QUESTIONS AND ANSWERS

- How does UlcerScreen™ work?

  The presence of the bacteria H.pylori is in the gastric epithelium causes specific antibodies to be produced by your immune system. UlcerScreen™ specifically detects these antibodies to H.pylori in your blood and shows that you have, or have recently had, an infection with this bacteria.

- When should the test be used?

  The UlcerScreen™ test should be performed if you have repeated stomach or intestinal pains (stomach ache, acidic, reflux etc.). The test can be performed at anytime of the day.

- Is the test result correct?

  UlcerScreen™ has been validated against laboratory tests and is accurate provided the instructions are followed carefully. Please note however that the test result can be adversely affected if the cassette gets wet before the test is performed or if insufficient blood is used. It is important to ensure that the correct volume of blood is collected, as indicated by the black line marked on the pipette. If used correctly studies have shown UlcerScreen™ has an accuracy of over 90% compared to reference methods.

- How to interpret the test if the colour and intensity of the lines are different?

  The colour and intensity of the test lines are of no importance in the interpretation of the result. The lines only need to be uniform and clearly visible and a line of any colour intensity by the 'Test' mark should be regarded as positive.

- If I read the result after 15 minutes, will the result still be valid?

  No, the result should be read within 10 minutes of adding the test diluent and is reliable only up to 15 minutes.

- What should I do if the test result is positive?

  UlcerScreen™ is a screening device for antibodies to H. pylori and a positive test result indicates that you have, or recently had an infection with H. pylori. We would recommend that you should seek medical advice from your doctor who will take into account any symptoms of the condition that you may have before making a definitive diagnosis.

- What should I do if the test result is negative?

  A negative test result indicates that H. pylori antibodies could not be detected in your blood. However, as no test is 100% effective we would recommend that you consult your doctor if you have worrying symptoms.

REF	PD 52091	Σ 1	Sufficient for 1 test
CE	0483		Storage temperature +4 to +30°C
	Read the instructions before use		Do not re-use
	Caution in handling	STERILE	Sterile (Lancet)
IVD	In vitro diagnostic test		Expiry date of test
LOT	Batch number		Manufacturer

personal diagnostics™

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UlcerScreen™

Home test for Peptic ulcers

ABOUT THIS TEST

UlcerScreen™ is a self-testing device to detect the IgG antibodies to H.pylori associated with peptic ulcers.

Peptic ulcers can occur in the stomach and intestine, and in up to 90% of cases are due to an infection by the bacteria Helicobacter pylori (H. pylori).

The infection causes inflammation and acid erosion of the lining of the stomach to form ulcers, which can result in anaemia and other serious side effects if untreated. UlcerScreen™ detects the IgG antibodies to H.pylori that result from the infection and indicate the presence of stomach and/or duodenal ulcers currently or in the recent past.

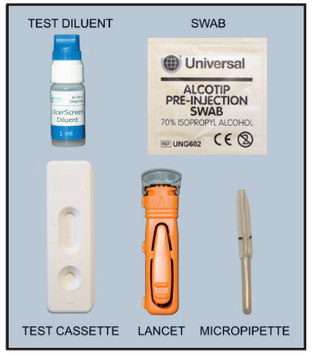
The most common symptom of peptic ulcers is abdominal discomfort. A dull or burning pain occurring mainly between meals or during the night is common. The pain may be briefly relieved by eating food or by taking antacids, and it lasts for periods of minutes to hours and comes and goes for several days or weeks. Other symptoms can include weight loss, poor appetite, bloating and burping and nausea.

An infection with H.pylori can usually be easily treated with specific antibioticsso if you have these symptoms UlcerScreen™ can help in identifying their cause quickly.

KIT CONTENTS

- 1x sealed foil pouch containing;
  - 1x test cassette
  - 1x micropipette
  - 1x desiccant bag (discard after opening)
- 1x dropper bottle containing 1ml of test diluent
- 1x sterile single use lancet for blood sampling
  (Dir.93/43/EEC CE0120 Owen Mumford Ltd, Brook Hill, Woodstock, Oxforshire OX020 1TU, UK)
- 1x Alcohol swab 70% Isopropyl Alcohol
  (Dir. 93/42/EEC - Class I. Bunzl Healthcare Supplies, 6 Delta park Industrial Estate,Enfield EN3 7QJ, UK)
- 1x Instruction sheet

  Please note you will also need a watch with a second hand, clean paper tissues and a plaster (optional)



PRECAUTIONS

Important – Read these test instructions carefully before use

1. Always read the instructions carefully before performing the test as it is only possible to interpret the results if the procedure is carried out exactly as instructed.
2. Keep out of the reach of children.
3. FOR EXTERNAL USE ONLY. DO NOT SWALLOW. Use only as an in vitro diagnostic device for self-testing purposes.
4. Do not use this test if you suffer from a blood clotting disease or are being treated with the anticoagulant heparin.
5. If blood comes in contact with any surfaces, wipe clean with disinfectant.
6. DO NOT RE-USE. This is a single use test.
7. Do not use after the expiry date printed on the box label and on the foil pouch, or if the pouch is damaged.
8. Store between +4°C and +30°C. Do not freeze.
9. DISPOSAL. After use place the test cassette, used lancet, micropipette, buffer bottle and swab inside the foil pouch, replace in box and dispose of with your normal household waste.

PREPARATION

- Open the foil pouch and remove the test cassette. The desiccant bag is not required and can be discarded with the pouch.

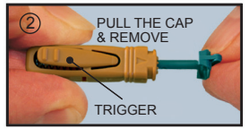
  Familiarise yourself with the components of the test.
- Ensure you have a hard flat surface available on which to lay the cassette and perform the test.
- Read the instructions thoroughly before taking the test.
- You will also need to have a watch with a second hand ready and a clean paper tissue.
- When ready to start the test wash your hands with soap in warm water to soften the skin and encourage blood flow in your fingers. Rinse thoroughly and dry.

TEST PROCEDURE

1 Collect the blood sample

- Hold the lancet by its sides.
  Grip the grey cap and twist ①.

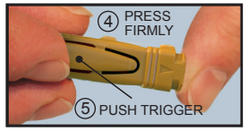
- Twist off the grey lancet cap until you feel it separate from the device. Pull gently to remove ②.
- Caution: The lancet is single use only so be careful not press the lancet trigger button ② until you are ready to use it.



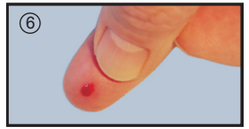
- Choose a site on the finger as indicated by the shaded areas of the picture ③. Avoid areas of hard skin.
- Clean the site with the alcohol swab provided in the kit.
- Allow the site to dry thoroughly.

- Press the end of the lancet firmly against the cleaned site on your finger ④.

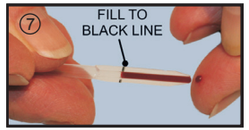
  Press the trigger button ⑤.



- A small drop of blood will appear. Massage the finger towards the tip to encourage the blood to flow and a drop to form ⑥.

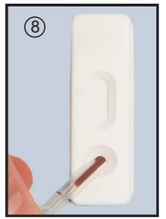


- Touch the end of the micropipette against the blood drop ⑦. Do not squeeze the bulb of the pipette as the blood will be drawn into the pipette automatically.
- Quickly continue to massage the finger to give the next drop of blood and draw the blood into the pipette in quick succession until it reaches the black line on the pipette ⑦.

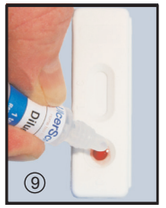


- Note: If the blood flow stops during collection let your arm hang loosely at your side for a short time and then massage your finger again. This usually restarts the blood flow.

2 Testing the sample

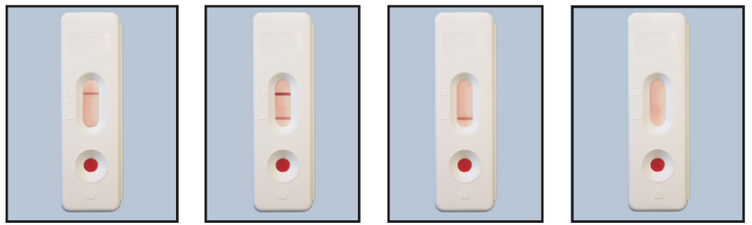


- Quickly drop the blood from the pipette into the round well on the cassette labelled with an arrow ⑧ by squeezing the bulb at the end of the pipette.
- Ensure all of the blood in the pipette is removed and if necessary also squeeze the tube of the pipette.
- Add 4-5 drops of test diluent into the sample well from the dropper bottle ⑨.
- Make a note of the time and wait 10 minutes exactly.
- You will start to see the blood sample/diluent mix migrate up the test cassette. Do not move the cassette until the test time has completed.
- At the end of the 10 minutes check for the presence of a line in the cassette window near to the control (C) mark and a possible second line near to the test (T) mark.
- Do not read the result after 15 minutes.



3 Reading the results

- Negative: One pink coloured line appears in the window near to the control (C) mark. This means the test is negative.
- Positive: Two pink coloured lines appear; one near the control (C) mark and the second near the test (T) mark positive.
- Failed test: A pink coloured line should always appear near the control (C) mark. If there is no pink coloured line near this mark the test is invalid even if a line appears near the test (T) mark.



Negative Positive Invalid Invalid

Please note: In addition to the pink line by the control (C) mark, ANY pink line seen near the test (T) mark of the cassette at the 10 minute time is considered POSITIVE.
The intensity of the line does not matter.