Autoimmune diseases comprise a highly complex category of diseases affecting practically any organ of the human body. There is no single diagnostic test capable of identifying all autoimmune-based diseases. However, given the fact that not infrequently, more than one autoimmune disease coexist in the same patients, offers an opportunity to make screening of the patients with divergent symptoms, to confirm or exclude the potential autoimmune origin of the symptoms by using a diagnostic test panel.

Biohit Oyj has designed a test panel composed of four tests diagnosing specific diseases, all having a close link to autoimmune pathogenesis: 1) GastroPanel (GP), 2) Celiac Disease Quick Test (CDQT), 3) Biohit Calprotectin ELISA Test, and 4) Anti-Telomere IgG Test. These autoimmune conditions, of which possibly the first clue can be obtained with this test panel include the following: 1) pernicious anemia (PA), 2) type 1 diabetes mellitus (DM1), 3) autoimmune thyroiditis (AT), 4) rheumatoid arthritis (RA), 5) celiac disease (CD), 6) inflammatory bowel disease (IBD), and 7) systemic lupus erythematosus (SLE). These conditions share one thing in common, they all represent high-risk groups for developing autoimmune atrophic gastritis (AG), which makes them a suitable target for screening by GastroPanel test, supplemented with the additional disease-specific tests in the panel.

1) PA develops as a result of gastric mucosal atrophy (AG) due to an autoimmune mechanism, leading to B12-vitamin malabsorption and megaloblastic anemia that require life-long vitamin substitution. PA is much more rare than DM1, affecting some 850 000 Europeans. The stomach-specific biomarkers of the GP test readily identify AG, irrespective whether caused by autoimmune disease or Helicobacter pylori infection, thus detecting the subjects at risk to develop vitamin-B12 malabsorption and PA as well as some other risks, such as gastric and oesophageal cancers.

2) Of these 7 conditions, DM1 is by far the most common, affecting 55 million inhabitants of Europe. DM is a multi-organ disease with highly divergent symptoms, including AG and vitamin-B12 deficiency (PA), estimated to affect 12% of all DM1 patients.

3) AT is not an uncommon condition, affecting 17 million people in Europe. AT is known to be associated with high frequency of other autoimmune conditions, e.g. autoimmune AG estimated to affect up to 18% of all AT patients.

4) RA has an estimated prevalence of 8.5 million Europeans. Only anecdotal data are available on AG prevalence among RA-patients, but anti-telomere antibodies are found in 5% of RA patients and up to 18% of those with other autoimmune rheumatic diseases.

5) Celiac Disease (CD) is increasingly common, reported to be encountered in 1% of all people. CD is associated with a wide range of autoimmune diseases including DM1 and AG, although the exact excess risk of AG among CD patients is not known. CDQT is a highly specific test for CD.

6) Inflammatory bowel disease (IBD), comprising ulcerative colitis (UC) and Crohn’s disease (CrD) is increasing in frequency, with the current prevalence in Europe being estimated to vary between 300,000 and 2.5 million people. The prevalence of associated AG is unknown, but suspected to be elevated like in the other autoimmune conditions, where multi-organ involvement is a common feature. Biohit Calprotectin ELISA test is highly accurate in diagnosing IBD apart from IBS (irritable bowel syndrome) with overlapping symptoms.

7) Of the listed conditions, SLE is the least common, affecting around 250,000 Europeans, i.e., prevalence of 0.1-0.2%. Human antibodies against telomeric DNA have proven to be a specific and sensitive test for SLE. Because SLE resembles autoimmune rheumatic diseases, the Biohit anti-telomere IgG test is useful in making the distinction between SLE and RA, >60% of the former testing positive in contrast to only 5% of RA patients.
The rational for using the 4-test panel for screening of both symptomatic and asymptomatic individuals is three-fold. First, a fully normal result in all four tests excludes (with a high negative predictive value) the existence of a wide range of stomach diseases and functional disturbances, as well as CD, IBD and SLE (1,3). Second, in subjects testing positive for tests 2-4 in the panel, the specific diagnosis can be confirmed by relevant clinical tests. Third, detecting AG in the GP test should alert the clinician to consider the potential co-existence of all other autoimmune diseases in this list, known to increase the risk of AG (2,4-16). When used together, these four tests can give the potential first-hand clues on the existence of an autoimmune-type disease and thus help guiding the patients to further examinations for confirmation of the specific diagnosis.

**GastroPanel®- and Acetium®- innovations**

The GastroPanel® blood examination reveals *Helicobacter pylori* infection and atrophic gastritis with related risks, including an increased risk of gastric and oesophageal cancer. Acetium® capsule, that binds the carcinogenic acetaldehyde to form a harmless compound in the stomach, may decrease the risk of these cancers [www.biohithealthcare.com/additional-information](http://www.biohithealthcare.com/additional-information).

**Acetium® capsules** bind carcinogenic acetaldehyde in the stomach with individuals suffering from an anacitic stomach due to the following reasons: 1) a corpus atrophic gastritis, 2) long-term PPI medication or 3) a stomach surgery, as well as in individuals with 4) gene mutation affecting acetaldehyde metabolism or 5) chronic helicobacter infection that also produces acetaldehyde.

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**GastroPanel®, the unique *Helicobacter pylori* test can detect the following conditions:**

1) *Helicobacter pylori* (*HP*) infection which is an independent risk factor of both gastric cancer and peptic ulcer disease (gastric- and duodenal ulcer).

2) *HP* infection -induced atrophic gastritis (AG), which in most cases is asymptomatic, as well as the topographic site of AG either in the corpus or in antrum. Apart from *HP* infection, AG in the corpus with all its clinical sequels can also develop through an autoimmune disease of the gastric mucosa.

2.1) AG of the corpus mucosa leads to low acid output or eventually achlorhydric (acid-free) stomach. This increases the risk of gastric or esophageal cancer, as well as malabsorption of vitamin B12, calcium, magnesium and zinc. In addition, absorption of some medicines, e.g. dipyridamol, some iron preparations and anti-fungal drugs (fluconazol, itraconazol), thyroxin and atazanovir is impaired due to acid free stomach. Calcium deficiency can cause osteoporosis, and vitamin B12 deficiency can contribute to development of Alzheimer’s disease, dementia, depression or peripheral neuropathies. Reduced acid output in the stomach can also increase the risk of serious infections in the gastrointestinal- and respiratory tract, including giardiasis, malaria, Clostridium difficile, E. coli EHEC and pneumonia.

2.2) AG of the antrum that increases the risk of gastric cancer. Co-existent AG of the corpus and antrum (pan-gastritis) is the single most important risk condition for gastric cancer.

3) *HP* infection also in subjects with AG, MALT-lymphoma or bleeding peptic ulcer, and in those taking PPI medication or antibiotics. In these cases, 13C-urea breath test (UBT) or stool *HP* antigen test frequently give false negative results, and *HP* infection (with all its possible consequences) remains undetected. UBT may give false positive results in subjects with acid-free stomach. In addition, UBT and *HP* antigen or antibody tests do not detect AG due to *HP*-infection or autoimmune disease [http://www.biohithealthcare.com/limitations-of-helicobacter-pylori-diagnostics](http://www.biohithealthcare.com/limitations-of-helicobacter-pylori-diagnostics).
4) High acid output of the gastric mucosa, which predisposes to esophageal reflux disease with potential complications. These are ulcerative esophagitis, Barrett’s esophagus or lower esophageal cancer.

Symptomatic *Helicobacter pylori (HP)* infection, atrophic gastritis (AG) and high acid output are recommended indications for gastroscopy.

The GastroPanel® innovation is based on follow-up studies on gastritis patients conducted by research groups in Finland and Estonia (1) and the discovery of the role of *Helicobacter pylori* in pathogenesis of gastritis and peptic ulcer disease, which led to Nobel Prize in 2005 (2), as well as on Biohit’s R&D and the microplate immunoassay analyzers based on the invention of the vertical light beam measurement principle (3,4).

4. www.biohithealthcare.com/About-Us/ Suovaniemi O. Aggressive innovation and patenting strategy. Additional information

REFERENCES


