

GastroPanel® Patient Preparation, Sample Collection and Handling

GastroPanel is intended as the first-line diagnostic test for dyspeptic complaints to detect helicobacter infection and atrophic gastritis (mucosal atrophy) caused by helicobacter or autoimmune disease, disclose the associated risks like gastric and esophageal cancer as well as deficiency of B12 vitamin, calcium, magnesium, zinc and iron. Use of GastroPanel-examination is recommended also in health controls because helicobacter infection and particularly atrophic gastritis, with increased risk of gastric cancer and other conditions, are in most cases asymptomatic. Autoimmune diseases (e.g. type 1 diabetes, autoimmune thyroiditis, celiac disease, rheumatoid arthritis) are not infrequently associated with autoimmune atrophic gastritis. GastroPanel-disclosed i) symptomatic helicobacter infection after eradication attempt, ii) atrophic gastritis, or iii) reflux symptoms due to high acid output are indications of gastroscopy with targeted biopsies.^{1,2}

GastroPanel is ELISA-test panel and measures the following biomarkers from the blood plasma sample:

- Pepsinogen I
- Pepsinogen II
- *Helicobacter pylori* Ab
- Gastrin-17b

GastroPanel analysis is optimally carried out from fasting samples, and the results are interpreted by GastroSoft™ software¹.

Patient Preparation

The patient should not eat, drink, or smoke for 4 (minimum) to 10 hours before sample collection (e.g. preferably an overnight fasting). The patient is allowed to take his/her prescribed, regular medication. However, kindly report any use of Proton-Pump Inhibitors (PPI-medicines *, and possible pause time taking PPI) on the Test Request Form¹ because these medicines might interfere with the output of the gastric biomarkers.

(*) Esomeprazole, Lansoprazole, Omeprazole, Pantoprazole, Rabeprazole.

Data Protection and Data Processing

Care must be taken that patient rights are not violated. The patient must be informed about the processing of the personal data and in certain cases also the patient explicit consent is needed.

More information about Biohit Oyj's Patient register privacy policy on our website www.biohithealthcare.com.

Sample Collection and Handling

It is recommended that the blood sample (min. 2 ml) is drawn after overnight fasting (4–10 hours) into an EDTA plasma tube (e.g. Cat. No. 454 235 Vacuette 4 ml tube containing K2EDTA).

Plasma must be separated by centrifugation, preferably immediately or at latest within 2 hours (e.g. StatSpin® Express 2 centrifuge, for 2 minutes at 4000 x g; please refer to centrifuge manufacturer's instructions for plasma separation).

After separation of the plasma, add GastroPanel stabilizer to the sample (four drops or 100 µl in 2 ml of plasma; Biohit Oyj, GastroPanel stabilizer, Cat. No. 606 050 and 606 051)¹. The addition of GastroPanel stabilizer (Gastrin-17 stabilizer) enables the storage of the sample for 3 days at room temperature (20–25 °C), or 7 days in a refrigerator at 2–8 °C.

For temporary storage, please freeze the sample immediately after separation and addition of GastroPanel stabilizer. The plasma samples can be stored frozen at -20 °C, but for periods exceeding two weeks, the storage should be at -70 °C. Mix the sample thoroughly after thawing. Avoid repeated freezing and thawing of the plasma sample. Grossly hemolyzed, lipemic or turbid plasma sample should be discarded.

IMPORTANT

DO NOT USE GastroPanel stabilizer in whole blood samples, as it may cause hemolysis of the red blood cells. Use GastroPanel stabilizer **ONLY** for plasma samples (see Sample Collection and Handling above).

Stimulated Gastrin-17s

If Gastrin-17b (basal) concentration is low (below 1.0 pmol/l) and the patient has no *H. pylori* infection (antibodies below 30 EIU, with no eradication history), the result suggests high acid output (with no atrophic gastritis in the antrum). In this case, there is no need for testing of Gastrin-17s (stimulated).

If GastroPanel reveals *H. pylori* infection (antibodies over 30 EIU) and low Gastrin-17b (below 1.0 pmol/l), the result can indicate either high acid output of the corpus or atrophic gastritis in the antrum. Distinction between these two conditions can be made by measuring protein drink stimulated Gastrin-17s.

Drink made of protein powder (Biohit Oyj, Cat. No. 601 037 or 601 038) should be ingested after fasting for a minimum of 4 – 10 hours. Twenty minutes (20 min) after drinking the protein mixture, blood is drawn into an EDTA tube, centrifuged and stabilized as above (see Sample Collection and Handling).

If stimulated Gastrin-17s concentration is over 3.0 pmol/l, atrophic gastritis in the antrum is excluded. If, however, Gastrin-17s remains below 3.0 pmol/l after protein stimulation, atrophic gastritis in the antrum is likely, advocating further examinations, e.g., gastroscopy¹.

Protein stimulation should not be performed for subjects who report being sensitive to lactose (lactose intolerance or hypolactasia).

Delivery of the Samples to the Testing Laboratory

1) Delivery of Plasma Samples (preferred)

The use of GastroPanel stabilizer is the preferred option for preparing EDTA samples for delivery. EDTA samples stabilized with GastroPanel stabilizer enables the sample transportation without coolers within three days (3 d), and with coolers (at +4 °C) within seven days (7 d). If GastroPanel stabilizer is not used, plasma samples must be transported frozen (please refer to Sample Collection and Handling, above).

2) Delivery of the whole blood samples (optional)

If the facility to centrifuge a blood sample and stabilize the plasma sample at the sampling site is not available, samples may be transported as whole blood following these precautions:

- a. (Preferred) Whole blood samples must be put into an ice box (at 2–8 °C) immediately after collection and delivered to the testing laboratory within 24 hours (max.).
- b. (Optional) If whole blood samples cannot be transported in an ice box (at 2–8 °C), then whole blood samples must be transported at ambient temperature to the laboratory within 48 hours (max.).¹

IMPORTANT NOTE REGARDING THE WHOLE BLOOD SAMPLES

The transportation of whole blood samples is **ONLY** advisable where the facilities for processing plasma samples are not available. If whole blood samples are to be used, then it is essential that the sampling person records the precise time and date of the blood sample collection, and the temperature at which the blood sample is stored/transported (up to 32 °C), on the Test Request Form¹. Failure to record this information may result in false interpretation of Gastrin-17 results. By providing this information, the sample collection time, date and transportation temperature may be entered into the GastroSoft™ application, to enable a corrected estimation of the true (at the time of sampling) concentration of Gastrin-17¹.

Ordering materials

- ✓ GastroPanel Standard: Gastrin-17 stabilizer, Cat. No. 601 050 (1 x 5.5 ml), 601 051 (5 x 5.5 ml)¹.
- ✓ GastroPanel Unified: GastroPanel stabilizer, Cat. No. 606 050 (1 x 5.5 ml), 606 051 (5 x 5.5 ml)¹.
- ✓ Protein stimulation powder Cat. No. 601 038 (50 x 20g), 601 037 (5 x 20g)

All materials can be ordered from your local Biohit representative. You may also contact Biohit Oyj, Helsinki, Finland by phone +358 9 773 861 or by email info@biohit.fi.

Delivery Address for Biohit Laboratory Services

Biohit Oyj
Laippatie 1,
00880 Helsinki, Finland
Tel. +358 9 773 861, mon-fri 9 am – 3 pm.
www.biohithealthcare.com

References:

1. More information about GastroPanel innovation on our website www.gastropanel.com:
 - GastroPanel Municipality model for decision-makers
 - GastroPanel results interpretation and reference values
 - Forms and instructions
2. Visit our website for Acetium® innovation www.acetium.fi:
 - Acetium capsule – protect your stomach
 - Acetium lozenge – quit smoking