Kimberly-Clark®
CloTest®
Rapid Urease Test

The Kimberly-Clark® CloTest® Rapid Urease Test is recognized by medical professionals as the “Gold Standard” among urease tests because of its accuracy, convenience and affordability. CloTest was developed by Barry Marshall, M.D. who, along with Robin Warren, M.D., was the first to discover the correlation between Helicobacter pylori and gastric ulcers. Today, CloTest has become the most widely used rapid urease test worldwide for the diagnosis of H. pylori.

One of the most common chronic infections worldwide, H. Pylori is associated with 95% of duodenal ulcers and 80% of gastric ulcers. Clinical studies have shown that eradicating H. pylori is effective in eliminating or reducing the recurrence of ulcers and may also lower the risk of gastric cancer. The National Institutes of Health recommends testing for H. pylori in all patients with gastric or duodenal ulcers.

CloTest Rapid Urease Tests feature:

- **Accuracy**
  - 98% sensitivity and 97% specificity¹
  - Diagnosis of 75% of H. pylori infections with no false positives within 20 minutes²
  - Bacteriostatic agent in gel to ensure a lower incidence of false positives

- **Convenience**
  - Easy to read color changes
  - CLIA waived

- **Affordability**
  - Less expensive diagnosis than culture or histology

From medical devices to surgical apparel – everything we do, everything we make, is focused on protecting healthcare professionals and patients. This means we work every day to develop and deliver quality products and to provide responsive customer service that you can depend on to meet your protection needs.

¹, ²—see charts on reverse side

Barry Marshall, M.D.
Commitment to Excellence
If, for any reason, our products do not meet your expectations, please let us know your comments or suggestions for improvement. Your input will result in a concerted effort on our part to meet your requirements. Our goal is to provide quality products that completely meet your needs time after time.

For more information, please call 1-800-528-5591 in the United States, +801 572 6800 internationally, or visit our web site at www.kchealthcare.com.

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**Accuracy**

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity</th>
<th>Specificity</th>
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</thead>
<tbody>
<tr>
<td>CLOtest</td>
<td>98%</td>
<td>97%</td>
</tr>
<tr>
<td>Histology</td>
<td>91%</td>
<td>100%</td>
</tr>
<tr>
<td>Culture</td>
<td>70%</td>
<td>100%</td>
</tr>
</tbody>
</table>

*Similar results have been documented in the United States and Europe*

In a U.S. study of 122 consecutive routine endoscopy patients, Dye et al. took separate antral biopsies for histology (Giemsa Stain) and CLOtest. Eighty-two of these patients also had specimens cultured.

**Reaction Time**

![Graph showing % Positive Detection over time in minutes]

CLOtest will diagnose 75% of *H. Pylori* infections with no false positives within 20 minutes. Within one hour, 85% of positive patients will be detected by CLOtest, at 3 hours, 90% are detected, and between 3 and 24 hours another 5% of patients will be detected by CLOtest.

**Comparison to Other Diagnostic Methods**

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid Urease:</td>
<td>Comparable to histology in accuracy but much less expensive and more timely</td>
</tr>
<tr>
<td>(CLOtest)</td>
<td></td>
</tr>
<tr>
<td>Culture:</td>
<td>Expensive, not timely, useful for antibiotic sensitivities</td>
</tr>
<tr>
<td>Histology:</td>
<td>Accuracy depends on experience and appropriate stains, relatively expensive</td>
</tr>
<tr>
<td>Serology:</td>
<td>Does not define current <em>H. pylori</em> activity and less accurate than histology or rapid urease testing</td>
</tr>
</tbody>
</table>

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2 Reaction Time

271 Consecutive Patients

158 *Hp* + 113 *Hp* -

<table>
<thead>
<tr>
<th>Time in Minutes</th>
<th>0</th>
<th>20</th>
<th>40</th>
<th>60</th>
<th>80</th>
<th>100</th>
<th>120</th>
<th>140</th>
<th>160</th>
<th>180</th>
<th>% Positive Detection</th>
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<tbody>
<tr>
<td></td>
<td>0</td>
<td>25</td>
<td>50</td>
<td>75</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
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