PHARMA *SOUTHERN AFRICA*

PYLORI-SCREEN ®

Ref. 17084/ZA

Self Diagnostic Test for the detection of antibodies against Helicobacter Pylori

GENERAL POINTS

The presence of highly pathogen strains of *Helicobacter pylori* (HP) colonizing the epithelium surface of the stomach or intestine can induce chronic gastritis that could lead to ulcer and/or cancer. Currently, 90% of the patients suffering of gastric ulcers are infected with bacteria HP. Therefore, it is important to spot the bacteria in order to easily eliminate it using specific antibiotic drugs. The detection of circulating antibodies directed against the bacteria is the most efficient way to diagnose its presence as antibodies are produced by the immune system during the infection process. A positive result can be obtained for patients previously infected with the bacteria HP. PYLORI-SCREEN® is a highly specific immuno- logical rapid test easy to use for the detection of anti-HP antibodies with a finger prick of whole blood sample.

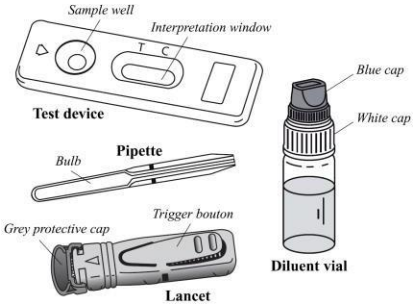
PRESENTATION

The box contains all the material necessary to perform a test:

- **1 sealed aluminium pouch** containing:
  1 test device, 1 plastic pipette, 1 desiccant bag.

Only open the protective pouch when you are ready to perform the test. The desiccant bag should not be used.

- **1 dropper bottle containing 1 mL of diluent.**
- **1 sterile lancet for blood sampling.**
- **1 instruction leaflet.**



Not provided necessary material: absorbent cotton and alcohol 70 % vol. or alcohol pad.

PRECAUTIONS

1. This test is exclusively intended for *in vitro* diagnostic. For external use only. DO NOT SWALLOW.
2. Carefully read the instructions before performing the test. **The test is only reliable if the instructions are carefully respected. Follow strictly the indicated time, blood and diluent quantities.**
3. Store between +4°C and +30°C. Do not freeze.
4. Do not use after the expiry date indicated on the label and the pouch. Do not use the test if the protective aluminium pouch is damaged.
5. Do not re-use PYLORI-SCREEN®.
6. **Keep out of the reach of children.**
7. After use, all components can be discarded in a dustbin.

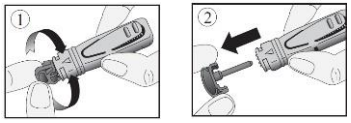
PROCEDURE

Testing procedure always starts with a good preparation. Place the content of the box on a clean, dry and flat surface (e.g. table). Then the testing follows:

1. Wash your hands thoroughly. Use soap and warm water. Dry your hand with clean towel.

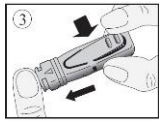
2. Prepare the test device and the pipette. Take them out from the protective pouch (tear at the notch) and place them in the reach of your hands (you will need them later). Discard the desiccant bag.

3. **Prepare the lancet.** Hold the lancet **without touching the trigger button.** Unlock the lancet cap twisting it off ¼ turn until you feel it separates from the lancet and then continue twisting it (2-3 rotations). **Don't pull just twist** and discard the cap when finished ① & ②.

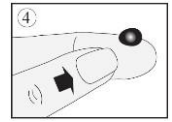


4. Clean the end of the middle finger or ring finger with cotton damped with alcohol.
Rub the chosen finger towards the tip for 10 to 15 seconds to enhance the blood flow.

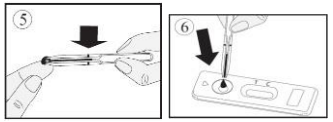
5. **Press platform firmly against the lateral side of the previously cleaned finger, and press the release trigger button**③.



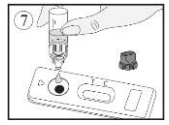
6. The tip will automatically retract into the body of the device.
7. Rub the finger's end to obtain enough whole blood sample.④.



8. Without pressing the bulb, put in contact the plastic pipette with the blood sample⑤. The blood migrates into the pipette through capillarity **to the line indicated on the pipette**. You may rub again your finger to obtain more blood if the line is not reached. As far as possible, avoid air bubbles.
9. Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb⑥.



10. Wait 30-40 sec for the blood being totally absorbed into the sample well. **Unscrew the blue cap** of the diluent dropper bottle (leave the white cap tightly screwed) and add the diluent as follows:
Hold the diluent dropper bottle vertically and slowly add exactly 4 drops in the sample well of the device⑦ with an interval of 2-3 seconds between each drop.



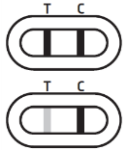
11. Read the result after10 minutes. Do not interpret after 15 minutes.

RESULTS INTERPRETATION

The intensity and the colour of the lines do not have any importance for the interpretation of the test results.

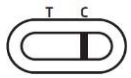
1. Positive result

Two coloured lines appear in the window under the marks T (Test) and C (Control). The colour intensity of the T line may be clearer than the intensity of the C line. This result means that blood sample contains anti-HP antibodies and **that you should consult a doctor.**



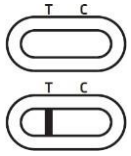
2. Negative result

Only one coloured line appears under the mark C (Control). This result means that no anti-HP antibodies are detected in the blood sample.



3. Invalid result

No line appears or a coloured line appears under the mark T (Test) without any line under the mark C. In this case, it is not possible to interpret the test, which must be considered as invalid. It is recommended to repeat the test with another PYLORI-SCREEN® and new blood sample.



QUESTIONS AND ANSWERS

How does PYLORI-SCREEN® work?
When present in gastric epithelium, HP bacteria induce the production of specific antibodies by the immune system. These circulating antibodies are able to recognize the bacteria and to stick on them. The PYLORI-SCREEN® allows the detection of these anti-HP antibodies thanks to specific biologicals and therefore shows the bacteria presence. When present in your blood at a detectable concentration level, anti-HP antibodies are detected by producing one coloured test line in the interpretation window of the cassette. A control line appears under the C mark of the cassette showing that the test was performing well.

When should the test be performed?
PYLORI-SCREEN® should be performed in condition of repeated stomach or intestine pains (stomach ache, acidic reflux…). The test can be performed at any time of the day.

Can the results be incorrect?
The results are accurate as long as the instructions are carefully respected. Nevertheless, the result can be incorrect if PYLORI-SCREEN® gets wet before test performing or if the quantity of blood added to the sample well is not correct. The pipette provided in the box makes sure the collected whole blood volume is correct.

How to interpret the test if the colour and the intensity of the lines are different?
The colour and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and complete. The test should be considered as positive regardless of the colour intensity of the test line (T), even weak.

What is the line that appears under the mark C (Control) for?
When this line appears, it only means that the test has been performed well.

If I read the result after 15 minutes, will the result be reliable?
No. The test should be read within 10 minutes after adding the diluent. The result is reliable up to 15 minutes.

What do I have to do if the result is positive?
If the result is positive, it means that anti-HP antibodies are present in blood and that you should consult a doctor to show him the test results. Then, the doctor will decide whether additional investigation should be performed as the anti-HP antibodies could be due to previous infection already cured.

What do I have to do if the result is negative?
If the result is negative, it means that the test could not detect anti-HP antibodies in blood sample. Meanwhile it is recommended to consult a doctor if stomach ache or gastric reflux persists.

What is the accuracy of PYLORI-SCREEN®?
The PYLORI-SCREEN® is accurate and has been used for more than 10 years by professionals in the field. Evaluation reports show an overall agreement higher than 93.48% [85.74 – 97.72**] with reference methods. Although this test is reliable, false positive or false negative results could be obtained.
***** IC 95%: 95 % Confidence Interval.***

Information on *Helicobacter pylori*
https://www.has-sante.fr/jcms/c_2775406/fr/infection-par-helicobacter-pylori-chez-l-adulte-la-has-precise-les-actes-de-diagnostic-et-les-modalites-de-traitement

https://www.science.org.au/learning/general-audience/history/interviews-australian-scientists/professor-barry-marshall/teacher

https://www.mayoclinic.org/diseases-conditions/h-pylori/symptoms-causes/syc-20356171

Sterile lancet: STERILE R CE 1639

Owen Mumford Ltd
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EC REP GERMANY
Owen Mumford GmbH, Alte Häge 1, 63762 Großostheim, Germany

	Read the instructions before use	IVD	For *in vitro* diagnostic use		Do not reuse
	Store between +4°C and +30°C	LOT	Batch number		Expiration date
	Manufacturer	EC REP	Authorized EU representative		

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CHANGES DESCRIPTION
Changes type :

- N/A Not Applicable (creation)
- Technical change Addition, revision and/or removal of information related to the product.
- Administrative Implementation of non-technical changes noticeable to the end-user.

Changes type	Changes description
N/A	Creation

Note: Minor typographical, grammar, spelling and formatting changes are not reported in the change details.

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