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5.


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14.


15.


References


Whole Blood:
- After testing, dispose of the test kit to warm to room temperature (18–30°C) and then centrifuge at 10,000 for ten minutes at room temperature.

Plasma:
- Collect whole blood sample into a tube containing an 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 samples do not affect the test result, but will create an undesirable reddish background in the Result Window.

Storage of specimens
- Refrigerate all specimens at 2–8°C until ready for testing. If serum or plasma specimens will not be tested within 48 hours, they should be frozen and stored at -20°C or below. Storage should not be repeatedly frozen and thawed. Bring samples to room temperature (18-30°C) before testing. Frozen samples must be completely 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

Procedural notes
- 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.
- Several tests may be run at one time.

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 test position (T) and at the Control (C) position indicates that antibodies against H. pylori have been detected.

Negative
Only one colored Control line (C) indicates that antibodies against Helicobacter pylori have not been detected.

Invalidate
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.

Limitations
The results obtained by this kit should be used only to evaluate patients with other clinical symptoms of gastrointestinal disease. This assay is not intended for use with asymptomatic individuals. The performance characteristics of this test with specimens from pediatric patients has not been established. A positive result only means the presence of antibodies to H. pylori and does not indicate any disease status of the patient. A positive test result does not allow one to distinguish between active infection and colonization by H. pylori. A negative result suggests that antibodies to H. pylori are not present, or are present at a level below the detection limit of the test. The result is negative and infection of H. pylori is suspected, additional testing such as culture and histological analysis is recommended.

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. H. pylori status, ethnicity, different populations, geographical location and the type of clinical symptoms associated with the infection also contribute to the observed variations in prevalence.

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 62 years. The performance characteristics of Status H. pylori were evaluated by comparison to biopsy/histology, agglutination test and ELISA for detection of anti-H. pylori antibody. The results are summarized in tables below.

Table 1. Status H. pylori Test Result versus Biopsy/Histology

<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>71</td>
<td>14</td>
<td>85</td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
<td>115</td>
<td>118</td>
</tr>
<tr>
<td>Total</td>
<td>74</td>
<td>129</td>
<td>203</td>
</tr>
</tbody>
</table>

When biopsy/histology was used as a reference, the Status H. pylori test demonstrated 95.9% specificity, 89.1% sensitivity and 91.6% agreement. Four tests were excluded in the calculation due to indeterminate results.

Table 2. Status H. pylori Test Result versus Agglutination Test

<table>
<thead>
<tr>
<th>Status H. pylori</th>
<th>Agglutination Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>80</td>
</tr>
<tr>
<td>Negative</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>88</td>
</tr>
</tbody>
</table>

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

Table 3. Status H. pylori Test Result versus ELISA

<table>
<thead>
<tr>
<th>Status H. pylori</th>
<th>ELISA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>84</td>
</tr>
<tr>
<td>Negative</td>
<td>127</td>
</tr>
<tr>
<td>Total</td>
<td>211</td>
</tr>
</tbody>
</table>

When the ELISA was used as a reference, the Status H. pylori test demonstrated 93.3% 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 specimens in either serum or whole blood. Each technical or nontechnical personnel at four different institutions and these three different dates conducted the tests. 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.
**Specimen Collection and Preparation**

**Whole Blood:**
- Anticoagulated Blood:
  - Whole blood collected over sodium heparin, lithium heparin, citrate or EDTA can be used. Mix whole blood by inversion and use in the test as outlined in the Test Procedure. Whole blood can be stored at 2–8°C for 24 hours.
- Fingertip Blood:
  - Prick the finger and collect the blood in a capillary tube to the 25 µL mark. Follow the steps in Test Procedure.

**Plasma:**
- Collect whole blood sample into a tube containing an 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 samples do not affect the test result, but will create an undesirable reddish background in the Result Window.

**Storage of specimens**
- Refrigerate all specimens at 2–8°C until ready for testing. If serum or plasma specimens will not be tested within 48 hours, they should be frozen and stored at -20°C or below. Specimens should not be repeatedly frozen and thawed. Bring specimens to room temperature (18–30°C) before testing. Frozen samples must be completely 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**

**Procedural notes**
- 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.

**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 each at the Test position (T) and at the Control position (C) indicates that antibodies against H. pylori have been detected.

**Negative**
Only one colored Control line (C) 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.

**Limitations**
- The results obtained by this kit should be used only to evaluate patients with other clinical symptoms of gastrointestinal disease.
- This assay is not intended for use with asymptomatic individuals. The performance characteristics of this test with specimens from asymptomatic individuals have not been established. A positive result only means the presence of antibodies to H. pylori and does not indicate any disease status of the patient. A positive test result does not allow one to distinguish between active infection and colonization by H. pylori. A negative result suggests that antibodies to H. pylori are not present, or are present at a level below the detection limit. If the test result is negative and infection of H. pylori is suspected, additional testing such as culture and histological analysis is recommended.

**Quality Control**
- A quality control check is recommended using commercially available control sera. The frequency of Lot QC tests is determined according to your laboratory’s standard Q.C. procedures.
- Upon completion 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 800-526-2120.

**Expected Values**

1. **H. pylori** is detectable in nearly 100% of adult patients with duodenal ulcer and about 80% of patients with gastric ulcer.\(^{1,11}\) **Status H. pylori** demonstrated positive results for 94% of patients with a symptom of ulcer and positive results on 80% of gastritis patients.

2. The prevalence of H. pylori antibody increases with age, and is detectable in 5% of children, about 13% in blood donors, and approaches 50% at age 60 in the normal population of industrialized nations.\(^{11}\) 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 a historical resolution. Hence, positive results are strongly 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. The performance characteristics of **Status H. pylori** were evaluated by comparison to biopsy/histology, agglutination test and ELISA for detection of anti-H. pylori antibody. The results are summarized in tables below.

**Table 1. Status H. pylori** Test Result versus Biopsy/Histology

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<td>118</td>
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<td>Total</td>
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<td>129</td>
<td>203</td>
</tr>
</tbody>
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When biopsy/histology was used as a reference, the **Status H. pylori** test demonstrated 95.9% specificity, 89.1% sensitivity and 91.6% agreement. Four tests were excluded in the calculation due to indeterminate results.

**Table 2. Status H. pylori** Test Result versus Agglutination Test

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<th>Status H. pylori</th>
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<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>80</td>
<td>8</td>
<td>88</td>
</tr>
<tr>
<td>Negative</td>
<td>6</td>
<td>113</td>
<td>119</td>
</tr>
<tr>
<td>Total</td>
<td>86</td>
<td>121</td>
<td>207</td>
</tr>
</tbody>
</table>

When the agglutination test was used as a reference, the **Status H. pylori** test demonstrated 92.3% agreement.

**Table 3. Status H. pylori** Test Result versus ELISA

<table>
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<tr>
<th>Status H. pylori</th>
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<td>Positive</td>
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</tr>
<tr>
<td>Negative</td>
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<td>123</td>
<td>207</td>
</tr>
</tbody>
</table>

When the ELISA was used as a reference, the **Status H. pylori** test demonstrated 92.3% 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**

[For content related to proficiency studies, please provide the specific data or results related to proficiency in physician office laboratories.]

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\(^{1}\) Reproduced with permission from Fournier G et al. 1994

\(^{11}\) Data from the National Hospital Discharge Survey, 1980–90.
Interference Study
Possible interference materials found in blood, such as, bilirubin, hemoglobin, triglycerides, or albumin, were tested in the Status H. pylori test at approximately 10-fold higher than normal physiological concentrations. These substances did not alter the test result of Status H. pylori.

References

Summary and Explanation
 helicobacter pylori, formerly known as Campylobacter pylori, are gram-negative, microaerophilic spiral bacteria that have been identified and cultured since 1983. They can colonize the gastric mucosa for years, and their presence is strongly associated with chronic, diffuse, superficial gastritis of the fundus and antrum 3,4,5. As a result, they are now believed to have an etiologic role in gastritis 6,7. Recent evidence suggests that H. pylori gastritis may progress over several decades to chronic atrophic (type B) gastritis 4,5, a lesion that is a precursor of gastric carcinoma. The epidemiologic features of gastric carcinoma and H. pylori infection are similar 6,7, 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 subculturing the bacteria of the culture 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. 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 levels of H. pylori-specific antibodies. It is expected that tests for H. pylori-specific antibodies can be expected to fail significantly after successful antibacterial therapy 12,13.

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 conjugated to gold particles and a series of anti-human immunoglobulin antibodies coated on gold particles in the test membrane. The Developer solution is then added in the control position (C) to create a colored band regardless of the presence of H. pylori antibodies in the sample. The presence of two colored bands, one at the Test position and the other at the Control position, indicates a positive result, while the absence of a colored band at the Test position indicates a negative result.

Materials Required but Not Provided
• Vacuum tubes for either serum or plasma procedure
• Anticoagulant ( i.e., CPDA-1, heparin, or EDTA ) for plasma
• Centrifuge
• Lancet

Warning and Precautions
• For in vitro diagnostic use only.
• Do not mix results from different product lots and do not use beyond the expiration date.
• Use separate clean capillaries for different specimens. Do not pipette by mouth.
• Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.
• Wear disposable gloves while handling kit reagents or specimens and thoroughly wash hands afterwards.
• All patient samples should be handled as if they were capable of transmitting disease. Observe established precautions against microbiological hazard throughout all procedures and follow the standard procedures for proper disposal of specimens.
• Developer solution in this kit contains 0.1% sodium azide as a preservative, which may react with lead or copper in plumbing to form potentially explosive metal azides. Upon disposal, always flush with a large volume of water to prevent azide buildup in drains.

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.