BIOHIT Oyj’s INFORMATION FOR HEALTH CARE SECTOR AND ITS USERS

The purpose of this information is to draw the attention of the health care sector and its users to the significant benefits obtainable in the Finnish healthcare by implementing the diagnostic tests and other products of Biohit Oyj.

We hope you would find time to read this information and give us feedback e.g. by telling us about situations, where you have experienced that the diagnostic procedures and/or management strategies have not succeeded in the most optimal way.

Gastric- and oesophageal cancer

Gastric cancer decreases in Finland but identification of the risk factors is even more challenging, because the incidence of gastric cancer has steadily decreased since the 1960’s. Nevertheless, the risk factors remain the same. Two most important ones are Helicobacter Pylori (HP) and atrophic gastritis (atrophy of the stomach mucosa). In 2014, 650 patients developed gastric cancer and 430 died of it. The corresponding figures for oesophageal cancer were 307 and 257 persons.

The diagnosis for gastric cancer is still made too often in a stage when alarming symptoms, e.g., loss of weight and hematemesis, have already appeared and the prognosis is poor. One of the possible reasons might be that in our country, the clearly outdated 13C-urea breath test (UBT) and stool antigen test (SAT) are still used for HP diagnostic in patients suffering from upper abdominal complaints, despite the fact that these two tests might give false negative results. UBT might also give false positive results. In addition, these two tests, like HP antibody tests, fail to diagnose atrophic gastritis with the associated increased risk of gastric- and oesophageal cancer (above-mentioned limitations, study information).

From GastroPanel – blood test to the screening of the gastric- and oesophageal cancer risks

In patients suffering from dyspeptic symptoms as well as from asymptomatic subjects, GastroPanel detects, in addition to possible HP, also atrophic gastritis caused by HP or an autoimmune disease. GastroPanel is also suitable for screening of gastric- and oesophageal cancer risk groups (HP and atrophic gastritis). GastroPanel examination also gives a plenty of valuable additional diagnostic information for disease prevention and treatment (additional information, cost savings).

If GastroPanel detects 1) a symptomatic HP-infection after eradication therapy; 2) a usually asymptomatic atrophic gastritis, or 3) a symptomatic high acid output, it is recommended that a gastroenterologist performs gastroscopy with directed biopsies, which can detect even other diseases. In the basic- and occupational healthcare, GastroPanel should be an integral part of the diagnostic profile of all patients suffering from upper abdominal complaints. Also among asymptomatic subjects, GastroPanel detects the risk patients who should have an endoscopy performed with biopsies.

Worldwide, approximately 1.4 million people each year develop gastric- and oesophageal cancer. Due to the fact that the symptoms of these cancers are non-specific and the
pivotal risk factors, HP-infection and atrophic gastritis, are asymptomatic in most cases, the diagnosis is usually made too late. Only 15% of gastric cancer patients are alive after 5 years.

Because of this, and in part due to the reasons mentioned later, an international group of experts recommended already in 2012 that GastroPanel biomarkers should be used as the first-line diagnostic test for all patients suffering from dyspeptic symptoms.

One should keep in mind that in association with many relatively common autoimmune diseases, such as type 1 diabetes, thyroiditis or rheumatoid arthritis, an asymptomatic autoimmune atrophic gastritis can develop, an early diagnosis of which is important because of an increased stomach cancer risk.

**ColonView-FIT for screening of colorectal cancer**

ColonView-FIT, an immunochromatographic test specific and sensitive for human blood, is designed for early diagnosis and screening of colorectal cancer and its precursors. Especially among elderly people, the cause of upper abdominal complaints can be colon-derived even in half of the cases. Due to this fact, using GastroPanel and ColonView-FIT tests together in diagnosis of all patients suffering from such complaints helps and speeds the correct diagnosis, increasing the patient safety and saving costs.

Implementation of the national colorectal cancer screening program should be prompted because 3050 patients develop and 1220 dies of colorectal cancer in Finland each year. Because of this, the modern FIT test, specific to human blood, should be the test-of-choice for the national screening program for colorectal cancer. Screening of colorectal cancer would be the first national cancer screening, in which also the men can participate.

**Biologically active B12-vitamin**

The most important cause for vitamin-B12 deficiency is atrophic gastritis, which still often goes undiagnosed in an early stage (see above). When GastroPanel detects HP or atrophic gastritis caused by an autoimmune disease, the possibility of B12 deficiency should always be considered, caused by malabsorption due to atrophic gastritis. Deficiency of vitamin-B12 is very common especially among elderly people, being encountered in approximately one out of ten subjects over 65-years of age in Finland. A delayed diagnosis can be accompanied by permanent neurological damage, depression and dementia. When the atrophic gastritis in an asymptomatic subject has been detected, the eventual vitamin-B12 deficiency is easy to confirm with another Biohit test, which measures the level of active vitamin-B12 from a blood sample.

**Acetium capsule and Acetium lozenge**

Acetium capsules bind carcinogenic acetaldehyde in an acid-free stomach binding it into a harmless compound. As a result of a long-term PPI-medication, acid output in the stomach is decreased, with possible acid-free stomach as an end result. This is related to an increased risk of gastric cancer (among other things). Consequently, it is recommended that persons with long-term PPI-medication should start using Acetium-capsules. Approximately 10 % of the western population is using occasionally or continuously PPI-medication, which eliminates the symptoms and might delay the diagnosis of gastric cancer beyond the reach of curative treatment.
Because of this, it is always advisable that before starting PPI-medication, GastroPanel test is done to confirm that the patient does not already have an acid-free stomach.

Acetium capsule is the only product on the market, which significantly helps reduce the impact of carcinogenic acetaldehyde in the stomach and oesophageal mucosa. Globally, approximately 500 million people are estimated to suffer from an atrophic gastritis.

**New indications of use for Acetium capsule and lozenge**

The currently ongoing clinical studies are examining new potential indications of use for Acetium capsules. Preliminary evidence suggests e.g. that regularly used Acetium capsules can help prevent migraine ([Study Protocols](#)).

Acetium lozenge might also provide an effective means in smoking intervention. This type of evidence was provided by a preliminary study, during which a substantial proportion of study subjects were able to quit smoking with help of Acetium lozenge. To confirm these tentative observations, a more comprehensive study is ongoing.

Acetium lozenge with its xylitol context also promotes oral health, in addition to binding carcinogenic acetaldehyde dissolved into the saliva from cigarette smoke and alcohol converting it into a harmless compound. Because smoking and alcohol are the most important risk factors of oral cancer, Acetium lozenge might also provide protection against oral cancers. Nevertheless, Biohit recommends giving up smoking.

**Possibilities for improving treatment practices**

It is possible to improve the diagnostic and management practices in Finland by new domestic innovations (GastroPanel, ColonView-FIT and Acetium) designed for diagnosis and prevention, both increasing the patient safety and contributing to cost savings in healthcare.

For example, a clinic offering *Helicobacter pylori* urea test (13C-urea breath test, UBT) as a sub-contractor fails to inform its customers about the serious limitations of the test, with potential impact on the patient safety. This means that the patient safety and costs also depend on the information that the health care users do receive and/or are capable of demanding from their service providers. As mentioned above, you may submit your feedback to info(at)biohit.fi.

A patient suffering from dyspeptic complaints or those who want to make a health check, can ask for GastroPanel, ColonView-FIT and other Biohit tests at private practices and public health centers- or from their occupational healthcare providers. It is also possible to book an appointment for the test without a referral of a doctor at www.biohit.fi/varaaverkossa or by telephone +358 400 603 222, weekdays 9-15. Acetium products can be purchased at pharmacies prescription-free (www.biohitshop.fi)

**Additional information:**
CEO Semi Korpela, Biohit Oyj
tel. +358 9 773 861
investor.relations@biohit.fi
www.biohithealthcare.com
Biohit in brief

Biohit Oyj is a globally operating Finnish biotechnology company. Biohit mission is “Innovating for Health” – we produce innovative products and services to promote research and early diagnosis. Biohit is headquartered in Helsinki, Finland, and has subsidiaries in Italy and the UK. Biohit Series B share (BIOBV) is quoted on Nasdaq Helsinki in the Small cap/Healthcare group. www.biohithealthcare.com