H. pylori IgG Home Rapid Test

Cat. No.:DTS615
Pkg.Size:10T

Intended use

Helicobacter pylori is a one-step immunochromatographic test for the rapid and convenient screening of Helicobacter pylori antibodies in serum or whole blood for serodiagnosis of Helicobacter pylori associated gastroduodenal diseases.

General Description

Warren and Marshall isolated in 1983 Helicobacter pylori from a sample of gastric epithelium of a patient with active chronic gastritis. Since then data has accumulated indicating an association between Helicobacter pylori infection and gas¬troduodenal diseases such as active chronic gastritis, gastric and duodenal ulcers. Also, several reports have point¬ed out the connection between Helicobacter pylori infection and the elevated risk of gastric carcinoma.
Most diagnostic methods for verification of a Helicobacter py¬lori infection are based on samples taken by invasive means. They include culture, rapid urease test, histological methods, PCR-enhanced DNA-assay and immuno-blotting tests. The urea breath test and the serum antibody assays which do not require invasive sampling are practical for first step screening. The most widely used antibody tests are based on enzyme immunoassay and on latex agglutination.
The importance of testing serum or whole blood for an el¬evated level of IgG-class Helicobacter pylori antibodies has been demonstrated by Granberg et al.. In accordance with earlier reports, the study verified the diagnostic utility of an IgG-assay when the patient suffers from upper abdominal complaints or when chronic gastritis or peptic ulcer is sus¬pected. CD Helicobacter pylori IgG is a one-step antibody assay based on immunochromatography. The use of CD requires a minimum amount of manual work: just the addition of the diluted serum or whole blood sample into the test device. The conclusive result can be read with the naked eye in a few minutes. Sensitivity and specificity of the test are high and false negative results due to the excess of antibodies have not been demonstrated. The test device is stored in room temperature and has a long shelf-life.

Principle Of The Test

The functional parts of **CD Helicobacter pylori IgG test** are the filter and the chromatographic membrane. Both con¬tain immunological reagents in a dehydrated state which are rehydrated by the diluted sample during the assay process. A stationary reagent line has been applied onto the mem¬brane. The reagent line is otherwise invisible, but if the serum or whole blood sample passing through membrane contains antibodies to the specific Helicobacter pylori antigens, the line turns distinctly red under formation of a dyed antigen-antibody-anti human IgG -complex in the test line (= reagent line). The membrane contains also another stationary line in the control window invisible before use of the test. This con¬trol line turns red during the assay process, thus indicating proper performance of the test device.

Performance characteristics

When 132 serum samples were assayed by CD and by a commercially available IgG-EIA test with cut-off value at 300 U, the following results were obtained:

		CD	
		-	+
IgG-EIA	-	86	2
	+	3	41

The sensitivity and specificity of the **CD** was 93,2% and 97,7%, respectively.

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The diluted whole blood samples and plasma samples taken from 20 persons gave comparative test results by CD test.
A serum sample with exceptionally high antibody activity (over 50.000 EIA-U) gave a positive test result when diluted both normally 1:200 and by 1:50 and 1:10.

Reagents And Materials Provided

1. 10 disposable CD test units single-packed in aluminium foil pouches
2. 10 disposable pipettes
3. 10 vials of 1,2 ml sample dilution buffer
4. 10 disposable end-to-end 10 µl capillaries (Hep)
5. 10 disposable lancettes
6. 10 alcohol soaked swabs
7. 0,5 ml Positive control (diluted, ready for use)
8. Instructions for use

Materials Required But Not Supplied

Timer

Storage

Store the test devices, dilution buffer and accessories in room temperature (+2°C…+27°C). Store the positive control refrigerated (+2°C…+8°C). The self life of the tests is 24 months provided that the storage conditions are followed. The date of expiry is indicated on the aluminium pouch of the test device, on the label of the sample buffer and on the outer carton box.

Specimen Collection And Preparation

Serum, plasma and whole blood can be used as a sample for CD Helicobacter pylori IgG Test, but this test kit is intended for whole blood samples. EDTA and heparin in ordinary concentrations are acceptable as antico¬agulants. Sodium azide (0,09 %) can be used as a preserva¬tive. Serum and plasma samples shall be stored refrigerated (+2...+8 °C) for up to two days. Whole blood samples shall be analyzed within one working day. Serum and plasma can be frozen (under -20 °C) for long-term storage. The diluted sam¬ples shall be used during the same working day.

Assay Procedure

All components required for the test should be at room temperature.
Before taking the blood sample, prepare all the test components: the automatic lancet, the alcohol-soaked swab and the glass capillary. Open the tube containing the buffer by remov¬ing the cap. Then take the test card and the pipette out of the aluminium sachet. Place the test card horizontally on a level dry surface (with application fields up). When the aluminium sachet has been opened you should carry out the test within 15 minutes.
① Twist the grey cap until it bounces up. Continue to rotate the cap for at least 2 full rounds and then pull it out.
② Gently massage the fingertip then clean it with the alcohol-soaked swab. Leave until the finger is dry Warming up your finger will make sample collection easier.
③ Press the automatic lancet with the round opening firmly against the cleaned fingertip, and activate it with the button. The puncture is practically painless.
④ Press a drop of blood out of your fingertip. Open the plastic vessel and remove with caution the glass capillary Hold one end of the glass capillary horizontally in the drop of blood until it has completely filled.
⑤ Place the filled glass capillary in the tube containing buffer and close the tube firmly with the cap. Shake the tube several times until blood from the capillary is mixed completely with the buffer.

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⑥ Open the buffer tube and take a few drops of diluted sam¬ple with the pipette. Hold the pipette containing the diluted blood sample vertically over the round sample well (S) and drop 3 drops in it.
After applying the drops, do not touch the test card for 2 min¬utes. The test result can be read after 5 minutes. Do not read the test result after more than 10 minutes

Quality Control

Proper performance of the CD Helicobacter pylori IgG can be checked by means of the CD Helicobacter pylori control or by a pool of known positive sera. The sample diluent and a pool of negative sera (diluted in 1/200) are recommended as negative controls. Note that the positive control shall be of human origin. The sera used for the negative control ought to be tested for negativity with a CD test unit before pooling.
Good laboratory practice recommends the daily use of controls to ensure the proper performance of the kit. When tested according to the instructions for use, the positive control shall lead to a positive

Interpretation of Results

Positive:
The test indicates that there are IgG antibodies to Helicobacter pylori in the tested blood. The detection of these antibodies indicates with a high probability an existing or recent infection with Helicobacter pylori.
Figure 1.

Negative:
The test indicates that there are no IgG-antibodies to Helicobacter pylori in the tested blood. An existing infection with Helicobacter pylori can virtually be ruled out. If gastrointestinal complaints are present, further medical investigation is necessary.
Figure 2.

Invalid test results:
The absence of a distinctly visible red line in the control indicator window is a sign that the test unit is damaged. In such a case, repeat the testing with a new test unit.

Warnings and Limitations

1. The accuracy of CD Helicobacter pylori IgG results depends on the proper testing.
2. If the instructions for use or the rules of good laboratory practice are not strictly followed, false and misleading results may occur. Poor observation of the general laboratory precautions in conjunction with the use of the CD tests can expose persons to microbial hazards.
3. If the instructions for use are not followed in detail, outcome of the test may be false. Do not reuse tests or accessories.
4. A diagnosis should not be made solely according to the CD Helicobacter pylori IgG-test result. The result should be used in conjunction with additional diagnostic information available for the physician.
5. All components, samples and used materials shall be disposed of following good laboratory practice.

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6. Do not use the test after the expiry date.

7. Do not use the test if the aluminium sachet is damaged or broken accessories. Do not use tests from a lot not shoving proper performance when tested with controls.

8. All test components are intended for this test only.

9. After the aluminium sachet has been opened, the test should be carried out within the next 10 minutes.

10. The sample buffer and positive control contain 0.09 % sodium azide. Avoid contact with the skin. Do not swallow!

11. Positive control has been made of pooled, commercial human serums. Although the positive control does not contain infectious agents, it should be handled as a potential biohazard.

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