* use only.
- Do not use after expiration date.
- Do not use the test if its pouch is damaged.
- Specimens should be considered as potentially hazardous and handle in the same manner as an infectious agent. A new test must be used for each sample to avoid contaminations errors. Single use device.
- Tests should be discarded in a proper biohazard container after testing.
- Reagents contain preservatives. Avoid any contact with the skin or mucous membrane. Consult safety data sheet, available on request.
- Components provided in the kit are approved for use with the **Vitassay H. pylori**. Do not use any other commercial kit component.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, goggles and mask. Do not eat, drink or smoke in the working area.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/35.6-86ºF).

The test is stable until the expiration date printed on the sealed pouch.

The test must remain in the sealed pouch until use.

Do not freeze.

MATERIALS

MATERIAL PROVIDED	MATERIAL REQUIRED BUT NOT PROVIDED
▪ **25** tests/kit **Vitassay H. pylori** ▪ Instructions for use. ▪ **25** vials with diluent for the sample dilution.	▪ Specimen collection container. ▪ Disposable gloves. ▪ Timer.

SPECIMEN COLLECTION

Collet sufficient quantity of feces: 1-2g or mL for liquid samples. Stool samples should be collected in clean and dry containers.

Samples can be stored in the refrigerator (2-8ºC/36-46.4ºF) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at -20ºC (-4ºF). Samples must be brought to room temperature before testing.

SPECIMEN PREPARATION

1. Remove the cap of the vial with diluent for the sample dilution (figure 1).
2. Use the stick to collect sufficient sample quantity. For solid stool, insert the stick in 4 different areas of the stool sample, taken approx. 125mg, (figure 2), and add it into the vial with diluent for the sample dilution. For liquid stool, take 125µL of the sample using a micropipette and transfer it into the vial with diluent for the sample dilution.

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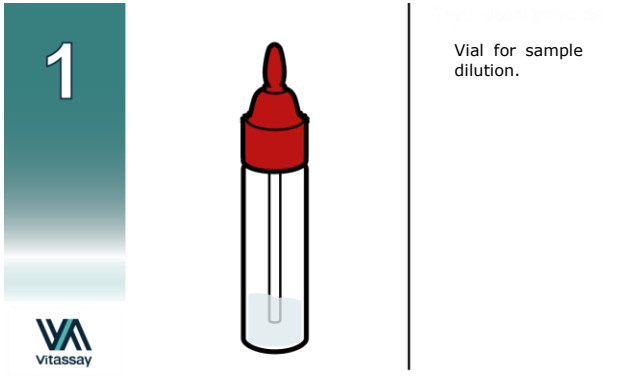
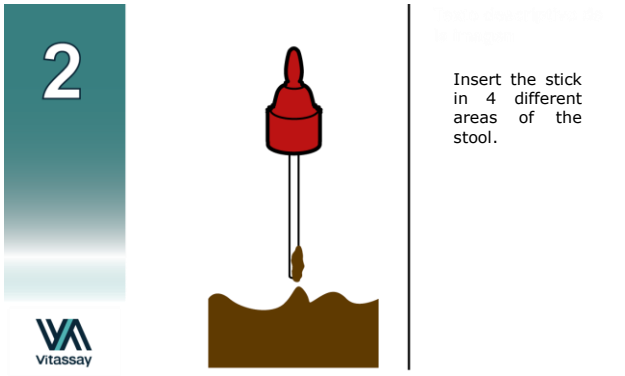
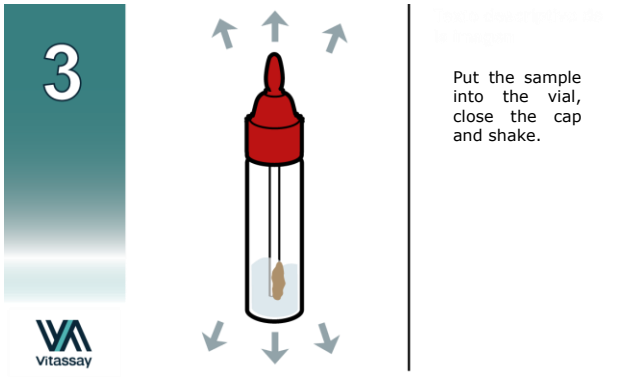
3. Close the vial with the diluent and stool sample. Shake vigorously the vial in order to assure good sample dispersion (figure 3).



Vial for sample dilution.



Insert the stick in 4 different areas of the stool.



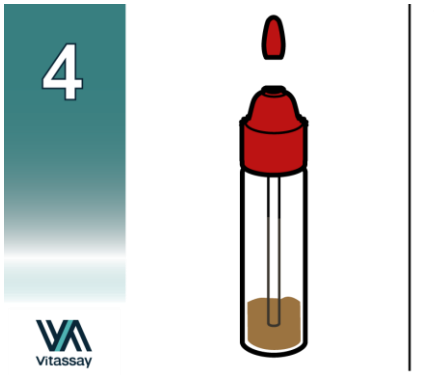
Put the sample into the vial, close the cap and shake.

PROCEDURE

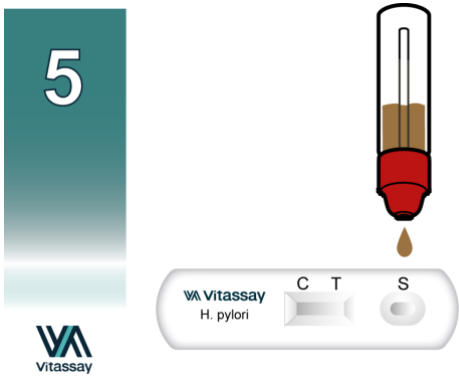
Allow the test, stool sample, controls and diluent to reach room temperature (15-30ºC / 59-86ºF) prior to testing. Do not open pouches until the performance of the assay.

1. Shake the vial with the sample to obtain a good sample dilution.
2. Remove the **Vitassay H. pylori** from its sealed bag just before using it.
3. Take the vial containing the diluted sample, cut the end of the cap (figure 4) and dispense 4 drops in the circular window marked with the letter S (figure 5).
4. Read the results at **10 minutes**. Do not read the results later than 10 minutes.

If the test does not run due to solid particles, stir the sample added in the sample window with the stick. If it does not work, dispense a drop of diluent until seeing the liquid running through the reaction zone.



Cut the end of the cap.



Dispense 4 drops in the circular window marked with the letter S

INTERPRETATION OF THE RESULTS

C T	**NEGATIVE** Only one **green** line in the control zone **(C).**	There is no Helicobacter pylori presence. No infection caused by Helicobacter pylori.
C T	**POSITIVE** In addition to the **green** line (**control line C**), a **red** line appears (**test line T**).	There is presence of Helicobacter pylori. Helicobacter pylori infection, which might mean gastrointestinal diseases (stomach and duodenum) like gastritis, peptic ulcer or gastric carcinoma.
ANY OTHER RESULTS		Invalid result, we recommend repeating the assay using the sample with another test. **Note**: Wrong procedural techniques or deterioration of the reagents are mostly the main reasons for control line failure. If the symptoms or situation persist, discontinue using the test kit and contact your local distributor.

Notes: The intensity of the red colored test line in the result line zone (T) will vary depending on the concentration of antigens in the specimen.

QUALITY CONTROL

Internal procedural control is included in **Vitassay H. pylori**. Green line appearing in the results window is an internal control, which confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

- **Vitassay H. pylori** must be carried out within 2 hours of opening the sealed bag.
- An excess of stool sample could cause wrong results (brown bands appear). Dilute the sample with the diluent and repeat the test.
- The intensity of test line may vary depending on the concentration of antigens.
- The use of other samples different from human samples has not been established.
- The quality of **Vitassay H. pylori** depends on the quality of the sample; Proper fecal specimens must be obtained.
- Positive results determine the presence of Helicobacter pylori in fecal samples. A positive result should be followed up with additional invasive techniques (endoscopy) to confirm the results. A confirmed infection should only be made by a physician after all clinical and laboratory findings have been

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evaluated and must be based in the correlation of the results with further clinical observations.

- Negative results should not be considered as conclusive; it is possible that the concentration of antigens is lower than the detection limit. If symptoms or situation still persist, a Helicobacter pylori determination should be carried out, on a sample from an enrichment culture or using an invasive technique.

EXPECTED VALUES

Helicobacter pylori is a common bacterium, and approximately 50 percent of the world's population has been estimated to be infected. Rates appear to be higher in developing than in developed countries, with most of the infections occurring during childhood.

The overall prevalence of H. pylori infection is strongly correlated with socioeconomic conditions. The prevalence among middle-aged adults is over 80 percent in many developing countries, as compared with 20 to 50 percent in industrialized countries.

PERFORMANCE CHARACTERISTICS

Clinical sensitivity and specificity

An evaluation was performed comparing **Vitassay H. pylori** and another commercial ELISA test (Amplififed IDEIA™ Hp StAR™, Oxoid).

Results were as follows:

		Amplified IDEIA™ Hp StAR™		
		Positive	Negative	Total
Vitassay H. pylori	Positive	35	0	35
	Negative	2	10	12
	Total	37	10	47

Vitassay H. pylori vs Amplified IDEIA™ Hp StAR™			
Sensitivity	Specificity	PPV	NPV
>94%	>99%	>99%	>84%

The results showed that **Vitassay H. pylori** has a high sensitivity and specificity to detect Helicobacter pylori.

Cross reactivity

No cross reactivity was detected against gastrointestinal pathogens that are occasionally present in feces:

Campylobacter coli	*Salmonella enteritidis*	*Shigella dysenteriae*
Campylobacter jejuni	*Salmonella paratyphi*	*Shigella flexneri*
Clostridium difficile	*Salmonella typhi*	*Shigella sonnei*
E. coli O157:H7	*Salmonella typhimurium*	*Staphylococcus aureus*
Listeria monocytogenes	*Shigella boydii*	*Yersinia enterocolitica*

REFERENCES

1. LINDA MORRIS BROWN. "Helicobacter pylori: Epidemiology and Routes of Transmission". Epidemiologic reviews, Vol. 22, No. 2, 2000, pp. 283-297.

2. SEBASTIAN SUERBAUM, M.D., and PIERRE MICHETTI, M.D. "Helicobacter pylori Infection". N Engl J Med, Vol. 347, No. 15, Oct. 2002, pp. 1175-1186.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

IVD	*in vitro* diagnostic device		Keep dry
	Consult instructions for use		Temperature limitation
	Use by		Manufacturer
LOT	Batch code	Σ n	Contains sufficient for <n> test
DIL	Sample diluent	REF	Catalogue number

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