



## H.pylori Stool Antigen Test Medical Information

### Helicobacter pylori and Patient Management in Primary Care

It is now well documented that *Helicobacter pylori* is responsible for up to 90% of duodenal ulcers, 70% of gastric ulcers and the majority of MALT lymphomas.

As well, a recent epidemiological study confirmed the link between the infection and an increased risk of developing gastric cancer ([NEJM, Vol 345:784-789, 2001, No. 11](#)).

The eradication of the infection significantly decreases the development of gastric cancer in patients with precancerous lesions ([JAMA, 2004; 291: 187-194](#)).

The "Guidelines for the Management of *Helicobacter* Infection in Primary Care" ([Maastricht 2000](#)) address the basic problems faced by the general practitioners: 1. Who to treat, 2. How to treat, 3. How to diagnose.

Besides the biopsy based tests, available when an endoscopy is clinically indicated, the Guidelines mention the Urea Breath Test (UBT) and the Stool Antigen Test (HpSA) as acceptable non-invasive tests.

Serology is not mentioned any more, due to its lower accuracy.

### Helicobacter pylori Stool Antigen Test (HpSA)

Meridian Bioscience has developed the first totally non-invasive test for accurately diagnosing *Helicobacter pylori* infections. The Premier Platinum HpSA, an enzyme immunoassay for the detection of *Helicobacter pylori* antigens in human stool, cleared by the FDA and CE-marked, is now widely used in many countries, as a valuable tool for the H.pylori patients' management.

The test utilises polyclonal anti-H. pylori capture antibody adsorbed to microwells. Diluted patient samples and a peroxidase conjugated polyclonal antibody are added to the wells and incubated for one hour at room temperature. A wash is performed to remove unbound material. Substrate is added and incubated for ten minutes at room temperature. Colour develops in the presence of bound enzyme. Stop solution is added and the results are interpreted visually or spectrophotometrically.

The test can be performed in less than 90 minutes by any laboratory, since no special equipment is needed. Any number of tests can be run at the same time.

A new rapid one-step format (ImmunoCard STAT! HpSA) has been recently introduced. This single test provides the same accuracy as the microtiter assay in only 5 minutes.

For both tests, the specimens, collected by the patient at home into an empty, clean container and delivered to the laboratory, can be stored under refrigeration until they are tested.

### HpSA - Validation studies

The HpSA test was validated in studies including more than 10,000 patients, in many different countries world-wide. More than 40 studies, published in peer-reviewed journals, report an average accuracy exceeding 90%, in both adult and paediatric populations, for diagnosing the infection and for confirming the eradication after the therapy.

The test seems to be equivalent to the Urea Breath Test, with the exception of being less influenced by the medications (PPI's, H2 blockers and antibiotics) which strongly reduce the sensitivity of the urease-based techniques.

### The role of the Stool Antigen test in the Primary Care

The HpSA, being more accurate than the serology and more readily available than the Urea Breath Test, is an important option whenever the use of a non-invasive technique is recommended.

Cost/benefit analyses support the use of the HpSA in different situations and prevalence of infection.

#### Diagnosis of the infection

The use of non-invasive tests has been advocated in different strategies for the management of dyspeptic patients in the primary care.

The Maastricht Guidelines considers as acceptable a "test and treat" approach for patients below 45 years, with no alarm symptoms. "Diagnosis of the infection should be by UBT or Stool Antigen test."

While the serology has a low positive predictive value, because of the high rate of false positive results, the UBT and the HpSA are accurate enough for justifying an eradication therapy.

An alternative approach, "test and scope", suggests the use of non-invasive tests for screening the patients with higher risks to be further investigated with an endoscopy.

Both strategies produce a decrease of the endoscopy workload and a better patients' management.

#### Confirming the eradication

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**Confirming the eradication**

The uncertainty of patients' compliance and the increasing rate of antibiotic resistance to Clarithromycin and Metronidazole are strongly supporting the need for confirming the eradication for all treated patients, given the availability of a simple and accurate non-invasive test.

This information would avoid subsequent unnecessary therapies and investigations.

The Maastricht Guidelines state: "Always test for successful eradication, by UBT, or endoscopy-based test if endoscopy is clinically indicated. Stool antigen test is the alternative if UBT is not available