INTENDED USE

The Clearview® H. pylori test is a rapid immunochromatographic immunoassay designed for qualitative detection of IgG antibodies to Helicobacter pylori in whole blood samples in patients who are suspected of Helicobacter pylori infection. The test can be performed using whole blood from venipuncture whole blood. Whole blood samples must be tested immediately. Do not freeze whole blood samples.

SAMPLE COLLECTION AND PREPARATION

For professional use beyond the expiration date.

The test cassette contains a control region (C) and a test region (T). A negative result means that IgG antibody to H. pylori is not present in the test sample. A positive result indicates that IgG antibody to H. pylori is present in the test sample.

Note: The test should be used only to evaluate patients with gastrointestinal symptoms suspicious of Helicobacter pylori infection and not intended for use with asymptomatic patients.

INTERPRETATION OF RESULT

1. The Clearview® H. pylori test should be used only to evaluate patients with gastrointestinal symptoms suspicious of Helicobacter pylori infection and not intended for use with asymptomatic patients.

2. The Clearview® H. pylori test is in vitro diagnostic only. The test should be used for the detection of IgG antibodies to whole blood samples only. The qualitative detection of IgG antibodies in the sample can be determined by this qualitative test.

3. If a negative result indicates that IgG antibody to H. pylori is not present in the test sample, the test cassette must be discarded and a new test should be performed using a new test kit.

4. Generally, heliophyl samples will yield results. Shortly follow the manufacturer's instructions. Complete absence of a line in the test region (T) is strongly suggestive of negative laboratory equipment and moderate radiation exposure, and serological testing.

5. Non-invasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological testing.

8. As with all diagnostic tests, all results must be interpreted together with clinical and epidemiological considerations.

9. Literature reviews have suggested cross-reactivity of antibody to H. pylori and closely related organism, Borrelia burgdorferi. Performance of this assay has been evaluated with this organism. Therefore, the specificity of this test can only be determined by the test developer.

10. This assay has not been established for patients under 10 years of age.

EXPECTED VALUES

Helicobacter pylori infection is present in present world. There has been some controversy over age, other background, lab norm, and socioeconomic class. In the United States, the incidence of infection may range between 1% and 2% among individuals with signs and symptoms of gastroenteritis conditions such as diarrhea and chronic enteritis is present in only 1–2% of the population.

Performance characteristics

The test has a high degree of specificity for human immunoglobulin G (IgG) antibodies to Helicobacter pylori. This test can be used in the presence of IgG antibodies to H. pylori.

REFERENCES


The Clearview H. pylori whole blood, serum, plasma test is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies to Helicobacter pylori in whole blood, serum or plasma for in vitro diagnostic use only.

**INTENDED USES**

The Clearview H. pylori test is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies to Helicobacter pylori in whole blood, serum or plasma for in vitro diagnostic use only.

**SUMMARY**

Helicobacter pylori is a common worldwide infection affecting 30–50% of the human population. It is generally acquired in the first 2 years of life and can lead to chronic gastritis. Histology and rapid urease test are the gold standards. The test is more specific than other noninvasive tests. Using whole blood, serum or plasma for testing, the test is for diagnostic use only. The test should be used in conjunction with clinical and other diagnostic procedures to establish or exclude the presence of H. pylori infection.

**PREREQUISITES**

- Whole blood
- Serum
- Plasma

To use this test, a whole blood, serum, or plasma specimen must be collected in a container approved by the manufacturer and that contains the anticoagulant and preservative necessary to maintain the antibody in the sample for the duration of testing. Whole blood, serum, or plasma specimens may be stored at room temperature up to 4 days; for long term storage, specimens should be kept below 30°C. When using specimens to reconstitute protein samples, the test should be performed without additional membrane washing.

**REAGENTS**

- Whole blood
- Serum
- Plasma

**PROCEDURES**

- Whole blood
- Serum
- Plasma

**INTERPRETATION OF RESULT**

- Whole blood
- Serum
- Plasma

**LIMITATIONS**

- Whole blood
- Serum
- Plasma

**REFERENCES**

- Whole blood
- Serum
- Plasma

The test is intended for qualitative detection of IgG antibodies to Helicobacter pylori in whole blood, serum, or plasma for diagnostic use only. The test should be used in conjunction with clinical and other diagnostic procedures to establish or exclude the presence of H. pylori infection. The test is for diagnostic use only. The test should be used in conjunction with clinical and other diagnostic procedures to establish or exclude the presence of H. pylori infection. The test is for diagnostic use only. The test should be used in conjunction with clinical and other diagnostic procedures to establish or exclude the presence of H. pylori infection.
<table>
<thead>
<tr>
<th>Description</th>
<th>US Clearview IHP-402 PI</th>
<th>Part Number</th>
<th>115589710S</th>
<th>Size</th>
<th>55.8x284.5mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printing Contents</td>
<td></td>
<td>F-number</td>
<td>I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Designer</td>
<td>Tina</td>
<td>Design</td>
<td>Data Version</td>
<td>Jan 16, 2014</td>
<td>/</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Writer</td>
<td></td>
<td>/</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Checked By</td>
<td></td>
<td>/</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Approved By</td>
<td></td>
<td>/</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Approved By</td>
<td></td>
<td>/</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Approved By</td>
<td></td>
<td>/</td>
<td></td>
</tr>
<tr>
<td>Approved By</td>
<td></td>
<td>ACHC audits</td>
<td></td>
<td>/</td>
<td></td>
</tr>
<tr>
<td>Approved By</td>
<td>ACHC audits</td>
<td>ACHC audits</td>
<td></td>
<td>/</td>
<td></td>
</tr>
<tr>
<td>Effective Date</td>
<td></td>
<td>Effective</td>
<td></td>
<td>/</td>
<td></td>
</tr>
</tbody>
</table>