The GastroPanel®-innovation from Finland

GastroPanel[®] - test for stomach health

- GastroPanel[®] is a unique *Helicobacter pylori* test based on four biomarkers (Pepsinogen I, Pepsinogen II, Gastrin-17 and *H. pylori* antibodies)
- Reimbursed by NHI (KELA) when remitted by a doctor
- www.biohithealthcare.com/test-request-form
- GastroSoft[®] aids the doctor in interpreting the results (www.gastropanel.com)
- Based on vertical measurement- and ELISA-technologies of the company
- www.biohithealthcare.com/history
- www.biohithealthcare.com/additional-information

UPPER ABDOMINAL SYMPTOMS

- Present in some 20–40% of the population
- Correct diagnosis cannot be reached on the basis of symptoms alone
- Treatment trial with anti-acid compounds (eg. PPImedication) may obscure the correct diagnosis and preclude the timely access to curative therapy

Dyspepsia may be accompanied by:

- *Helicobacter pylori* -infection (5–70% of population)
- as well as HP-induced or autoimmune-type atrophic gastritis (over 10% of the elderly people)
- These are accompanied by increased risk of gastric and oesophageal cancer
- And malabsorption of B12-vitamin, iron, calcium, magnesium and zinc (with severe sequels)
- As well as of some medicines, and particularly among elderly, severe and even fatal gastrointestinal and respiratory infections
- Dyspeptic symptoms can be of colorectal origin, particularly among the elderly, thus advocating the use of another Finnish innovation (**ColonView-FIT**, specific for human blood) to screen for the risk of colorectal cancer and early detection of its precursors

Among the dyspeptic patients, the unique GastroPanel® – Helicobacter test diagnoses

- Helicobacter pylori -infection
- Atrophic gastritis (gastric mucosal atrophy and dysfunction) and its location in antrum and/or corpus
- Level of gastric acid output. Continuous high acid output predisposes to oesophageal reflux disease, with associated ulcerative oesophagitis, Barrett's oesophagus and lower oesophageal cancer

THE GASTROPANEL-DETECTED

i) symptomatic post-treatment Helicobacter infection,ii) atrophic gastritis oriii) symptomatic high acid output

are indications for gastroscopy and biopsies

• The Finnish recommendations of the current management guidelines for "Dyspepsia and reflux symptoms" (PPI-test treatment and use of UBT- or SAT-tests) are incapable of accurately diagnosing H. pylori-infection and completely fail to detect atrophic gastritis, with the risk of gastric and oesophageal cancer and other conditions

BIOMARKERS

- Pepsinogen is the precursor of pepsin
 - Pepsinogen I level reflects the function of gastric corpus (body) mucosa
 - Pepsinogen II level reflects the mucosal function of the whole stomach
- Gastrin-17 is a peptide hormone synthesized by the G-cells in the gastric antrum
 - regulates the acid output of gastric corpus and reacts to changes in this output
- *Helicobacter pylori* -antibody levels disclose an ongoing *H.pylori* infection or previous exposure to this bacteria
- Jointly with pepsinogen I and II levels, *H. pylori* –antibody test also discloses whether eradication has been successful
- Use of GastroSoft application for interpretation of the results of 4 biomarkers, together with the anamnestic data, gives a more comprehensive and accurate view on gastric mucosal function and integrity than possible to obtain by the stand-alone use of each marker (www.gastropanel.com)

WHY IS STOMACH HEALTH SO IMPORTANT

Atrophic gastritis (AG) is mostly asymptomatic (mucosal injury and dysfunction), and has two divergent etiologies:

- *H. pylori* infection can progress to AG if untreated
- Autoimmune mechanism

AG results in hypoacidid or acid-free stomach, which increases the risk of gastric and oesophageal cancer

- This risk can be reduced by **Acetium-capsules** which bind carcinogenic acetaldehyde born in acid-free stomach
- Autoimmune-type AG is frequentlyt accompanied by another autoimmune disease, e.g. celiac disease, IBD, rheumatoid arthritis, SLE, type 1 diabetes (DM1) and autoimmune thyroid disease (AITD)

As compared to subjects with healthy stomach, AGpatients have an increased risk for gastric cancer (GC) that remains asymptomatic for a long time:

- AG in the corpus: 5 x risk
- AG in the antrum: 18 x risk
- AG in both corpus and antrum: 90 x risk for GC

GASTRIC AND OESOPHAGEAL CANCER IN FINLAND

- Annually, 570 new cases of GC are encountered and 460 patients die of GC, the respective numbers for oesophageal cancer being 330 and 270 (high >70% mortality)
- Dyspesia and Reflux symptoms Best Practice Guidelines- recommended measures (PPI-test treatment and UBT- or SAT-testing) do not reliably detect H.pylori-infection and completely fail to diagnose AG with the risks of GC, oesophageal cancer and others
- AG remaining undetected on time (increases with age; 10% among elderly) or prolonged unnecessary PPI (test) treatment might delay the correct diagnosis and preclude the patients' access to curative therapy
- Nationwide implementation of GastroPanel in the first-line diagnosis and screening could potentially avoid unnecessary cancer deaths and numerous other diseases as well as reduce the ever increasing health care costs

WHY GASTROPANEL BLOOD TEST

1. To increase patient safety and to reduce costs, for symptomatic dyspeptic patients and for health checks of asymptomatic subjects, GastroPanel as the first-line diagnostic test before endoscopy, unless the patient has alarming symptoms

- Endoscopy with biopsies is an expensive procedure and as the first-line examination, up to 80% are unnecessary and felt unpleasant by most patients
 - Current management guidelines make referral for endoscopy often only when the patient has alarming symptoms, when the outlook is poor
 - GastroPanel-diagnosis and screening help on timely finding of the subjects for endoscopy, treatment and follow-up

2. GastroPanel corrects the severe shortcomings of the current management guidelines (*Dyspepsia and reflux symptoms*). The recommended UBT (13C-urea breath test) and SAT (stool antigen test) do not detect AG, and in addition, they can give false negative results on *H. pylori*, and do not give any information on gastric acid output.

- Without correct *H. pylori* -diagnosis and/or timely diagnosis of AG, patients may develop or even succumb of gastric and oesophageal cancer or *H. pylori* -associated peptic ulcer disease
- Atrophic gastritis is the major cause of vitamin-B12 deficiency and the resulting diseases, like peripheral neuropathy, depression, dementia and possibly Alzheimer's disease
- Atrophic gastritis can contribute to calcium deficiency, and the resulting osteoporosis with bone fractures, as well as iron deficiency and the consequent diseases

3. Coinciding the increased age, B12-vitamin-, calciumand iron deficiency have become an increasing burden

4. AG remaining undetected by UBT- and SAT tests, can cause severe and even fatal respiratory and gastroin-testinal infections particularly among elderly people

Dyspepsia and Reflux symptoms -Management Guidelines do not include any warning about the severe shortcomings of the UBT and SAT tests.

HUSLAB laboratory test directory includes the following indications for GastroPanel test:

- The tests are used for the diagnostic workup of the symptoms in dyspeptic patients,

- in diagnosis of *Helicobacter pylori* infection, as well as
- for early detection of atrophic gastritis

http://www.huslab.fi/Tutkimusohjekirja search with helikobakteeri: 20609 fP-Mabi-La fP-Mahalaukun biomerkkiainetutkimus, laaja

ADDITIONAL INFORMATION:

GastroPanel, ColonView-FIT and Acetium-innovations: www.gastropanel.com, www.colonview.com, www.acetium.com State of the art diagnosis of *Helicobacter pylori*: www.biohithealthcare.com Links / State of the art diagnosis of *Helicobacter pylori* www.biohithealthcare.com/Biohit-state-of-art-diagnosis-of-heliobacter-pylori-and-its-clinical-sequels GastroPanel test request form: www.biohithealthcare.com/test-request-form Screening model: www.gastropanel.com/decision-makers/screening-model Critisism about current care recommendations: www.biohithealthcare.com/Critisism-about-current-care-recommendations

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