PRODUCT CATALOGUE

Innovations to prevent illnesses and improve quality of life

GastroPanel® | ELISA tests | Quick tests | Acetaldehyde binding products | Monoclonal antibodies

BIOHIT
Innovating for Health

# BIOHIT in brief

Biohit Oyj is a globally operating Finnish biotechnology company established in 1988. Biohit's mission is "Innovating for Health".

Biohit shoulders its social responsibility by creating innovative new technologies and services that help physicians and research institutions to promote diagnostics and research. Our innovations help prevent diseases of the gastrointestinal tract, reduce human suffering and avoid financial loss, thereby fostering wellbeing for people, healthcare providers, and society. Our social responsibility reaches beyond traditional product delivery by adopting a duty to raise public awareness of acetaldehyde, a group 1 carcinogen, and to innovate, develop and market products and services, globally, ensuring their maximum availability to the world´s public. Biohit is headquartered in Helsinki and has subsidiaries in Italy and the UK. Biohit's Series B share (BIOBV) is quoted on NASDA Q OMX Helsinki since 1999, Small cap/Healthcare.

## Innovations

Gastrointestinal disorders are a growing worldwide phenomenon exacerbated by an ageing population, that generate significant medical, ethical and financial issues. Gastrointestinal disorders are also the most common reasons to consult health professionals and require fast and effective management to deliver earlier diagnosis, tailored treatment, and better patient outcomes. This patient-centered approach helps tackle the growing financial and resource constraints borne by general healthcare sectors worldwide.

Biohit's products and services are safe, ethical and cost efficient innovations for diagnosing and preventing gastrointestinal diseases and the associated risks.

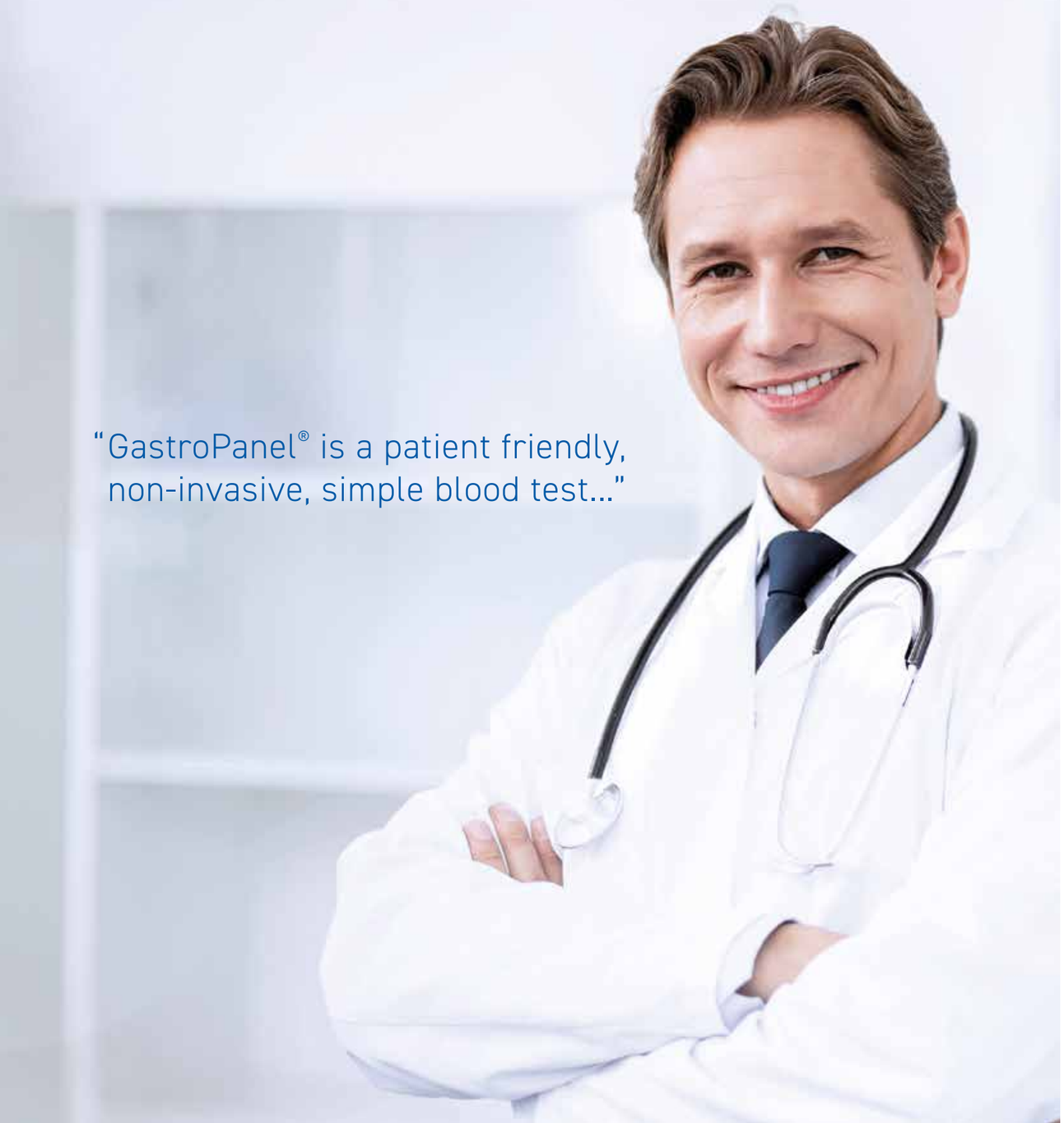
www.biohithealthcare.com

# Contents

# GastroPanel®

INNOVATION IN THE DIAGNOSIS OF ATROPHIC GASTRITIS FROM A BLOOD SAMPLE

GastroPanel® innovation has been developed as a result of decades of research in order to reliably diagnose *Helicobacter pylori* infection and atrophic gastritis. Until the development of GastroPanel, gastroscopy and biopsy examination were the only reliable methods for the diagnosis of these conditions.



"GastroPanel® is a patient friendly, non-invasive, simple blood test..."



# GastroPanel®

SCREENING AND DIAGNOSIS OF ASYMPTOMATIC AND DYSPEPTIC SUBJECTS

GastroPanel® is a patient friendly, non-invasive, simple blood test to evaluate the function and structure of stomach mucosa. GastroPanel is intended as the first-line diagnostic test for patients suffering from dyspepsia. It is particularly useful for general practitioners and occupational health doctors, because the results can be used to triage patients for further investigations (e.g. gastroscopy).

GastroPanel measures four biomarkers. Three of these biomarkers are secreted by the cells in gastric mucosa: pepsinogen I (PGI), pepsinogen II (PGII) and gastrin-17 (G-17). These are complemented by *Helicobacter pylori* antibody measurement. This complete panel of all four biomarkers provides a more comprehensive profile of the gastric mucosa than could be achieved using any of these as stand-alone biomarkers.

GastroPanel identifies *Helicobacter pylori* infection and indicates whether chronic infection has progressed to atrophic gastritis. GastroPanel also accurately confirms abnormalities in acid output. Since *Helicobacter pylori* infection and atrophic gastritis are the most important risk factors for stomach cancer, GastroPanel can also be used for screening of asymptomatic subjects for the risks of gastric cancer.

**GastroPanel® can be used to:**

- Identify patients with healthy gastric mucosa
- Diagnose *H. pylori*
- Diagnose atrophic gastritis
- Identify patients with abnormal (high or low) acid output
- Identify patients who need gastroscopy
- Screening asymptomatic subjects for the risks of stomach cancer

**GastroPanel® will highlight the following risks:**

- Deficiency of Vitamin B12 and other micronutrients
- Peptic and duodenal ulcers
- Gastric and esophageal cancer

**GastroPanel® will disclose the need for further investigations:**

- Gastroscopy and biopsy
- *Helicobacter* eradication treatment
- Additional investigations for malabsorption or anemia

GastroPanel kits are based on the ELISA (enzyme-linked immunosorbent assay) principle and hence can be used with a variety of analysis equipment (manual or automated). The latest kits feature unified reagents and reaction conditions, making them even more accessible.

**GastroPanel® Standard**

| REF | Product | Qty |
|---|---|---|
| 601300 | GastroPanel® Standard | 1 package |
| 601010.01 | Pepsinogen I | 96 wells |
| 601020.02 | Pepsinogen II | 96 wells |
| 601035 | Gastrin-17 Advanced | 96 wells |
| 601040.02 | *Helicobacter pylori* IgG | 96 wells |

**GastroPanel® Unified**

| REF | Product | Qty |
|---|---|---|
| 606400 | GastroPanel® Unified | 1 package |
| 606010 | GastroPanel® Pepsinogen I | 96 wells |
| 606020 | GastroPanel® Pepsinogen II | 96 wells |
| 606035 | GastroPanel® Gastrin-17 | 96 wells |
| 606040 | GastroPanel® *Helicobacter pylori* | 96 wells |

CE IVD

# GastroPanel Four-in-One™

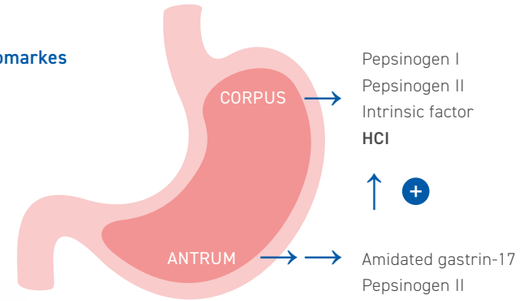
GastroPanel Four-in-One™ is based on the well-established GastroPanel Unified®. Instead of having four individual kits, Four-in-One provides all analytes on one ELISA plate.

The main advantage is that all analytes can be analyzed during a single analysis cycle. This radically shortens the turn-around times for laboratories, delivering fast results to doctors and patients alike. Up to 18 patient samples can be analyzed on a single plate, with performance that is equal to the GastroPanel Unified. The assay supports both manual and automated ELISA methods. Additionally, ready-made protocols already exist for some of the most common ELISA automates.

Like all GastroPanel family products, GastroPanel Four-in-One™ provides a minimally invasive tool for identifying the organic origin of dyspepsia symptoms, and to diagnose *Helicobacter pylori* infection. The levels of PGI and PGII, G-17 and *H. pylori* antibodies provide information on both the structure and the function of the stomach mucosa, assisting health care professionals to treat dyspetic patients and to screen subjects at risk of gastric cancer. In combination with the dedicated GastroSoft™ analysis software (available free-of-charge as a cloud service), it is truly a superior tool for firstline diagnosis of dyspeptic patients and for population-based screening. For more information on the type of clinical information provided by this assay, please see page 5. of the catalogue.

"GastroPanel Four-in-One™ provides all analytes on one ELISA plate."

**GastroPanel® biomarkes**





**GastroPanel Four-in-One™**

| REF | Product | Qty |
|---|---|---|
| 606080 | GastroPanel Four-in-One™ | 96 wells |

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# GastroPanel® Report

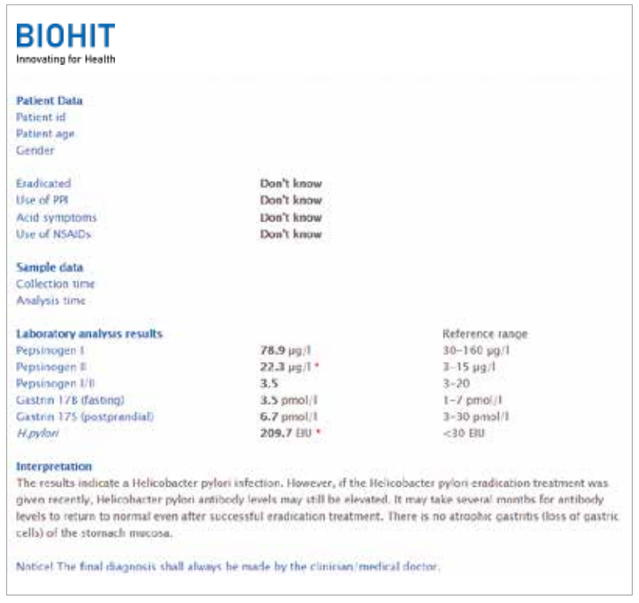
GastroSoft™ is a software application designed to assist clinicians/general practitioners in interpreting GastroPanel® test results in the context of the recorded anamnestic information. The GastroPanel report is intended for healthcare professionals only. The final responsibility of the diagnosis and treatment always rests with the patient's doctor.

The GastroPanel flowchart (below) depicts the eight distinct biomarker profiles and their interpretation. A more detailed written report covering all these profiles is produced by the GastroSoft application.

**Create your own GastroPanel® report at www.gastropanel.com**

- → **Healthcare professionals and laboratories**
- → **GastroPanel® report**

**GastroPanel® report by the GastroSoft™ helps interpret the results**



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**Patient Data**
Patient id
Patient age
Gender

| | |
|---|---|
| Eradicated | **Don't know** |
| Use of PPI | **Don't know** |
| Acid symptoms | **Don't know** |
| Use of NSAIDs | **Don't know** |

**Sample data**
Collection time
Analysis time

| **Laboratory analysis results** | | Reference range |
|---|---|---|
| Pepsinogen I | **78.9** µg/l | 30–160 µg/l |
| Pepsinogen II | **22.3** µg/l * | 3–15 µg/l |
| Pepsinogen I/II | **3.5** | 3–20 |
| Gastrin 17B (fasting) | **3.5** pmol/l | 1–7 pmol/l |
| Gastrin 17S (postprandial) | **6.7** pmol/l | 3–30 pmol/l |
| *H.pylori* | **209.7** EIU * | <30 EIU |

**Interpretation**
The results indicate a Helicobacter pylori infection. However, if the Helicobacter pylori eradication treatment was given recently, Helicobacter pylori antibody levels may still be elevated. It may take several months for antibody levels to return to normal even after successful eradication treatment. There is no atrophic gastritis (loss of gastric cells) of the stomach mucosa.

Notice! The final diagnosis shall always be made by the clinician/medical doctor.

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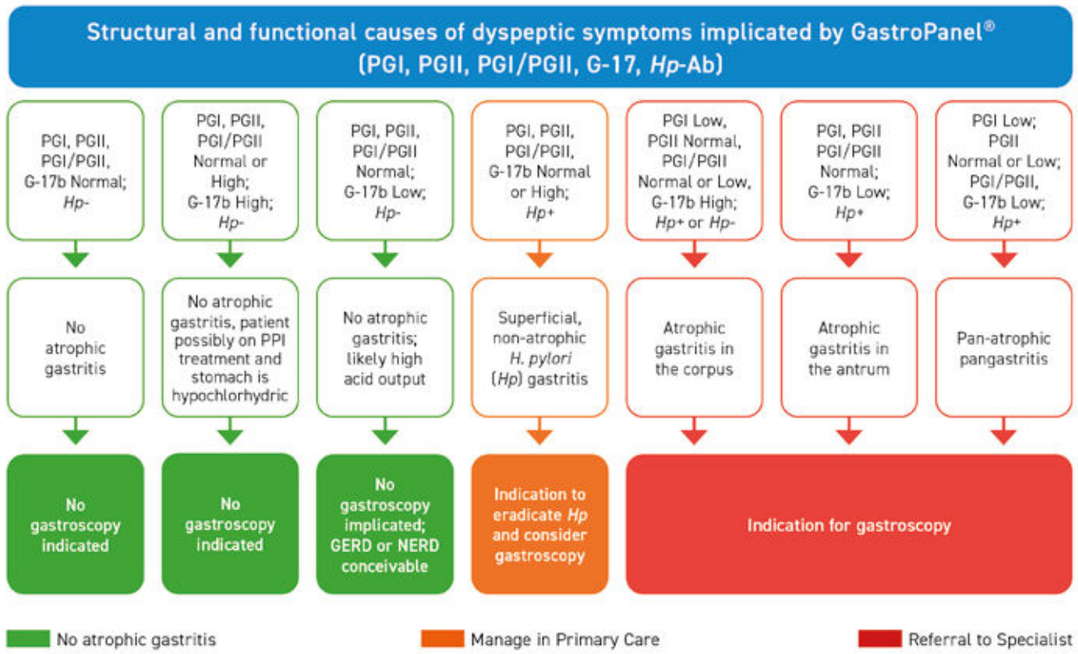
**GastroPanel® - interpretation guide snapshot**



# BIOHIT Laboratory tests

BIOHIT Calprotectin | BIOHIT Active B12 (HoloTC) | BIOHIT Total 250H Vitamin D

"Our mission, "Innovating for Health", describes our innovative products and services, which aim to promote medical research and early diagnosis, and prevent serious illnesses."



# BIOHIT Calprotectin

FOR MONITORING TREATMENT AND DIFFERENTIATING BETWEEN IBD AND IBS

BIOHIT Calprotectin is a quantitative test which provides a reliable differentiation between inflammatory bowel diseases (IBD) and irritable bowel syndrome (IBS). IBD is a disease classification characterized by chronic inflammation and includes ulcerative colitis and Crohn's disease. Patients suffering from either IBS or IBD may experience similar symptoms and a clinical examination alone may not be sufficient to give a specific diagnosis. Furthermore, these conditions may appear from early childhood to late adulthood and the diagnosis is often delayed due to vague symptoms or reluctance to perform endoscopy.

With BIOHIT Calprotectin, the differentiation between IBS and IBD can be made non-invasively and in-expensively from a stool sample. In organic disorders like IBD, the concentration of fecal calprotectin increases significantly, whereas with functional disorders like IBS this does not occur.

BIOHIT Calprotectin ELISA can also be used for monitoring the disease activity and mucosal healing of a patient with IBD. This for example helps to support the practitioner in making informed decisions concerning medication and the need for medical procedures such as endoscopy or surgery.

## Applications

- Differentiates inflammatory bowel diseases (IBD) from non-inflammatory bowel diseases (such as irritable bowel syndrome (IBS)).
- Monitoring of mucosal healing in IBD patients
- Relapse prediction (loss of therapeutic respons)

## Sampling made easy

- Consistency of the feces does not affect the result
- Only a small amount of sample required
- Easy handling with hygienic extraction tubes = reduced processing time

## Straightforward analysis

- Wide assay range with only one dilution 25 – 2500 mg/kg in feces
- Fits directly onto automated systems (*e.g.*, Dynex DS2)
- Validated results from a proven assay

**BIOHIT Calprotectin**

| REF | Product | Qty |
|---|---|---|
| 602260 | BIOHIT Calprotectin | 96 wells |
| 602270 | BIOHIT Extraction tubes | 50 pcs |

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# BIOHIT Active B12 (HoloTC)

FOR A CONCLUSIVE DETERMINATION OF VITAMIN B12 STATUS

The traditional method of diagnosing vitamin B12 deficiency has been to measure the concentration of total vitamin B12 in the serum. The total vitamin B12 concentration essentially reflects vitamin B12 which is bound to its two carrier proteins forming holohaptocorrin (holoHC) and holotranscobalamin (holoTC). Whilst HoloHC accounts for 70 % - 80 % of the vitamin B12 in serum, only holoTC (active vitamin B12) can be used by human cells. Measurement of total vitamin B12 can hence give erroneous results because it measures the vitamin B12 which is in circulation but does not indicate the active vitamin B12 proportions that is available to the cells of the body.

The BIOHIT Active B12 (HoloTC) test provides a solution to the above diagnostic paradox: this test directly measures (holoTC) – the biochemically active form of vitamin B12 – in the human serum. This test is well suited for the screening of patients with a suspected vitamin B12 deficiency. BIOHIT Active B12 test can also be used for confirming the vitamin B12 status in the large number of patients who get an inconclusive result from total vitamin B12 tests.

" Proven ELISA technology, support for both automated and manual analysis methods."

### BIOHIT Active B12 (HoloTC)

- Measures the concentration of active vitamin B12 (holotranscobalamin) available to the cells
- Proven ELISA technology, support for both automated and manual analysis methods
- Unlike total B12 kits, no issues with Intrinsic Factor Blocking Antibody (IFBA) interferences
- Numerous clinical studies proving the performance of active B12 over total B12


### BIOHIT Active B12 (HoloTC)

| REF | Product | Qty |
|---|---|---|
| 602290 | BIOHIT Active B12 (HoloTC) | 96 wells |

CE IVD



# BIOHIT Total 25OH Vitamin D

FOR A CONCLUSIVE DETERMINATION OF THE VITAMIN D STATUS

Vitamin D has multiple roles in the human body. In addition to its well-established role in the regulation of calcium absorption and promoting bone growth, it is recognized for other health benefits including reducing risk of diseases such as type 1 diabetes and common cancers.

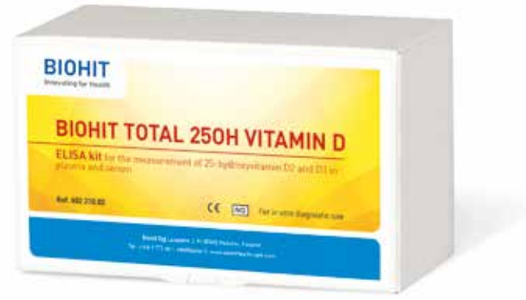
The best indicator of vitamin D status is the serum concentration of 25OH vitamin D. For a correct diagnosis of vitamin D deficiency, the assay must recognize two vitamins important in the human body, vitamin D2 and D3.

The BIOHIT Total 25OH vitamin D kit is a quantitative immunoenzymatic assay. Bydetecting both 25OH vitamin D2 and D3, the kit provides clinically relevant information on the vitamin D status. Reliability of the results is assured by validation against the ID-LC - MS/MS Reference Measurement Procedure (Ghent method) as approved by the Vitamin D Standardization Program (VDSP) with R>0.97.

" The best indicator of vitamin D status is the serum concentration of 25OH vitamin D."

### BIOHIT Total 25OH Vitamin D

- Detects both 25OH vitamin D2 and D3 for a clinically meaningful assessment of vitamin D status
- Calibrated against the ID-LC-MS/MS Reference Measurement Procedure
- User-friendly and fully automatable assay protocol




### BIOHIT Total 25OH Vitamin D

| REF | Product | Qty |
|---|---|---|
| 602310.02 | BIOHIT Total 25OH Vitamin D | 96 wells |

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# BIOHIT quick tests

GastroPanel® quick test NT | BIOHIT Celiac quick test | BIOHIT ColonView® quick test | BIOHIT *Helicobacter pylori* UFT300 | *Helicobacter pylori* quick test | Lactose Intolerance quick test

"Cost-effective innovations for healthcare."



## GastroPanel® quick test NT

GastroPanel® quick test NT is the Point-of-Care (POC) version of the well-established GastroPanel® test.

It is a semi-automated immunological lateral flow test for the quantitative detection of pepsinogen I (PGI), pepsinogen II (PGII), and gastrin-17 (G-17) and qualitative detection of antibodies against *Helicobacter pylori* from human fingerprick whole blood, venous whole blood or EDTA plasma samples. GastroPanel quick test NT is used with the GP Reader NT device (REF 740450). The test is to be used by healthcare professionals, either in a laboratory-based or Point-of-Care setting.

GastroPanel quick test NT is intended for diagnosing *H. pylori* infection and atrophic gastritis (AG) from patients with dyspeptic symptoms or at risk of developing malignant cellular changes in the stomach mucosa. In addition, the test can aid in screening settings to identify individuals at risk who may require additional examinations or treatment.

Dyspepsia management in primary care varies considerably and often treatment is determined without a proper diagnostic test. This can lead to overuse of expensive and burdensome endoscopy and even health issues caused by a long-term use of proton pump inhibitors, or failure to diagnose and treat a *Helicobacter pylori* infection. *H. pylori* is known to be a root cause for many gastric pathologies, including gastric cancer, gastritis and ulcer, and a chronic infection caused by this pathogen may be associated with various neurological and metabolic disorders, as well as some cardiac and respiratory diseases.

GastroPanel was developed to meet the need to have a minimally invasive tool for identifying the organic origin of dyspepsia symptoms, and to diagnose *H. pylori* infection. The levels of PGI and PGII, G-17 and *H. pylori* antibodies provide information on both the structure and the function of stomach mucosa, hence assisting health care professionals to treat dyspepsia and to screen subjects at risk of developing malignant cellular changes. The GastroPanel quick test NT system utilizes the same combination of validated biomarkers and decision algorithm in a Point-of-Care setting. This next-generation version of the GastroPanel can save time and costs and can be deployed in any clinical setting, expediting referral to further examinations and treatment for patients that need it.



**GastroPanel® quick test NT**

| REF | Product | Qty |
|---|---|---|
| 602410 | For plasma and venous whole blood | 30 tests |
| 602420 | For fingerprick whole blood | 30 tests |

**GP Reader NT**

| REF | Product |
|---|---|
| 740450 | GP Reader NT |

CE IVD

# BIOHIT Celiac quick test

### Accurate results from fingertip blood

BIOHIT Celiac quick test enables non-invasive and accurate testing of celiac disease from only a drop of blood. The test is based on the detection of anti-tissue transglutaminase antibodies (tTG; IgA, IgG and IgM). The test therefore delivers a superior sensitivity, especially in patients with IgA deficiency.

### Easy testing at the Point-of-Care

The blood sample for BIOHIT Celiac quick test is taken as a fingerprick sample. The sample is placed on a lateral flow test cassette along with a buffer solution. The test result is clearly visible within 10 minutes.

"Easy-to-Use lateral flow quick test - Results in 10 minutes!"

**BIOHIT Celiac quick test**

- Sample: fingerprick / whole blood, plasma or serum samples
- BIOHIT Celiac quick test helps to enable accurate and patient-friendly testing of celiac disease from only a drop of blood.
- Results available in 10 minutes
- Detects antibodies (IgA/IgG/IgM) against human tissue transglutaminase



**BIOHIT Celiac quick test**

| REF | Product | Qty |
|---|---|---|
| 602070 | BIOHIT Celiac quick test | 20 tests/package |
| 602080 | BIOHIT Celiac quick test | 50 tests/package |

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# BIOHIT ColonView® quick test (FIT)

### Detects bleeding derived from lower GI tract

BIOHIT ColonView® quick test is an immunological lateral flow test which detects hemoglobin and hemoglobin-haptoglobin complex (i.e., degraded hemoglobin) from a stool sample. The test can be used to detect bleeding derived from the lower parts of the GI tract. Due to the Hb/Hp complex, ColonView quick test is highly effective in detecting bleeding from the entire colorectal tract, including the proximal colon. This gives the ColonView test a superior sensitivity and specificity to detect bleeding cancer tumors as well as their precursors (small polyps and adenomas).

### One sample is enough for dual testing

Clever design of the ColonView sampling tube eliminates patient errors and ensures that there will always be the correct sample amount. The sampling tube is also a closed system which makes it hygienic to handle by the patient, safe during transportation, and precise in the laboratory. The sampling tube contains all the necessary reagents and no additional accessories are needed for the analysis. One sample is enough to test both Hb and Hb/Hp complex.

"One sample is enough to test both Hb- and Hb/HP complex - Results in 15 minutes!"

**BIOHIT ColonView® quick test (FIT)**

- Advanced tool to detect bleeding accurately from both proximal and distal colon
- Superior sensitivity and PPV
- Clever design of the sampling tube eliminates patient errors
- Closed system → hygienic sampling, transportation and analysis
- Specificity 100 %


**BIOHIT ColonView® quick test (FIT)**

| REF | Product | Qty |
|---|---|---|
| 602250.02 | BIOHIT ColonView® quick test (FIT) | 30 tests |
| 602390 | BIOHIT ColonView® QT Control | 1 bottle |

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# BIOHIT *Helicobacter pylori* UFT300

### Ultra-fast *H. pylori* detection from a biopsy

BIOHIT *Helicobacter pylori* UFT300 is a true quick test for the detection of *H. pylori* from a biopsy specimen. The biopsy taken during gastroscopy, can be tested immediately to diagnose *H. pylori* infection or to determine the success of eradication therapy. The test results are ready in just 5 minutes enabling diagnosis and reporting at the same time. This saves the patient from an unnecessary follow-up visit to the doctor for their test results.

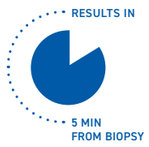
BIOHIT *H. pylori* UFT300 quick test has excellent sensitivity and specificity compared to gold standard which makes it a highly reliable and accurate tool for diagnostics.

### Biopsy testing could not be easier

BIOHIT *H. pylori* UFT300 quick test is easy and effortless to use. The biopsy specimen is placed into the test tube or well of the plate and mixed with the test reagent. A clearly visible color change indicates the presence of *H. pylori* in the specimen. The procedure is safe and efficient for the user, and the interpretation of the result doesn't require specialist training.

### BIOHIT *Helicobacter pylori* UFT300

- Ready-to-use test kit
- Results ready in 5 min (both positive and negative)
- Storage at room temperature
- Sensitivity 94.5 %, Specificity 100 %
- Testing and reporting during one appointment






**BIOHIT Helicobacter pylori UFT300 with plate**

| REF | Product | Qty |
|---|---|---|
| 602005PLA | BIOHIT *Helicobacter pylori* UFT300 | 5 tests |
| 602019PLA | BIOHIT *Helicobacter pylori* UFT300 | 50 tests |
| 602017 | BIOHIT *Helicobacter pylori* Control | 1 bottle |

**BIOHIT Helicobacter pylori UFT300 with tube**

| REF | Product | Qty |
|---|---|---|
| 602019 | BIOHIT *Helicobacter pylori* UFT300 | 50 tests |
| 602021 | BIOHIT *Helicobacter pylori* UFT300 | 100 tests |
| 602017 | BIOHIT *Helicobacter pylori* Control | 1 bottle |

*In the United States and Japan for research use only.*

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# *Helicobacter pylori* quick test

### Easy testing from a biopsy specimen

*Helicobacter pylori* quick test is a one-step test method to detect *H. pylori* infection from a biopsy sample during gastroscopy. *Helicobacter pylori* quick test can be used to diagnose *H. pylori* infection or to determine the success of eradication therapy. The positive results for *H. pylori* are ready in a few minutes, and the final confirmation of a negative test result is ready in just 30 minutes.

Using *Helicobacter pylori* quick test is an easy one-step procedure. The biopsy specimen is immersed into the gel medium, and if *H. pylori* urease is present in the specimen, a red color develops in the gel. Interpretation of the indicator color is simple and does not require any specialist training.

### Background information on the *H. pylori* test

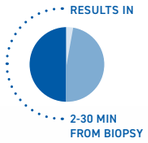
*Helicobacter pylori* infection is the most important cause of chronic gastritis. Another mechanism for gastritis and severe atrophic gastritis is the autoimmune mechanism, which can also be triggered by an *H. pylori* infection.

The epidemiological evidence of a link between *H. pylori* infection and gastric adenocarcinoma or mucosa associated lymphoid tissue (MALT) lymphoma has resulted in classification of the organism as a group I carcinogen.

"Reliable, rapid *H. pylori* testing from a biopsy specimen."

### *Helicobacter pylori* quick test

- Testing and reporting during gastroscopy
- One-step test procedure
- Clear visual interpretation
- Positive results in 1-2 min (negative max. 30 min)





**Helicobacter pylori quick test**

| REF | Product | Qty |
|---|---|---|
| 602015 | *Helicobacter pylori* quick test | 50 tests |
| 602017 | BIOHIT *Helicobacter pylori* Control | 1 bottle |

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# Lactose Intolerance quick test

**Confirmed results during gastroscopy**
Lactose Intolerance quick test detects all types of lactase deficiency from biopsy specimens. This gives added value to gastroscopies with minimum effort. The test is based on the normal lactase enzyme reaction and can detect lactase deficiency and indicate the enzyme's functionality. The Lactose Intolerance quick test is not only a sensitive diagnostic tool, but it has also been found to be more accurate than lactose breath tests in predicting clinical response to a lactose-free diet.

**Easy testing from a duodenal biopsy specimen**
The test procedure of the Lactose Intolerance quick test is fast and simple. The biopsy specimen is placed in the test plate and test reagents are added to the sample. A clear color change indicates the test result within 20 minutes enabling testing and reporting during the procedure

"The test procedure of the Lactose Intolerance quick test is fast and simple."

**Lactose Intolerance quick test**

- Results in 20 minutes
- Simple color chart interpretation
- All reagents ready-to-use
- Sensitivity 95 %, specificity 100 %
- Superior sensitivity compared to lactose breath test



**Lactose Intolerance quick test**

| REF | Product | Qty |
|---|---|---|
| 602010 | Lactose Intolerance quick test | 25 tests |
| 602012 | Lactose Intolerance quick test | 10 tests |
| 602018 | BIOHIT Lactase Control | 1 bottle |

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# Acetaldehyde Binding Products

Acetium® lozenge - quit smoking | Acetium® capsule

"Acetium® is a patented family of consumer products developed to eliminate acetaldehyde, a common, yet poorly known carcinogenic substance."

# Acetaldehyde

GROUP I HUMAN CARCINOGEN THAT WE ARE EXPOSED TO EVERY DAY

### Group I carcinogen

The World Health Organization (WHO) has classified acetaldehyde contained in alcoholic beverages and endogenously produced from alcohol as a Group I human carcinogen. This means that acetaldehyde is in the same group as asbestos and tobacco. Continuous exposure to acetaldehyde increases the risk of cancer.

### Where is acetaldehyde present?

Alcohol and tobacco are the major sources of acetaldehyde. Acetaldehyde is the most significant byproduct of alcohol metabolism and one of the most harmful substances in tobacco smoke.

In addition, acetaldehyde is present in foods. It is particularly abundant in food produced by fermentation, such as alcoholic beverages, vinegar, dairy products, home-brewed beer and mead. In some foods, acetaldehyde occurs naturally, such as in fruits and fruit-based products.

Due to its pleasant fruity smell, acetaldehyde is also used as a flavoring in the manufacture of yoghurts, sweets, pastries, fruit juices and alcoholic beverages.

### Acetaldehyde in the mouth and stomach

Acetaldehyde in tobacco smoke dissolves easily in saliva and is distributed through the throat to the stomach. Another significant source of acetaldehyde in the body is microbial metabolism.

The normal microbial flora within the body produce acetaldehyde by oxidizing ethanol and by fermentation from sugar. Yeasts and bacteria belonging to the normal microbial growth within the mouth are constantly distributed to the stomach with saliva. In a normal, healthy stomach, hydrochloric acid (HCl) can kill the microbes. In some people, acid-producing cells of the mucous membrane of the stomach disappear due to atrophy of the mucous membrane (a condition called atrophic gastritis), and therefore microbes are able to colonize and multiply in the stomach and produce acetaldehyde. People who have taken antacid medicines for a long time to treat acidic stomach conditions are also at risk of microbial growth in the stomach. Unlike the liver, the mucous membrane of the digestive tract and the microbes of the stomach are not able to process acetaldehyde and turn it into acetic acid and water. Therefore, an abundance of acetaldehyde accumulates in the saliva, anacidic stomach, and the lower digestive tract.

*Helicobacter pylori* is capable of surviving in acidic stomachs and in chronic cases - can cause atrophic gastritis. In addition, *H. pylori* produces acetaldehyde.

### Millions are among the risk groups

People in certain risk groups are significantly more exposed to acetaldehyde than others. If a person belongs to one of the following groups, acetaldehyde is an increased risk factor to their health:

- Smokers
- Those with an acid-free or a low-acid stomach
- Those who use acid-suppression medicines to treat heart burn or upper abdominal discomfort and pain
- Individuals with a chronic *H. pylori* infection



# Acetium® lozenge

HELPS QUIT SMOKING

Acetium® lozenge is a nicotine-free smoking intervention product intended for those who want to quit smoking. It is easy to use: take one lozenge with every cigarette smoked. Smoking cessation with Acetium takes on average 3-6 months of regular use. Regular use of Acetium reduces the pleasure of smoking and changes the taste of the cigarette, therefore helping to quit smoking.

Acetium lozenge contains L-cysteine, which is a natural amino acid. L-cysteine effectively binds the acetaldehyde in saliva derived from cigarette smoke.

L-cysteine removes up to 90 % of the acetaldehyde dissolved into saliva during smoking. The lozenge dosage is 1 or 2 lozenges during smoking. The recommended maximum daily dose is 40 lozenges.

"Nicotine-free smoking intervention product."

### Acetium® lozenge - quit smoking

- Removes acetaldehyde from saliva during smoking.
- Sensations of smoking change during intervention.
- Tooth-friendly, contains xylitol. Poor oral hygiene increases local acetaldehyde formation.

### Acetium® lozenge - quit smoking

| REF | Product | Qty |
|---|---|---|
| 620430 | Acetium® lozenge - quit smoking | 10 x 30 lozenges |

*Not available in the United States.*


CE MD

**Acetium® lozenge is a breakthrough in smoking cessation therapy:**

- Acetium does not contain nicotine nor maintain addiction to nicotine
- Acetium contains only safe ingredients that are commonly found in foods
- Acetium is devoid of the side effects of conventional smoking intervention methods (such as nicotine dependence and possible adverse side effects of medicines)

# Acetium® capsule

PROTECTS STOMACH

Acetium® capsule protects the gastric mucosa from acetaldehyde in people who have an acid-free stomach, for example in the case of chronic atrophic gastritis or prolonged proton pump inhibitor use. Acetium capsules contain L-cysteine, which is a natural amino acid. L-cysteine effectively binds acetaldehyde locally in the stomach.

The World Health Organization (WHO) has classified acetaldehyde contained in alcoholic beverages and endogenously produced from alcohol as a Group I human carcinogen.

When an individula takes antacid medicines on a regular basis or suffers from an anacidic stomach, the bacteria and yeasts from the mouth can colonize the stomach. These bacteria and yeasts produce acetaldehyde every time they consume alcoholic beverages and food that contains alcohol or sugar.

*Helicobacter pylor*i thrives in the stomach even in the precense of acid and chronic infection can lead to an acid-free stomach, due to atrophic gastritis. In addition, *H. pylori* produces acetaldehyde.

## “Suitable *e.g.*, for PPI users.”

### Acetium® capsule

- Protects the stomach, especially in individuals who suffer from an anacidic (low- or no-acid) stomach or take antacid medicines
- Effectively removes acetaldehyde when taken during meals and alcohol consumption

### Acetium® capsule

| REF | Product | Qty |
|---|---|---|
| 620140 | Acetium 100 mg fi-sv-en | 4 x 15 blisters |
| 620095 | Acetium 100 mg ita-ger-fra | 4 x 15 blisters |

*Not available in the United States.*


CE 0537 MD

**Acetaldehyde is an increased risk factor to your health if:**

- you are suffering from an anacidic (low- or no-acid) stomach
- you are taking antacid medication (PPI or H2 blockers)
- you are suffering from a chronic *H. pylori* infection

The innovation of Acetium slow release formula effectively binds acetaldehyde locally in stomach.



# Monoclonal Antibodies

| Specificity | Clone# | Host | Subclass | Format | Qty* | Applications** | Paraffin*** | Ordering# |
|---|---|---|---|---|---|---|---|---|
| **Monoclonal Antibodies to Human Gastric Biomarkers** | | | | | | | | |
| Pepsinogen I | 4C6.1 | mouse | $IgG_1$ | purified | 100 µg | IHC | yes | 610055 |
| Pepsinogen II | L10CC10 | mouse | $IgG_1$ | purified | 100 µg | IHC | yes | 610056 |
| **Monoclonal Antibodies to Phytoestrogen** | | | | | | | | |
| Genistein | L22FA2 | mouse | $IgG_1$ | purified | 100 µg | EIA, FIA | - | 610058 |
| **Monoclonal Antibodies to Human Extracellular Matrix Components** | | | | | | | | |
| Cellular Fibronectin (cFn) | DH1 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB, EIA | no | 610001 |
| Tenascin-C | EB2 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB, EIA | no | 610002 |
| Tenascin-C | DB7 | mouse | $IgG_{2a}$ | purified | 100 µg | IHC, WB | yes | 610003 |
| Laminin ($ß_1$-chain) | DG10 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | no | 610004 |
| Laminin ($\gamma_1$-chain) | BC7 | mouse | $IgG_1$ | purified | 100 µg | IHC, IP | no | 610005 |
| Plasma Fibronectin (pFn) | BF12 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | no | 610006 |
| Vitronectin | BE10 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | no | 610007 |
| **Monoclonal Antibodies to Human Integrins** | | | | | | | | |
| $ß_1$-Integrin | DF5 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | yes | 610008 |
| $ß_1$-Integrin | DF7 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | yes | 610009 |
| $ß_3$-Integrin | BB10 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | no | 610010 |
| $\alpha_{IIb}$-Integrin | CA3 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | no | 610011 |
| **Monoclonal Antibodies to Human Endothelial Cell Surface marker** | | | | | | | | |
| PECAM-1 | CE6 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | no | 610027 |
| **Monoclonal Antibodies to Human Neurotransmitter Substances** | | | | | | | | |
| GABA | 5A9 | mouse | $IgG_1$ | purified | 100 µg | IHC, EIA | yes | 610025 |
| CGRP | CD8 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB, EIA | yes | 610026 |
| **Monoclonal Antibodies to Human Cytoskeletal Polypeptides** | | | | | | | | |
| α-Actinin | CB11 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | no | 610012 |
| α-Fodrin | AA6 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | no | 610013 |
| Vinculin | FB11 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | no | 610014 |
| Cytokeratin 18 | 4B11 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB, IP | no | 610015 |
| Cytokeratin 8, 18, 19 | 2A4 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | no | 610016 |
| Cytokeratin 7, 17, 19 | 4F5 | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | no | 610017 |
| Vimentin | 65E | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | no | 610018 |
| Neurofilaments 150, 200 | 13AA | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | no | 610021 |
| Neurofilaments 70, 200 | 14BA | mouse | $IgG_1$ | purified | 100 µg | IHC, WB | no | 610022 |
| **Monoclonal Antibodies to Human Spectrins** | | | | | | | | |
| Erythroid α-Spectrin | AF10 | mouse | $IgG_1$ | purified | 100 µg | IP, WB, IHC | no | 610023 |
| Erythroid ß-Spectrin | DB2 | mouse | $IgG_1$ | purified | 100 µg | IP, WB, IHC | no | 610024 |

*MAbs in other concentrations and in different buffer systems are available on request.*
**Other sizes available on request*
***The Biohit monoclonal antibodies are applicable in: IHC = Immunohistochemistry, WB = Western Blotting, FIA = Time-resolved Fluorescence Immunoassay, IP = Immunoprecipitation, EIA = Enzyme Immunoassay*
**** Reactivity with paraffin sections*

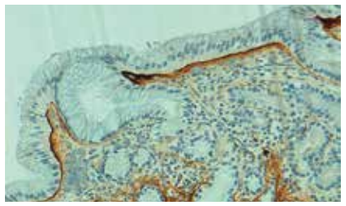
# Human Gastric Biomarkers

## Pepsinogen I

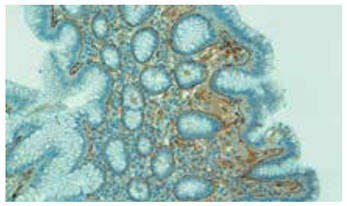
Pepsinogen I is a group of precursor molecules for pepsin. These proteins are solely synthetized and secreted into gastric lumen by chief (pepsin) cells and mucous neck cells in the gastric corpus (oxyntic mucosa). In atrophic corpus gastritis these cells disappear resulting in a decrease of the serum level of pepsinogen I and in a reduction of the number of pepsinogen I positive cells in gastric biopsies. The presence of positive immunostaining for pepsinogen I is a highly reliable indicator of the acid-secreting oxyntic glands. In gastric heterotopia of the duodenal bulb, but not in gastric metaplasia, the oxyntic-type glands give a positive immunohistochemical reaction for pepsinogen I.

## Pepsinogen II

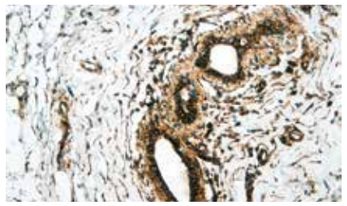
Pepsinogen II is a group of precursor molecules for pepsin. These proteins are secreted into the gastric lumen by the pyloric glands of the gastric antrum and by the chief and neck cells of the gastric corpus (oxyntic mucosa). In the presence of atrophic gastritis, negative immunohistochemical reaction for pepsinogen I but positive reaction for pepsinogen II, is a typical sign that the antral mucosa positive glands and cells are metaplastic and "pyloric" in differentiation (so called pseudopyloric metaplasia).



Tenascin-C



$ß_1$-Integrin



α- Fodrin (normal breast)

## Human Extracellular Matrix Components

The extracellular matrix (ECM) consists of interstitial connective tissue and basement membrane (BM). The ECM acts as a backbone for cells and provides a physical barrier. It also influences functions such as cell proliferation, differentiation, adhesion, migration, gene expression, and tissue integrity.

ECM also plays a profound role in tissue injury and healing. The detection of ECM components in various parts of the body provides an efficient tool for following malignant change, invasion and metastasis. Biohit provides monoclonal antibodies to: **Fibronectins, Tenascin, Laminins and Vitronectin**.

## Human Integrins

Integrins are the largest known family of receptors for ECM proteins. They are glycoproteins that mediate cell-extracellular matrix as well as cell-cell interactions. Integrins consist of several protein subfamilies that share a common ß-subunit and have a distinct α-subunit. Monoclonal antibodies to **$ß_1$-Integrin** and **$ß_3$-Integrin** as well as to **$α_{IIb}$-Integrin** are offered by Biohit.

## Human Cytoskeletal Polypeptides

The cytoplasmic cytoskeleton determines cell organization, shape and adhesion among other functions. Furthermore, the cell type-specific expression of intermediate filaments allows determination of the origin of many, otherwise unspecific tumours. Biohit offers monoclonal antibodies to the following cytoskeletal peptides: **α-Actinin, α-Fodrin, Cytokeratin 18, Cytokeratin 8, 18, 19, Cytokeratin 7, 17, 19, Neurofilament 70, 200, Neurofilament 150, 200, Vinculin and Vimentin.**



## Human Spectrins

Erythroid spectrins, some other proteins of erythroid cytoskeleton, and the transmembrane protein band 3 are highly specific for erythrocytes and their progenitors. They are more reliable markers for erythroid differentiation than Glycophorin A, the commonly used marker for erythroid differentiation, because Glycophorin A is expressed also in many cell lines otherwise exhibiting mainly megakaryocytic characteristics. Both **erythroid α-spectrin** and **erythroid ß-spectrin** monoclonal antibodies can be used for example in identification of erythroid leukemias.

## Human Endothelial Cell Surface Marker

The endothelium is the thin layer of cells that lines the interior surface of blood vessels forming an interface between circulating blood in the lumen and the rest of the vessel wall. These cells are called endothelial cells. Platelet endothelial cell adhesion molecule (**PECAM-1**) is an antigen typically shared by both endothelial and distinct hematopoietic cells. It is widely expressed among leukocytes and functions as a cell adhesion molecule.

## Human Neurotransmitter Substances

Neural and neuroendocrine cells are able to synthesize a variety of peptides as well as amino acids that can function either as inhibitory or stimulatory substances in neurotransmission. Such neurotransmitter substances are **gamma aminobutyric acid (GABA)** and **calcitonin gene-related peptide (CGRP)**.

## Phytoestrogen

**Genistein** is an isoflavone belonging to the group of phytoestrogens (plant estrogens), which have been implicated in the prevention of cancer, cardiovascular and other chronic diseases. The main source of genistein is the soybean and various soy foods. Its determination in biological fluids and tissues by immunoassay is of increasing importance and for that purpose a specific antiserum is now available.

"MAbs in other concentrations and in different buffer systems are available at request."

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# Notes

# Products

We specialize in digestive disease diagnostics, offering a portfolio of unique and patented tests designed to transform clinical practice by making screening, diagnosis and monitoring of gastrointestinal diseases more efficient and cost effective.

| | Product | Lab | Clinic | Endoscopy | Consumer |
|---|---|---|---|---|---|
| **Gastroduodenal** | **GastroPanel®** | | | | |
| | GastroPanel® Unified (plasma) | ● | | | |
| | GastroPanel® Pepsinogen I (PGI) (plasma) | ● | | | |
| | GastroPanel® Pepsinogen II (PGII) (plasma) | ● | | | |
| | GastroPanel® *Helicobacter pylori* (plasma) | ● | | | |
| | GastroPanel® Gastrin-17 (G-17) (plasma) | ● | | | |
| | GastroPanel® Standard (serum, plasma) | ● | | | |
| | Pepsinogen I (serum, plasma) | ● | | | |
| | Pepsinogen II (serum, plasma) | ● | | | |
| | Gastrin-17 Advanced (serum, plasma) | ● | | | |
| | *Helicobacter pylori* IgG (serum, plasma) | ● | | | |
| | GastroPanel® quick test NT (whole blood, plasma) | ● | ● | ● | |
| | GastroPanel Four-in-One™ (plasma) | ● | | | |
| | *Helicobacter pylori* quick test (biopsy) | | | ● | |
| | BIOHIT *Helicobacter pylori* UFT300 (biopsy) | | | ● | |
| | BIOHIT Celiac quick test (whole blood, serum, plasma) | ● | ● | ● | |
| | Lactose Intolerance quick test (biopsy) | | | ● | |
| **Bowel** | BIOHIT Calprotectin (stool) | ● | | | |
| | BIOHIT ColonView® (FIT) quick test (stool) | ● | | | |
| **Nutrition** | BIOHIT Active B12 (HoloTC) (serum) | ● | | | |
| | BIOHIT Total 25OH Vitamin D (serum, plasma) | ● | | | |
| **Acetaldehyde** | Acetium® lozenge | | | | ● |
| | Acetium® capsule | | | | ● |

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