clarity h. pylori — one-step anti- h. pylori antibody test

intended use
clarity h. pylori qualitatively detects anti-helicobacter pylori IgG antibody in human whole blood, serum, or plasma specimens. the test is intended for use as an aid in the diagnosis of h. pylori infection in adult patients with symptoms of gastrointestinal disorders.

summary and explanation
Helicobacter pylori, formerly known as Campylobacter pylori, are gram-negative microaerophilic spiral bacteria that have been identified and cultured since 1983.1 They can colonize the gastric mucosa for years,2-3 and their preence is strongly associated with chronic, diffuse, superficial gastritis of the fundus and antrum.4-5 As a result, they are now believed to have an etiologic role in chronic gastritis.5-7 recent evidence suggests that H. pylori gastritis may progress over several decades to chronic atrophic (type B) gastritis,8-9 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.11-15 positive results can justify a short empiric trial of antimicrobial therapy in gastritis of unknwon origin, and response to treatment can be serially monitored because levels of H. pylori specific IgG antibody concentrations can be expected to fall significantly after successful antibacterial therapy.16-18

principle
The Clarity H. pylori — One-Step Anti-H. pylori Antibody Test utilizes indirect solid-phase immunoassay technology for the qualitative detection of H. pylori antibodies. Clarity 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 the results of Clarity H. pylori may differ from the results of assays using only anti-IgG as a detector. In the test procedure, patient specimens are added to the upper area of the sample well (S) located below the Result window. The Develop- oper solution is then added in the Sample well. The solution mobilizes the Clarity H. pylori antigen and to anti-human immunoglobulin antibodies. If any anti-H. pylori antibody is present in the sample, the dye conjugate will bind to the H. pylori antigen band impregnated on the test membrane. Visualization of the antigen band at the Test position (T) will occur only when the anti-H. pylori antibody is present in the sample. As the antibody-dye conjugate continues to move along the test membrane, it will be captured by a specific antibody located at the Control position (C) to generate 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.

Reagents and Materials Provided
- Each Clarity H. pylori test kit contains enough reagents and materials to perform all the tests.
- Each Clarity H. pylori test device contains a membrane strip coated with H. pylori antigen and a pad with indicator conjugates in a protein matrix.
- Capillary tubes
- Each kit contains a dropper bottle of Developer solution containing 0.1% sodium azide.
- Directions for Use
- Procedure Card

Materials Required But Not Provided
- Vacutainer tubes for either serum or plasma samples
- Anticoagulants (i.e., CPDA-1, heparin, or EDTA) for plasma
- Centrifuge
- Lancet

Warnings and Precautions
- For in vitro diagnostic use only.
- Do not use for testing different product lots and do not use beyond the expiration date.
- Use separate clean capillary tubes 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 sodium azide as a preservative, which may react with lead or copper in plumbing to form potentially toxic metal azides. Upon disposal, always flush with a large volume of water to prevent azide buildup in drains.
- The Clarity H. pylori device should remain in its original sealed packaging until ready for use. Do not use the test if the pouch is damaged.

Storage and Stability
The Clarity H. pylori test kit should be stored at 2-30°C (35-86°F) in its original packaging. The storage conditions and stability dating given were established under these conditions. The kit is stable until the expiration date.

References
22. Interference Study

2. The prevalence of H. pylori antibiotic increases with age, and is detectable in 5% of children, about 33% in blood donors, and approaches 50% at age 60 in the normal population of industrialized nations.\textsuperscript{14,15} More than 25% of these infected patients are asymptomatic. Other factors such as socioeconomic status, ethnic group, different populations, geographcal 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 organsims are present, even after histological resolution.\textsuperscript{14} Hence, positive results are simply consistent with the diagnosis of H. pylori-associated gastritis or duodenal ulcer; whereas, 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. The performance characteristics of this test with specimens from pediatric patients have not been established.

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.

### User Quality Control

- A quality control check is recommended using commercially available control sera. The frequency of O.C. tests is determined according to your laboratory's standard O.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. Repeat the test or contact Clarity Diagnostics Technical Services.
- When the test has been performed correctly and the device is working properly, a distinctly colored line will always appear at the Control position. If the colored line is not detectable in nearly 100% of adult patients with duodenal ulcer and about 80% of patients with gastric ulcer\textsuperscript{11} H. pylori Clarity demonstrated positive results for 94% of patients with a symptom of ulcer and positive results on 80% of gastritis patients.

### Expected Values

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

### Table 1. Clarity H. pylori Test Result versus Biopsy/Histology

<table>
<thead>
<tr>
<th>Biopsy/Histology</th>
<th>Clarity H. pylori Test</th>
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</thead>
<tbody>
<tr>
<td>Clarity H. pylori</td>
<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>71</td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>74</td>
</tr>
</tbody>
</table>

When biopsy/histology was used as a reference, the Clarity H. pylori test demonstrated 95.9% sensitivity, 91.1% specificity and 91.6% agreement. Four tests were excluded in the calculation due to indeterminate results.

### Table 2. Clarity H. pylori Test Result versus Agglutination Test

<table>
<thead>
<tr>
<th>Agglutination test</th>
<th>Clarity H. pylori Test</th>
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</thead>
<tbody>
<tr>
<td>Clarity H. pylori</td>
<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>80</td>
</tr>
<tr>
<td>Negative</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>86</td>
</tr>
</tbody>
</table>

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

### Table 3. Clarity H. pylori Test Result versus ELISA

<table>
<thead>
<tr>
<th>ELISA</th>
<th>Clarity H. pylori Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarity H. pylori</td>
<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>76</td>
</tr>
<tr>
<td>Negative</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>82</td>
</tr>
</tbody>
</table>

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

### Procedure Notes

- Allow specimens and the Clarity H. pylori kit test 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 Clarity 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).

#### Step 3
Apply sample by lightly tapping the capillary on the pad of the UPPER 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), 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 form lines. Repeat the test with a new Clarity H. pylori test.