
References


Summary and Explanation

Helicobacter pylori, formerly known as Campylobacter pyloridis, are gram-negative microaerophilic spiral bacteria that have been identified and cultured since 1983. They can colonize the gastric mucosa for years 1, and their presence is strongly associated with chronic, diffuse, superficial gastritis of the fundus and antrum 2,3. As a result, they are now believed to have an etiologic role in gastritis 4,5. Recent evidence suggests that H. pylori gastritis may progress over several decades to chronic atrophic (type B) gastritis 6,7, a lesion that is a precursor of gastric carcinoma. The epidemiologic features of gastric carcinoma and H. pylori infection are similar 8,9, and recent studies suggest that H. pylori infection may be a risk factor for gastric carcinoma 10,11. Until recently, diagnosis of infection with H. pylori required endoscopy and identification of the organism by means of subsequent culture of the bacteria and/or recognition of spiral organisms in histologically evaluated sections of gastric tissue. However, the expense and invasive nature of this procedure make endoscopy impractical for epidemiologic studies. Serology has become the method of choice for such studies. There is excellent correlation between a classical clinical presentation of gastritis, the presence of H. pylori in the stomach and elevated serum levels of anti-H. pylori antibodies 12,13. Positive results can justify a short empirical trial of antimicrobial therapy in gastritis of unknown origin, and response to treatment can be serially monitored by elevated levels of H. pylori-specific antibodies. Antibody results are not expected to fall significantly after successful antibacterial therapy 14.

Principle

The Status H. pylori — One-Step Anti-H. pylori Antibody Test utilizes indirect solid-phase immunoassay technology for the qualitative detection of H. pylori antibodies. Status H. pylori consists of H. pylori antigen on the test membrane and H. pylori antigen plus anti-human immunoglobulin antibodies coated on gold particles in the dye pad. Thus, in principle, the results of Status H. pylori may differ from the results of assay using only anti-IgG as a detector. In the test procedure, patient specimen is added in the upper area of the Sample well (B) located below the Result window.

Storage and Stability

The Status H. pylori test kit should be stored at 2–30°C (35–86°F) in the original sealed pouch. The storage conditions and stability dating given were established under these conditions. The kit is stable until the expiration date.
Whole Blood:
- When adding the Developer Solution, hold the dropper bottle in a cylindrical tube to the 25 µL mark. Follow the steps in Test Procedure.
- Label the device with the patient’s name or control number.
- Do not reuse a lancet.
- Do not open the sealed pouch until you are ready to perform the test.
- Allow specimens and the result window to be frozen and stored at -20°C or below. Specimens should not be kept frozen for more than two days.
- Refract all specimens at 2–8°C until ready for testing. If serum or plasma is to be stored, it should be refrigerated at 2–8°C for 24 hours before testing.
- All specimens must be tested within 1 week of collection.
- Plasma: Collect whole blood sample into a tube containing anticoagulant such as CPDA-1, heparin, or EDTA.
- Remove the serum or plasma from the blood cells as soon as possible to avoid hemolysis. When possible, clear, non-hemolyzed specimens should be used. Mildly hemolyzed specimens do not affect the test result, but will create an undesirable reddish background in the Result Window.

Specimens containing any particulate matter may give inconsistent test results. Such specimens should be clarified by centrifugation prior to testing.

Storage of specimens
Refract all specimens at 2–8°C until ready for testing. If serum or plasma is to be stored, it should be refrigerated at 2–8°C for 24 hours before testing. Frozen samples must be fully thawed, thoroughly mixed, and brought to room temperature prior to testing. If specimens are to be shipped, they should be packed in compliance with Federal and carrier regulations covering transportation of etiologic agents.

Procedure
- Allow specimens and the Status H. pylori test kit to warm to room temperature (18–30°C) before testing.
- Do not open the sealed pouch until you are ready to perform the test.
- Several tests may be run at one time.
- Do not reuse a lancet.
- To avoid cross-contamination, use a new capillary tube for each specimen.
- To avoid contamination, do not touch the tip of the Developer Solution dropper bottle to skin or to the test device.
- Label the device with the patient’s name or control number.
- When adding the Developer Solution, hold the dropper bottle in a vertical position above the lower area of the Sample Well (S).
- After testing, dispose of the Status H. pylori device and the specimen dispenser or capillary tube following good laboratory practices. Consider each material that comes in contact with the specimen to be potentially infectious.

NOTE: The test result can be read as soon as a distinct pink-purple colored Test line (T) and a colored Control line (C) appear. Any shade of purple or pink is acceptable, and any color line should be considered a positive result.

Positive
One colored band at each the Test (T) and at the Control (C) indicates that antibodies against H. pylori have been detected.

Negative
Only one colored Control line (C), with no colored Test line (T), indicates that antibodies against Helicobacter pylori have not been detected.

Invalid
A distinctive colored Control line (C) should always appear. The test is invalid if no Control line forms. Repeat the test with a new Status H. pylori test.

Test Procedure
STEP 1 Remove a device from pouch and place on flat surface.
STEP 2 For serum or plasma fill a capillary tube to the red line (10 µl).
For whole blood fill a capillary tube to the black line (25 µl).
Apply sample by lightly tapping the capillary on the pad of the UPPER AREA of the Sample well (S).
STEP 3 Add 2 to 3 drops of Developer Solution onto the LOWER AREA of the Sample Well (S).
STEP 4 Read result at 10 minutes. (Do not read after 15 minutes).

Interpretation of Results
Positive
One colored band at each the Test (T) and at the Control (C) indicates that antibodies against H. pylori have been detected.

Negative
No colored bands at the Test (T) and at the Control (C) indicates that no antibodies against H. pylori have been detected.

Invalid
A distinctive colored Control line (C) should always appear. The test is invalid if no Control line forms. Repeat the test with a new Status H. pylori test.

Expected Values
1. H. pylori is detectable in nearly 100% of adult patients with duodenal ulcer and about 80% of patients with gastric ulcer, while 50% of patients with gastritis. Status H. pylori demonstrated positive results for 94% of patients with a symptom of ulcer and positive results on 80% of gastric patients.
2. The prevalence of H. pylori antibody increases with age, and is demonstrated in 5% of children, about 8% of blood donors, and approaches 50% at age 60 in the normal population of industrialized nations. More than 25% of these infected patients are asymptomatic. Other factors such as socioeconomic status, ethnic group, different populations, geographical location and the type of clinical symptoms associated with the infection also contribute to the observed variations in prevalence.
3. Asymptomatic and untreated patients continue to test IgG seropositive as long as the H. pylori organisms are present, even after histological resolution. In this case, negative results are strong evidence against these diagnoses.

Performance Characteristics
Clinical specimens were collected from 207 symptomatic and asymptomatic individuals who presented for endoscopic examination. The age range was 19–83 years with a mean age of 52 years.

<table>
<thead>
<tr>
<th>Status H. pylori</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>86</td>
<td>115</td>
<td>201</td>
</tr>
<tr>
<td>Negative</td>
<td>6</td>
<td>113</td>
<td>119</td>
</tr>
<tr>
<td>Total</td>
<td>92</td>
<td>228</td>
<td>320</td>
</tr>
</tbody>
</table>

When the ELISA was used as a reference, the Status H. pylori test demonstrated 93.2% agreement.

Matrices Effect Study
Effect of specimen matrices on the result of the Status H. pylori test was evaluated using 59 matched specimen sets each consisting of venous whole blood, capillary whole blood, plasma and serum. Of the 59 samples tested, 46 samples were positive and 13 samples were negative. Excellent agreement (>99%) was found between venous whole blood, capillary whole blood, plasma and serum indicating no significant effect of matrices on the test.

Reproducibility
Reproducibility of Status H. pylori was evaluated by testing negative, low positive and high positive samples. The samples were tested in replicates of 10 in a blind study by 4 technicians, on 3 different dates and at 4 different locations.

Proficiency(Physician Office Laboratory) Study
Status H. pylori was evaluated at 3 different physicians’ office laboratories using a panel of 90 coded samples. The proficiency testing contained negative, positive, and high positive samples in either serum or whole blood. Each technician was tested at these laboratories on three different days. The results obtained from 270 tests had a >99% agreement with the expected results. No significant differences were observed between the laboratories or personnel results.

Quality Control
A quality control check is recommended using commercially available control sera. The frequency of Q.C. tests is determined according to your laboratory’s standard Q.C. procedures. Upon confirmation of the expected results, the kit is ready for use with patient specimens. If external controls do not perform as expected, do not use the test kits, and contact LifeSign Technical Services at 800-526-2125.

When the test has been performed correctly and the device is working properly, a distinct colored line will always appear at the Control position (C). The colored line at the Control position (C) is considered an internal positive procedural control. If the line does not appear, a new device should be tested. If the problem persists, contact LifeSign Technical Services at 800-526-2125.

Expected Values
1. H. pylori is detectable in nearly 100% of adult patients with duodenal ulcer and about 80% of patients with gastric ulcer. Status H. pylori demonstrated positive results for 94% of patients with a symptom of ulcer and positive results on 80% of gastric patients.
2. The prevalence of H. pylori antibody increases with age, and is demonstrated in 5% of children, about 8% of blood donors, and approaches 50% at age 60 in the normal population of industrialized nations. More than 25% of these infected patients are asymptomatic. Other factors such as socioeconomic status, ethnic group, different populations, geographical location and the type of clinical symptoms associated with the infection also contribute to the observed variations in prevalence.
3. Asymptomatic and untreated patients continue to test IgG seropositive as long as the H. pylori organisms are present, even after histological resolution. In this case, negative results are strong evidence against these diagnoses.

Performance Characteristics
Clinical specimens were collected from 207 symptomatic and asymptomatic individuals who presented for endoscopic examination. The age range was 19–83 years with a mean age of 52 years.

<table>
<thead>
<tr>
<th>Status H. pylori</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>86</td>
<td>115</td>
<td>201</td>
</tr>
<tr>
<td>Negative</td>
<td>6</td>
<td>113</td>
<td>119</td>
</tr>
<tr>
<td>Total</td>
<td>92</td>
<td>228</td>
<td>320</td>
</tr>
</tbody>
</table>

When the ELISA was used as a reference, the Status H. pylori test demonstrated 93.2% agreement.

Matrices Effect Study
Effect of specimen matrices on the result of the Status H. pylori test was evaluated using 59 matched specimen sets each consisting of venous whole blood, capillary whole blood, plasma and serum. Of the 59 samples tested, 46 samples were positive and 13 samples were negative. Excellent agreement (>99%) was found between venous whole blood, capillary whole blood, plasma and serum indicating no significant effect of matrices on the test.

Reproducibility
Reproducibility of Status H. pylori was evaluated by testing negative, low positive and high positive samples. The samples were tested in replicates of 10 in a blind study by 4 technicians, on 3 different dates and at 4 different locations. The results showed 100% agreement with the expected results.

Proficiency(Physician Office Laboratory) Study
Status H. pylori was evaluated at 3 different physicians’ office laboratories using a panel of 90 coded samples. The proficiency testing contained negative, positive, and high positive samples in either serum or whole blood. Each technician was tested at these laboratories on three different days. The results obtained from 270 tests had a >99% agreement with the expected results. No significant differences were observed between the laboratories or personnel results.