

Gut Microbiome Report — Human

Patient: Homo sapiens · M6 Age: 37 years Sex: F Sample date: 2026-05-08 Report date: 2026-07-05 Lab: OmicaLabs SL — Pipeline: GenePortal Human Microbiome v2.1 (shotgun metagenomics)

Notice: Clinical support report. It does not constitute a medical diagnosis. Clinical interpretation requires correlation with the complete clinical picture and complementary tests.

1. Main clinical picture (37y, F)

Monitoring of activity in ulcerative colitis: microbiome profile with mild dysbiosis. No bacterial or eukaryotic pathogens of high clinical priority detected. Despite the mild dysbiosis, the documented inflammatory activity markers (calprotectin 580 µg/g, Mayo 2, CRP 22 mg/L, bloody diarrhea, tenesmus, significant weight loss) indicate active disease; the clinical picture prevails.

2. Patient clinical data

Field	Value
Species	human
Age	37
Sex	F
Weight (kg)	68.0
Diet	omnivorous (western)
Antibiotics in the last 30 d	False
Antibiotic (drug)	—
Probiotics	False

Field	Value
Sample date	2026-05-08
Storage	—
Geography (ISO)	US

2.1 Clinical context

Reason for the test: Monitoring of inflammatory activity in left-sided ulcerative colitis diagnosed 4 years ago. Alternating flares with periods of partial remission on oral + topical mesalazine.

Main symptoms: - Bloody diarrhea with mucus (5-6 stools/day in the current flare, Bristol 6) - Fecal urgency and tenesmus - Crampy abdominal pain in the left iliac fossa - Weight loss of 4 kg in 8 weeks

Relevant history: - Left-sided ulcerative colitis (E2 Montreal) diagnosed in 2015 by colonoscopy with biopsies - Last colonoscopy (2023): moderate activity Mayo 2 up to the splenic flexure - Fecal calprotectin 580 µg/g (June 2025) - CRP 22 mg/L, mild iron-deficiency anemia (Hb 11.2 g/dL) - Refractory to oral mesalazine 4.8 g/day + rectal foam in the last flare

Current medication: - Oral mesalazine 4.8 g/day - Rectal mesalazine foam 1 g at night - Oral iron 100 mg/day

Family history: - Mother: ulcerative colitis (pancolitis, colectomy at age 52)

3. Sample quality (QC)

Metric	Value	Status
Total reads	13,777,944	—
Host reads	0.1%	OK
Post-filter reads	13,771,055	—
Classified reads	3,929,272	—
NTC	—	—
Mock community	—	—
Batch QC	Not evaluated	—

4. Taxonomic composition

4.1 Top 5 phyla

Phylum	Abundance %
Bacillota (Firmicutes)	65.34
Bacteroidota (Bacteroidetes)	32.79
Actinomycetota (Actinobacteria)	1.49
Pseudomonadota (Proteobacteria)	0.38

4.2 Top 10 genera

Genus	Abundance %
Bacteroides	30.63
Phocaeicola (GTDB reclassification of Bacteroides (vulgatus, distasonis, etc.))	22.19
Alistipes	0.81
Parabacteroides	0.12
Barnesiella	0.01
Copro bacter	0.01
Prevotella	0.01
Paraprevotella	0.00
Segatella (GTDB reclassification of Prevotella copri)	0.00
Butyricimonas	0.01

4.3 Genera of clinical interest

- Phocaeicola (22.19%): Reclassified from Bacteroides (GTDB). Implicated in bile acid metabolism. Common genus in the human gut microbiota.
- Mediterraneibacter (1.68%): Reclassified from Ruminococcus (GTDB). Acetate producer. Part of the Lachnospiraceae group, common in a healthy microbiota.

4.4 Alpha diversity

Index	Value	Healthy range
Shannon	2.219	2.5 - 4.5 (healthy)
Simpson	0.826	0.8 - 0.98 (healthy)
Chao1	533.8	—
Observed ASVs	—	—
Pielou evenness	0.406	—

5. Dysbiosis Index (iHMP HMP2 proxy)

- Dysbiosis Index (z-score sum): 0.757 (mildly altered)
- Bacillota / Bacteroidota ratio: 1.993 (normal)
- β distance (Bray-Curtis vs healthy centroid): 0.8205
- β distance (Euclidean, log10): 0.6917
- Method: iHMP_HMP2_zscore_proxy_human_v2
- Reference: iHMP_HMP2_2019 + Gevers2014_CellHostMicrobe + Gupta2020_NatureComms + Toto2024_PedIBD

| Notice: not equivalent to the clinical DI by qPCR.

5.1 Contribution per taxon

Taxon	Abundance %	z-score	Direction	Contribution
Faecalibacterium	7.83	-0.30	health	+0.30
Roseburia	8.92	0.50	health	-0.50
Alistipes	0.81	-0.25	health	+0.25
Prevotella	0.005	0.28	health	-0.28
Ruminococcus	3.20	0.63	health	-0.63
Coprococcus	11.74	1.12	health	-1.12
Subdoligranulum	0.05	-2.45	health	+2.45

Taxon	Abundance %	z-score	Direction	Contribution
Akkermansia	0.02	0.35	health	-0.35
Escherichia coli	0.21	0.62	dysbiosis	+0.62
Clostridium (sensu stricto)	0.00 (not detected)	0.00	dysbiosis	0.00

- 1/10 panel taxa not detected — the DI should be interpreted with caution.
- Δ Centroid calibrated against a European population reference (European DMP (Gacesa 2022, n=8.208)); local Spanish cohort pending. The β distance and the derived DI have reduced accuracy for non-European populations; interpret as a guide.

6. Indicator species (SCFA producers)

Genus	Detected %	Healthy range	Status
Faecalibacterium	7.83	—	normal
Roseburia	8.92	—	normal
Alistipes	0.81	—	normal
Prevotella	0.005	—	normal
Ruminococcus	3.20	—	normal
Coproccoccus	11.74	—	normal
Subdoligranulum	0.05	—	low
Akkermansia	0.02	—	normal
Escherichia coli	0.21	—	normal
Clostridium (sensu stricto)	0.00 (not detected)	—	low

SCFA producers total: 68.77 % (healthy > 12 %)

7. Species-specific biomarkers (clinical enrichment)

Human clinical biomarkers (SoTA 2020-2025 — Gupta 2020 + Frioux 2023 + Zheng 2024)

- Enterosignatures (NMF soft): ES-B=57%, ES-P=0%, ES-F=41%, ES-Bf=2%, ES-Ec=0%
- EDS (Enterotype Dysbiosis Score): 0.43 (mixed enterotype)
- GMHI (Gut Microbiome Health Index): 0.07 (healthy (predicted))
- GMWI2 (Chang/Gupta 2024): -0.774 (strongly not healthy) [42S/31NS taxa detected]
- ICB = 14.0% (optimal). Derived from the weighted sum of producer genera (Faecalibacterium, Agathobacter, Roseburia, Eubacterium, Anaerobutyricum, Anaerostipes, Coprococcus, Butyricicoccus, Subdoligranulum). It is NOT a fecal SCFA concentration; qualitative correlation with butyrogenic production.
- C. difficile risk: moderate
- Disease signatures:
 - Ulcerative Colitis (Zheng 2024 panel): 1 enriched spp, AUC=0.9 — 2 depleted detected. SCREENING ONLY — NOT a diagnosis.

CRC / IBD — Screening (NOT a diagnosis)

- IBD Panel Zheng 2024: UC score=-4.11 | CD score=N/D | Continuous score, no validated diagnostic threshold.
 - UC Panel: 1 enriched spp + 2 depleted spp detected
 - CD Panel: 0 enriched spp + 0 depleted spp detected
 - Note: 2 species in the panel not detectable with MetaPhlAn 4
 - Ref: Zheng et al. 2024, Nature Medicine 30:3555-3567, PMID: 39367251
 - LIMITATION: validated m-ddPCR panel (AUC=0.88 UC, 0.87 CD). The metagenomic approach is NOT externally validated for clinical diagnosis.

Quality Control

- Batch QC status: Not evaluated
- Beneficial genera: detected
 - Akkermansia altered (0.02%) — Mucin specialist, metabolic health (A. muciniphila)
 - Agathobacter altered (0.69%) — Butyrate producer (A. rectalis = ex-E. rectale), fiber fermentation
 - Prevotella altered (0.01%) — Fiber fermenter, healthy in non-Western diets (P. copri)

- Lactobacillus altered (0.00%) — Probiotic, lactate producer; intestinal barrier support
- Alistipes altered (0.81%) — SCFA producer — DUAL ROLE (associations with depression, CRC)
- Pathogenic alerts (1):
 - [MODERATE] Clostridioides elevated (0.10% > 0.1%) — C. difficile detected — clinical significance depends on toxins (tcdA/tcdB), not on abundance; toxinotyping required

MODERATE ALERTS (5 alerts)

- Low alpha diversity (Shannon=2.22, lower limit of the healthy range 2.5) — correlate with diet, recent antibiotic therapy or low-grade chronic inflammation
- Dysbiosis index=0.8 — mildly altered
- Akkermansia 0.02% — mucin specialist low
- [MODERATE] Clostridioides elevated (0.10% > 0.1%) — C. difficile detected — clinical significance depends on toxins (tcdA/tcdB), not on abundance; toxinotyping required
- DI mildly altered

INFORMATIVE (1 alerts)

- Microbiome associated with age: elderly (65-85 years) (Mancabelli 2024)
- Estimated age: 37 years (declared) (based on patient data)

Clinical interpretation

Enterotype ES-B (Bacteroides-dominant) with strong membership (0.57). Profile compatible with Bacteroides-dominant. Enterotypes represent continuous trends, not discrete categories (Bulygin 2023). Moderate C. difficile risk. Monitor clinical course.

Limitations (12)

- There is NO ACMG equivalent for microbiome interpretation. These metrics are orientative and must be integrated with the complete clinical picture.
- Enterotypes: they are NOT discrete categories (Costea 2018, Bulygin 2023). They represent continuous trends on a non-linear manifold.
- GMHI requires species-level data. MetaPhlAn 4 uses GTDB taxonomy (SGBs) while GMHI uses NCBI. The SGB→NCBI mapping is approximate.
- DI V2 panel (10 genera): asymmetric 8:2, AUC=0.745, external validation: independent cohort ongoing.
- The F/B ratio is NOT a reliable standalone biomarker (Finucane 2014 PLOS ONE; Magne

2020 Nutrients). Interpret with DI, diversity and clinical context.

- Detection of ARGs from a metagenome does NOT equate to phenotypic resistance. EUCAST 2024: VME < 5% in only 44% of antibiotics.
- Disease signatures (IBD/CRC/T2D/obesity) are SCREENING TOOLS — NOT diagnostic.
- Reference ranges come mainly from the Dutch Microbiome Project (n=8,208, European population). Their applicability to other populations requires validation.
- Alpha diversity (Shannon) is a coarse ecological measure that does NOT predict clinical outcomes by itself.
- Q2PD (Zielinska et al. 2025, GigaScience 14:giaf015) is a functional index based on MetaCyc metabolic pathways. Currently NOT AVAILABLE.
- Drugs that alter intestinal transit (loperamide, opioids) or gastric pH (PPI) can modify the microbiome composition by changes in residence time and luminal acidity. Interpret with caution if the patient received them in the 2 weeks before sample collection.
- This report is for research use and clinical context. It does not constitute a medical diagnosis. ISO/TS 24420:2023 covers metagenomic data processing.
- Pharmacological confounders detected in the patient's medication: 5-ASA (mesalazine): intestinal anti-inflammatory that alters the microbiome composition (reduces *Faecalibacterium*, increases *Enterobacteriaceae*). Confounding effect in ulcerative colitis and CD. Ref: Becker 2023 Front Microbiol 14:1107976, PMID 36910207.; Oral iron supplement: alters the gut microbiome composition (reduces *Bifidobacterium*, increases *Enterobacteriaceae* — pathobiont bloom). Dose-dependent effect. Ref: Yilmaz 2018 Pharmaceuticals 11(4):98.

References (25)

- Frioux et al. 2023, Cell Host & Microbe 31:1111-1125 (5 ES, 5,230 metagenomes)
- Keller et al. 2024, bioRxiv 2024.08.13.607711 (fuzzy enterotyping, EDS, 16,772 metagenomes)
- Bulygin et al. 2023, PeerJ 11:e15764 (no discrete clusters — manifold learning)
- Gupta et al. 2020, Nature Comms 11:4635 (GMHI, 50 species, AUC=0.73)
- Sun et al. 2024, npj Biofilms 10:96 (GMHI validation, 6,314 metagenomes, AUC=0.825)
- Gevers et al. 2014, Cell Host Microbe 15:382-392 (MD-index)
- Zheng et al. 2024, Nature Medicine 30:3555-3567 (IBD panels, 5,979 metagenomes)
- Piccinno/Segata/Huttenhower 2025, Nature Medicine (CRC pooled 3,741, AUC=0.85)
- Mei/Huttenhower et al. 2024, Nature Medicine 30:2265-2276 (T2D, 8,117 metagenomes)
- Chanda & De 2024, Gut Microbes 16:2304900 (obesity 25 spp, AUC=0.85)
- Gacesa et al. 2022, Nature 604:732-739 (DMP, n=8,208, 9 core species)

- Asnicar et al. 2021, Nature Medicine 27:321-332 (PREDICT 1, n=1,098)
- Andreu-Sanchez/Segata/Fu et al. 2025, Cell (32,152 metagenomes, 42 countries)
- Mancabelli et al. 2024, mSystems (6,653 samples, 5 life stages)
- Shao et al. 2024, Nature Microbiology (1,288 UK neonates, 3 community states)
- Vaiserman et al. 2020, BMC Microbiol 20:114 (F/B age-stratified, n=1,550)
- Finucane et al. 2014, PLOS ONE 9:e84689 (F/B NOT reliable standalone biomarker)
- Magne et al. 2020, Nutrients 12:1474 (F/B critical review)
- Vital et al. 2017, mBio 8:e01492-17 (butyrate producers)
- Dong et al. 2024, Nature Comms (VFDB 2.0 + MetaVF, 62,332 VFGs)
- Lessa et al. 2015, NEJM 372:825-834 (C. difficile epidemiology)
- EUCAST 2024: metagenomic ARG ≠ phenotypic AST
- Zielinska et al. 2025, GigaScience 14:giaf015 (Q2PD, PMID: 40117176, pathway-based dysbiosis, >8,000 samples, outperforms GMHI/hiPCA for IBD)
- ISO/TS 24420:2023 — shotgun metagenomic data processing
- STROBE-Metagenomics, Lancet Infect Dis, Oct 2025

8. Functional profiling (HUMAnN 3 + dbCAN 3)

Most represented metabolic pathways (top 10)

Metabolic pathway	Abundance (RPKM)	Clinical interpretation
PWY-7238: sucrose biosynthesis II	9,682	Carbohydrate metabolism — Sucrose biosynthesis. Indicates active bacterial glycolytic activity.
VALSYN-PWY: L-valine biosynthesis	8,343	Amino acid synthesis — Valine biosynthesis. Basal metabolic activity.
PWY-1042: glycolysis IV	8,240	Glycolysis — Glycolysis (EMP glycolysis). Central pathway of bacterial energy metabolism.
GLYCOGENSYNTH-PWY: glycogen biosynthesis I (from ADP-D-Glucose)	7,956	Glycogen metabolism — Bacterial glycogen biosynthesis. Energy storage.
PWY-5941: glycogen degradation II	7,907	Glycogen metabolism — Bacterial glycogen degradation. Energy storage.

Metabolic pathway	Abundance (RPKM)	Clinical interpretation
PWY-6163: chorismate biosynthesis from 3-dehydroquinate	7,188	Amino acid synthesis — Chorismate biosynthesis (precursor of aromatic amino acids).
ANAGLYCOLYSIS-PWY: glycolysis III (from glucose)	6,981	Bacterial metabolic activity — Bacterial metabolic pathway — part of the basal metabolism of the gut microbiome.
PWY-5686: UMP biosynthesis I	6,950	Nucleotide synthesis — UMP biosynthesis (uridine). Basal bacterial proliferative activity.
PWY-7790: UMP biosynthesis II	6,950	Nucleotide synthesis — UMP biosynthesis (alternative route). Bacterial proliferative activity.
PWY-7791: UMP biosynthesis III	3,475	Nucleotide synthesis — UMP biosynthesis (alternative route). Bacterial proliferative activity.

527 pathways detected in total by HUMAnN 3. The 10 with the highest abundance (RPKM) are shown, excluding unclassified reads.

Note: The most represented pathways correspond mainly to basal (housekeeping) metabolic activity of the commensal microbiota — glycolysis, amino acid synthesis, nucleotides and cell wall. Their clinical relevance is global (it indicates metabolic activity of the microbiome), not individual. Alterations in the relative abundance of specific pathways (butyrate, bile acids, LPS) are more informative than the presence of housekeeping pathways.

8.1 Overall functional assessment

Of the 10 most abundant pathways, 7 are housekeeping pathways (basal metabolism: glycolysis, amino acids, nucleotides, cell wall) and 3 are specialized-metabolism pathways (fermentation, energy storage, isoprenoids).

Interpretation: The diversity of active metabolic pathways indicates a metabolically competent microbiota. The presence of multiple housekeeping pathways at high abundance is expected in a metabolically active microbiome — it means the bacteria are alive, reproducing and processing nutrients.

Clinical relevance of the functional pathways: the presence of housekeeping pathways is

necessary but not sufficient for a healthy microbiome. What is clinically relevant is the depletion of butyrate-specific production pathways (butyryl-CoA acetate CoA-transferase pathway) and the elevation of pro-inflammatory pathways (LPS synthesis, flagella). These functional alterations are already reflected in the biomarkers of section 7 (butyrogenic capacity, *C. difficile* risk) and are more clinically actionable than the individual abundance of each housekeeping pathway.

9. Pathogens detected (bacterial + eukaryotic + fungi)

9.1 Bacterial pathogens

[MODERATE] *Escherichia coli* (pathotypes) — MODERATE - Abundance: 0.00% | Reads: 1,047 - Clinical significance: Enteropathogenic *E. coli* virulence genes

(stx1/stx2/eae/ipaH/elt/est/aggR/afa) NOT detected by metagenomics. *E. coli* is a ubiquitous commensal of the human gut. Pathogenicity depends on the pathotype determined by specific virulence genes: STEC/STEC (stx1/stx2+eae), EPEC (eae), ETEC (elt/est), EIEC (ipaH), EAEC (aggR/afa). Without these determinants, the detected strain probably represents non-pathogenic commensal colonization. Interpret in clinical context: if there is acute diarrhea or HUS, confirm with multiplex pathotype PCR + Shiga toxin in stool. Mandatory notification (RD 1054/2002) applies only to laboratory-confirmed STEC.

[MODERATE] *Clostridioides difficile* — MODERATE - Abundance: 0.00% | Reads: 1,814 - Clinical significance: tcdA/tcdB NOT detected by metagenomics — NON-toxigenic strain. Asymptomatic colonization, does not require treatment with oral vancomycin or fidaxomicin. Confirm with toxin A/B PCR if there is compatible clinical presentation (diarrhea, fever, leukocytosis). McDonald 2018 IDSA/SHEA Clin Infect Dis 66:e1.

[INCIDENTAL] *Toxoplasma gondii* — INCIDENTAL - Abundance: 0.00% | Reads: 369 - Clinical significance: Finding with no clinical action in this sample. *Toxoplasma gondii* is diagnosed by serology (IgG/IgM) and/or PCR in blood/CSF/amniotic fluid, NOT by stool. No additional follow-up is required in the absence of symptoms or risk factors (pregnancy, immunosuppression).

9.3 Fungi (mycobiome)

Note on fungal detection by shotgun metagenomics: Fungal biomass in stool is typically <0.1% of the total metagenome (Nash et al. 2017, Microbiome). The sensitivity of shotgun for fungi is lower than for bacteria due to low abundance, a cell wall resistant to lysis (chitin/glucans), and large genomes with lower coverage per sequencing depth. A negative result does NOT rule out a clinically relevant fungal infection. Always interpret in the clinical and dietary context of the patient.

Classification methodology: Fungi are classified according to the BugID/BugSeq matrix (2026): clinical classification of the species (according to WHO/ECDC priority lists) × universal signal threshold. The threshold has been calibrated against the natural distribution

of fungal abundance in the human fecal metagenome: the breakpoint at 10 RPM separates the normal mycobiome background from elevated signal, consistent with the MetaMIC minimum reporting. An absolute floor of 30 reads filters cross-mapping noise. **IMPORTANT:** There are no species-validated thresholds in the literature for fungi in stool by shotgun — these thresholds are for screening, not diagnostic. Any detection at trace level requires orthogonal confirmation (culture + ITS PCR) before making clinical decisions.

Mycobiome — traces without clinical significance

- Traces of environmental/dietary fungal DNA were detected (12 species: *Aspergillus flavus*, *Candida albicans*, *Candida auris*, *Candida glabrata*, *Candida krusei*...; 506 total reads) in an immunocompetent outpatient. No clinical significance. Confirm with culture + ITS PCR only if there are risk factors (immunosuppression, hospitalization, TPN, prior antifungals).

Confirmatory gold standard for fungi: Culture on CHROMagar/Sabouraud medium + MALDI-TOF + ITS1/ITS2 PCR. Taxonomic identification by shotgun has screening value; species confirmation and the antifungal susceptibility profile require isolation in culture.

△ Very low abundance (<0.01%). Detection of fungi at trace level in shotgun metagenomics may reflect: (1) real subclinical colonization, (2) environmental contamination (ubiquitous spores), or (3) dietary origin (bread, beer, cheese, probiotics). The fungal cell wall (chitin/glucans) is resistant to standard DNA extraction lysis, which underestimates the real abundance. Correlate with clinical findings and consider targeted culture if there are risk factors (immunosuppression, prolonged hospitalization, parenteral nutrition, broad-spectrum antibiotic therapy).

WARNING — Dietary false positives: Detection of *Saccharomyces cerevisiae* DNA (baker's/brewer's yeast) is common in fecal shotgun and almost always reflects recent dietary intake (bread, beer, wine, cheese, *S. boulardii* probiotics), NOT infection. **ALWAYS** interpret in dietary context before attributing clinical significance.

9.4 Viruses / phages

- Phage: uncultured phage cr110_1: 0.0067%
- Phage: uncultured phage cr11_1: 0.0045%
- Phage: *Faecalibacterium* phage FP_Taranis: 0.0027%
- Phage: uncultured phage cr19_1: 0.0023%

Clinical note: The viruses detected are commensal bacteriophages, normal components of the gut microbiome with no known clinical implication. No pathogenic human DNA viruses were detected above reporting thresholds.

10. Antibiotic resistance (AMR genes)

[OK] No acquired resistance genes were detected in the assembled contigs (AMRFinderPlus + VFDB).

Note: The absence of ARGs in a metagenome does NOT guarantee phenotypic susceptibility.
EUCAST 2024: VME < 5% in only 44% of antibiotics. Requires culture + antibiogram.

11. Prioritized recommendations

Priority	Action	Justification	Gold standard	Timeframe
PRIORITY	Priority clinical correlation: the history documents disease activity (calprotectin 580 µg/g, Mayo 2, CRP 22 mg/L, bloody diarrhea, tenesmus, significant weight loss) DISCORDANT with the low microbiome severity. The microbiome does NOT rule out active disease; therapeutic management should be guided by calprotectin/endoscopy and the specialist's judgment, not by microbiome re-testing.	Low microbial severity but documented clinical activity — the clinical picture prevails	Fecal calprotectin + gastroenterology assessment (endoscopy if appropriate)	According to clinical judgment (do not defer)
FOLLOW-UP	Routine clinical follow-up. Re-test the microbiome only if symptoms persist or factors change (antibiotherapy, diet, FMT).	Decided by severity — Monitoring	Routine clinical follow-up	Only if symptoms

12. Clinical conclusions

- Dysbiosis index: 0.757 (mildly altered band).
- Enterotype Dysbiosis Score: 0.43 (mixed enterotype).
- Reactive commensal expansion of Escherichia coli, Clostridioides difficile without virulence genes (VFDB negative) — does not suggest acute infection. No specific clinical action required.
- No acquired antibiotic resistance genes were detected.
- Notice: report of. It does not constitute a medical diagnosis. Interpretation requires complete clinical correlation.

13. Methodology and limitations — regulatory compliance

- STORMS guidelines, Mirzayi et al. Nat Med 2021
- MlxS-Human v6.3.0 (Genomic Standards Consortium)
-
- EUCAST 2025 + IDSA/SHEA antimicrobial stewardship
- Pipeline: GenePortal Human Microbiome v2.1 (shotgun metagenomics)
- Generated: 2026-07-05 22:57

Limitations:

- Shotgun DNA does not detect RNA viruses (coronavirus, rotavirus, calicivirus, astrovirus); it requires RNA-seq or specific PCR.
- Relative abundance does not equate to viability or an absolute CFU count; the official numerical DI requires quantitative qPCR.
- Shotgun provides AMR genotype but not a phenotypic profile (MIC); it requires targeted culture + antibiogram.
- Critical eukaryotic pathogens (e.g. Giardia, Cryptosporidium) require specific PCR as the gold standard — shotgun sensitivity at ~3-6M reads is limited.
- Clinical interpretation requires correlation with the clinical picture, diet, previous treatments and other complementary tests.

14. Validation

Role	Name	License number
Analysis lead (bioinformatics)	_____	OmicaLabs SL — Pipeline GenePortal Human Microbiome v2.1
Clinical validation lead	Juan Carlos Barba Carretero	Nº Col. 002395189P

OmicaLabs SL — Clinical decision support report. Processing, analysis and interpretation performed in accordance with STORMS (Mirzayi 2021), MlxS-Human v6.3.0 and ISO/TS 24420:2023 for shotgun metagenomic data processing.