

Human gut microbiome

Complete characterization of the fecal microbiome by *shotgun* metagenomic sequencing: species-level taxonomy, resistome, virulence, functional profile and clinical indices integrated into a single report.

Shotgun WMS

~2,008 species

CARD 4,500+ genes

VFDB · toxins

HUMAnN3

8 clinical indices

Stewardship EUCAST/IDSA

Up to 30 days

1. Description

The **human gut microbiome** is the set of bacteria, archaea, fungi, protists and viruses that colonize the digestive tract. Its composition and function influence digestion, immunity, metabolism and the gut-brain axis.

This test analyses a stool sample by **whole-genome shotgun metagenomic sequencing** (PE150, ≥20 M paired-end reads, ~6 Gb per sample). Unlike 16S sequencing or PCR panels, *shotgun* allows the simultaneous characterization of **who is there** (species- and subspecies-level taxonomy), **what they do** (functional profile) and **what risk they carry** (resistance genes, virulence factors and toxins), all from the same DNA and in a single assay.

2. What it analyses

Block	Content
Taxonomic profile	~2,008 bacterial and archaeal species (Kraken2/Bracken PlusPFP + MetaPhlAn4, ~85,000 reference genomes). Includes enteropathogens (Salmonella, Shigella, Campylobacter, C. difficile, E. coli STEC/EIEC/ETEC/EAEC) and opportunistic pathobionts (Klebsiella pneumoniae, Enterococcus, Fusobacterium nucleatum, B. fragilis ETBF).
Resistome (AMR)	Resistance genes for β-lactams (blaKPC, blaNDM, blaOXA, blaCTX-M), vancomycin (vanA/B), colistin (mcr-1→10), linezolid and other classes. CARD 4,500+ gene coverage + AMRfinderPlus.
Virulence and toxins	VFDB and 10 specific panels: TcdA/TcdB and binary toxin CDT of C. difficile; CPE and NetF of C. perfringens; Shiga toxin (Stx1/Stx2); cholera toxin; BFT/ETBF; cagA/vacA island of H. pylori; invasins ipaH and invA.
Functional profile	HUMAnN3 (ChocoPhlAn + UniRef90): MetaCyc pathways with RPKM abundance, short-chain fatty acid (butyrate) synthesis, bile acid metabolism and other metabolic pathways.
Fungi, parasites and viruses	Mycobiome (Candida, Aspergillus, Saccharomyces, Malassezia), protozoa (Giardia duodenalis, Cryptosporidium, E. histolytica, Blastocystis) and enteric DNA viruses + phages. The standard DNA pipeline does not detect RNA viruses (rotavirus, norovirus, astrovirus).
Clinical indices	Eight validated indices (see section 3) with severity triage and detection of pharmacological confounders.

3. Eight clinical indices

Index	What it measures	Reference
GMHI		Gupta 2020, Nat Methods

Gut Microbiome Health Index (scale –10 to +10).
7 health-prevalent taxa and 43 health-scarce
taxa.

GMWI2	Lasso model with 95 taxa; balanced accuracy ~80%.	Chang/Gupta 2024, Nat Comms
DI V2	Dysbiosis Index (z-score, asymmetric 8:2 panel); calibrated on iHMP.	Gevers 2014 / iHMP
EDS	Enterotype Dysbiosis Score over 5 enterosignatures (0-1).	Frioux 2023, Cell Host Microbe
Butyrate Capacity	Butyrogenic capacity (7 producer genera); bands: critical <3%, deficient 3-5%, sufficient 5-7.5%, optimal >7.5%.	Vital 2017, mBio
CRC Risk	Species signatures enriched in colorectal cancer (≥ 2 species >0.1%).	Piccinno/Segata 2025, Nat Med
IBD CD vs UC	Microbial signatures of Crohn's disease and ulcerative colitis (independent scores).	Zheng 2024, Nat Med
C. difficile Risk	Abundance of C. difficile, toxins and ecological environment associated with recurrence.	IDSA/SHEA 2024

Severity triage

Each finding is classified as **HIGH** (urgent attention), **MODERATE** (follow-up) or **INFORMATIONAL** (context).

Pharmacological confounders

Detection of PPIs, metformin, mesalazine and oral iron, plus post-antibiotic dysbiosis, flagging their mechanism so that pharmacological effects are not attributed to the clinical picture.

4. Indications

Clear indications

- Irritable bowel syndrome (IBS-D / IBS-M) refractory to dietary management and probiotics.
- Inflammatory bowel disease: CD vs UC characterization and support for therapeutic decisions.
- Recurrent C. difficile infection (≥ 2 episodes): toxigenic profile and ecological environment.
- Suspected SIBO with a positive or indeterminate hydrogen breath test.
- Post-antibiotic dysbiosis with persistent diarrhea >2 weeks.
- Chronic diarrhea (>4 weeks) with normal calprotectin and negative colonoscopy.

Also recommended

- Supportive screening in FIT+ with deferred colonoscopy (risk triage).
- Monitoring of response to fecal microbiota transplantation (FMT).
- Pre-treatment evaluation for immunosuppressive or biologic therapy.
- Oncology patient: support for predicting response to immunotherapy.
- Metabolic syndrome / type 2 diabetes and the gut-brain axis.

Not indicated

Self-limiting acute diarrhea <3 days · population screening for CRC as a single test · routine monitoring in asymptomatic individuals without risk factors · replacement of colonoscopy in the presence of alarm signs.

5. Sample and logistics

Sample type	Fresh stool (2-5 g) in a tube with DNA/RNA Shield stabilizer (Zymo Research). Minimum volume: 2 g.
Kit	DNA/RNA Shield tube + spatula + instructions + prepaid envelope. Shipping to the laboratory included.
Storage and shipping	

Stable at room temperature for up to 30 days. Refrigerate at 4 °C if not shipped the same day. Express courier in a padded envelope with UN3373 label. Collection at the clinic or at home at no additional cost.

Preparation	No fasting or special preparation required. No fixatives (formalin, PVA).
Contraindications	Recent barium contrast (<7 days); active antibiotic therapy (unless its impact is to be assessed).

6. Pipeline: from sample to report

- 1 **Collection** — 2-5 g stool in DNA/RNA Shield.
- 2 **DNA extraction** — ZymoBIOMICS with bead-beating; Qubit quantification.
- 3 **Sequencing** — shotgun PE150 (Illumina/MGI), ≥20 M reads (~6 Gb).
- 4 **QC + host depletion** — fastp (Q≥20, L≥50) + GRCh38 via Bowtie2 (<5% human reads retained).
- 5 **Taxonomic profile** — Kraken2/Bracken (PlusPFP) + MetaPhlAn4.
- 6 **Functional profile** — HUMAnN3 (ChocoPhlAn + UniRef90).
- 7 **Pathogens, AMR and virulence** — AMRFinderPlus + CARD + VFDB + enteric pathogen panels.
- 8 **Clinical context** — integration of age, sex, BMI, indication, symptoms, medication and diet; confounder detection.
- 9 **Indices + triage** — 8 clinical indices + HIGH/MODERATE/INFORMATIONAL triage.
- 10 **Final report** — structured clinical PDF, signed by a health biologist.

7. Results, turnaround time and price

Deliverable

Clinical PDF report structured in 14 sections: clinical context, patient data, quality control, taxonomic profile, indices, indicator species, biomarkers, functional profile, pathogens, resistome, recommendations, conclusions, methodology/limitations and validation. Available for download from the portal and for the physician.

Turnaround: up to 30 days from receipt of the sample at the laboratory (indicative; may vary with courier incidents).

Price per sample

180 €

Includes kit, extraction, sequencing, full bioinformatics, clinical report, interpretation consultancy and longitudinal follow-up per sample.

8. Methodology, validation and limitations

GRCh38 reference base (Ensembl 113) for human read removal, CARD 2025, VFDB and HUMAnN3 with UniRef90. Clinical indices are reported with their cohort AUC and 95% bootstrap confidence interval; GMHI, GMWI2 and EDS follow the implementation of the original publications. Indicative compliance with the requirements of the *Lancet Gastroenterology & Hepatology* consensus (2025) for microbiome tests: external validation, methodological transparency and declaration of clinical use.

Notice. Clinical decision support tool; it does not constitute a medical diagnosis on its own. The CRC, IBD, NAFLD, obesity and T2D scores **are not diagnostic tests** and do not replace colonoscopy with biopsy or endoscopy with biopsy and calprotectin. Detection of resistance genes by metagenomics (CARD/AMRFinderPlus) **does not equate to phenotypic resistance** (EUCAST 2025): confirmation requires an antibiogram. Interpretation and therapeutic decisions rest with the responsible physician according to current guidelines. The standard DNA pipeline does not detect RNA viruses. Detection of fungal traces does not replace culture + ITS PCR in immunocompromised patients.

Signed by a licensed health biologist. Product technical document. OmicaLabs — Genomics Laboratory.

9. References

- Gupta VK et al. GMHI. *Nature Methods* 2020. · Chang Y, Gupta VK et al. GMWI2. *Nature Communications* 2024. · Zheng D et al. IBD signatures. *Nature Medicine* 2024. · Piccinno G, Segata N, Huttenhower C et al. CRC metagenomics. *Nature Medicine* 2025. · Frioux C et al. Enterosignatures. *Cell Host & Microbe* 2023. · Franzosa EA et al. IBD microbiome. *Nature Microbiology* 2019. · Vital M et al. Butyrate producers. *mBio* 2017. · Gevers D et al. MD-index. *Cell Host & Microbe* 2014. · Wirbel J et al. CRC metagenomics. *Nature Medicine* 2019. · Imhann F et al. PPI and microbiome. *Gut* 2017. · Forslund K et al. Metformin. *Nature* 2015. · IDSA/SHEA 2024 C. difficile guideline · EUCAST Clinical Breakpoints v15.0 (2025).