

THE "GOLD STANDARD" AMONG UREASE TESTS



Barry Marshall, M.D.

The CLOtest* Rapid Urease Test is recognized by medical professionals as the "Gold Standard" among urease tests because of its accuracy, convenience and affordability. CLOtest* Rapid Urease Test 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* Rapid Urease Test 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% specificity[†]
- Diagnosis of 75% of *H. pylori* infections with no false positives within 20 minutes^{††}
- 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

^{††} - see charts on reverse side

1 ACCURACY

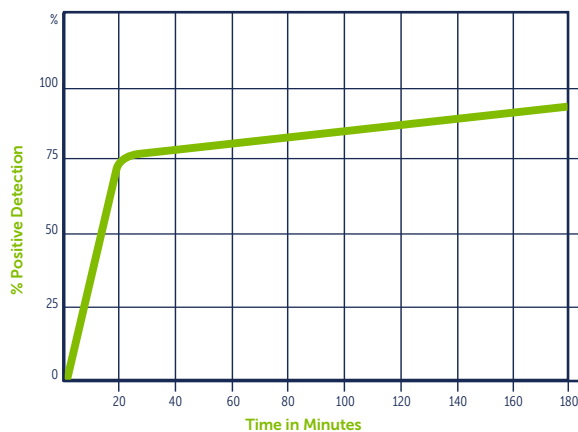
Similar results have been documented in the United States and Europe

| | Sensitivity | Specificity |
|-----------|-------------|-------------|
| CLOtest* | 98% | 97% |
| Histology | 91% | 100% |
| Culture | 70% | 100% |

In a U.S. study of 122 consecutive routine endoscopy patients, Dye et al¹ took separate antral biopsies for histology (Giemsa Stain) and CLOtest*. Eighty-two of these patients also had specimens cultured.

2 REACTION TIME

271 Consecutive Patients
158 Hp + 113 Hp -



CLOtest* will diagnose 75% of **H. pylori** infections with no false positives within 20 minutes². 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

| | |
|---------------------------------|--|
| Rapid Urease: (CLOtest*) | Comparable to histology in accuracy but much less expensive and more timely |
| Culture: | Expensive, not timely, useful for antibiotic sensitivities |
| Histology: | Accuracy depends on experience and appropriate stains, relatively expensive |
| Serology: | Does not define current H. pylori activity and less accurate than histology or rapid urease testing |

HALYARD* CLOTEST* RAPID UREASE TEST

| Stock # | Description | Packaging |
|---------|--|-----------|
| 60407 | HALYARD* Jack Bean Urease Control Tablets, Positive Control for CLOtest* | 50 Each |
| 60480 | HALYARD* CLOtest* Rapid Urease Test | 25 Each |



For more information for clinicians and product code ordering information, please visit:

www.halyardhealth.com/digestivehealth

Call 1-844-HALYARD (1-844-425-9273) in the United States and Canada.