Besurence H. 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.

Carefully read the instructions for use before testing. To perform Besurence H. pylori you will also need a timer. Perform the test in a well-illuminated place.

Introduction

Warren and Marshall (1) 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 gastroduodenal diseases such as active chronic gastritis, gastric and duodenal ulcer (2, 3, 4). Also, several reports have pointed out the connection between Helicobacter pylori infection and the elevated risk of gastric carcinoma (5, 6, 7, 8). Most diagnostic methods for verification of a Helicobacter pylori 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 (9, 10). 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 (11) and on latex agglutination (12).

The importance of testing serum or whole blood for an elevated level of IgG-class Helicobacter pylori antibodies has been demonstrated by Granberg et al. (13). 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 suspected.

Besurence H. pylori IgG is a one-step antibody assay based on immunochromatography (14). The use of Besurence H. pylori 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.

Test principle

The functional parts of Besurence H. pylori are the filter and the chromatographic membrane. Both contain 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 membrane. 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 control line turns red during the assay process, thus indicating proper performance of the test device.

Contents

1. Aluminium pouch containing 1 test cassette and 1 plastic pipette
2. Sterile automatic safety lancet
3. Plastic vessel containing a 10 microlitre glass capillary
4. Alcohol-soaked swab
5. Plastic pipette
6. Tube containing 1.2 ml sample dilution buffer
7. Instructions for use

Material needed but not provided in the test kit

- Clock or timer
- Automatic lancet
- Glass capillary
- Alcohol-soaked swab
- Plastic vessel containing a 10 microlitre glass capillary
- Container for used lancets

Test procedure

All components required for the test should be at room temperature.

Before taking the blood sample, prepare all the test components: Automatic lancet, alcohol-soaked swab and glass capillary. Open the tube containing the buffer by removing the cap.

1. Twist off the blue thin protective cap by rotating it ¼ turn and pull it straight out.

2. Open the aluminium pouch just before use. Take the test out of the pouch and place it on a flat surface.

3. Remove a few drops of diluted sample with the pipette. Hold the pipette containing the diluted blood sample vertically over the round application field (S) and drop 3 drops onto it. After applying the drops, do not touch or move the test card for 2 minutes.

4. The test result can be read after 5 minutes. Do not read the test result after more than 10 minutes.

Interpretation of results

The test result is positive if a red control line appears in the control field (C) and a light to dark red line forms in the test field (T). Note that the positive result may be read as soon as both lines have formed. This usually takes place within two minutes time.

The test result is negative if a red control line appears in the control field (C) and no red line forms in the test field (T).

If no control line is formed, you have likely not followed the instruction for use or test unit is damaged. In such a case repeat the testing with new test unit.

- 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.

- 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.

Before removing the cap of the buffer tube again, let the liquid settle back to the bottom of the tube. Open the cap and place the tube on a flat surface.

Introduction...

...good to be sure
## Controls

Proper performance of the Besurence H. pylori can be checked by means of a 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 Besurence 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 result and the negative one shall lead to a negative result.

## Performance characteristics

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

<table>
<thead>
<tr>
<th></th>
<th>Besurence</th>
<th>-</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgG</td>
<td>-</td>
<td>86</td>
<td>2</td>
</tr>
<tr>
<td>EIA</td>
<td>+</td>
<td></td>
<td>41</td>
</tr>
</tbody>
</table>

The sensitivity and specificity of the Besurence H. pylori was 93.2% and 97.7%, respectively.

The diluted whole blood samples and plasma samples taken from 20 persons gave comparative test results by Besurence H. pylori. A serum sample with exceptionally high antibody activity (over 50,000 ELISA-U) gave a positive test result when diluted both normally 1:200 and by 1:50 and 1:10.

## Warnings and limitations

- The accuracy of Besurence H. pylori results depends on the proper testing.
- 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 Besurence H. pylori can expose persons to microbial hazards.
- If the instructions for use are not followed in detail, outcome of the test may be false. Do not reuse tests or accessories.
- A diagnosis should not be made solely according to the Besurence H. pylori IgG–test result. The result should be used in conjunction with additional diagnostic information available for the physician.
- All components, samples and used materials shall be disposed of following good laboratory practice.
- Do not use the test after the expiry date.
- Do not use the test if the aluminium sachet is damaged or broken accessories. Do not use tests from aged or broken accessories. Do not use tests from or accessories.
- All test components are intended for this test only.
- After the aluminium sachet has been opened, the test should be carried out within the next 10 minutes.
- The sample buffer and positive control contain 0.09% sodium azide. Avoid contact with the skin. Do not swallow!
- Positive control has been made of pooled, commercial human sera. Although the positive control does not contain infectious agents, it should be handled as a potential biohazard.

## Bibliography