

Gut Zoomer

Key Clinical Messages

What is Gut Zoomer?

The Gut Zoomer is a stool test that measures over 170 species of bacteria and gut pathogens along with markers of inflammation, digestion, and gut metabolites.

Why Order the Gut Zoomer?

The Gut Zoomer provides a comprehensive gut overview, including insight on common gut imbalances such as loss of beneficial organisms, excessive growth of potentially harmful organisms, and loss of overall microbial diversity.

Knowing the abundance of bacteria in your patient's gastrointestinal tract is important because gut microbiota impacts several critical aspects of health, including:

- · Shaping the immune system
- Fortifying the intestinal mucosal barrier
- Influencing nutrient metabolism

- Balancing neurotransmitters
- Aiding in detoxification
- And hormonal regulation

Vibrant's Gut Zoomer aids practitioners in detecting root causes of acute or chronic illness that stem from the gastrointestinal tract—including gastrointestinal disorders like Crohn's disease, autoimmune conditions like Hashimoto's thyroiditis and rheumatoid arthritis, and extraintestinal conditions like atherosclerosis, diabetes, eczema, and psoriasis.

Regulatory Statement:

This test has been laboratory developed and their performance characteristics determined by Vibrant America LLC, a CLIA-certified laboratory performing the test CLIA#:05D2078809. The test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). Although FDA does not currently clear or approve laboratory-developed tests in the U.S., certification of the laboratory is required under CLIA to ensure the quality and validity of the tests.

Which Patients Benefit from This Test?

Conditions, signs, and risks associated with gut dysbiosis include:

- GERD
- · Gas and bloating
- Indigestion
- Liver and gallbladder disease
- Small intestinal bacterial overgrowth (SIBO)
- Malnutrition
- Nutrient deficiencies
- Fatigue
- · Food sensitivities
- Intestinal permeability ('leaky gut syndrome')
- Diabetes

- Skin rashes (eczema or dermatitis)
- · Inflammatory symptoms
- Infections
- · Autoimmune conditions
- Celiac disease
- Inflammatory bowel disease (Crohn's, ulcerative colitis)
- Irritable bowel syndrome (IBS)
- · Cardiovascular disease
- · Metabolic syndrome
- · Neurological disorders
- · Mood abnormalities

What Markers Are Included on the Gut Zoomer?

Vibrant's Gut Zoomer includes three sections: gut commensal microbes, gut digestive markers, and gut pathogens. The Gut Zoomer also highlights low levels of probiotic organisms to guide personalized probiotic recommendations.

Gut Commensal Microbes

- Proteobacteria (e.g., Enterobacteriaceae, Escherichia coli, Proteus mirabilis)
- Actinobacteria (e.g., Bifidobacterium, Micrococcus, Eggerthella lenta)
- Firmicutes (e.g., Clostridum, Streptococcus, Staphylococcus, Feacalibacterium, Roseburia)
- Bacteroidetes (e.g., Prevotella copri, Bacteroides vulgatus, Prophyromous gingivalis)
- Verrucomicrobia (e.g., Akkermansia muciniphila)
- · Euryarchaeota (e.g., Methanobrevibacter smithii)

Gut Digestive

- Diversity Indexes, Phyla Overview, Key Ratios
 - Inflammatory Markers
 - Calprotectin
 - Fecal lactoferrin
 - Beta defensin
 - Fecal eosinophil protein X
- Markers of Digestive Insufficiency and Malabsorption
 - Pancreatic elastase-1,
 - Meat and vegetable fibers
 - Fecal fats

- Gut Metabolites
 - Bile acids
 - Short-chain fatty acids
- · Other Markers
 - Secretory IgA
 - Fecal occult blood
 - 。PH
 - Beta-glucuronidase
 - Fecal zonulin
 - Fecal anti-gliadin

Gut Pathogens

- 22 Bacteria
- 13 Protozoans
- 15 Helminths
- 11 Viruses
- 5 Fungi
- 6 Antibiotic Resistance Genes

Methodology

Gut Zoomer uses microarray, RTPCR, sandwich ELISA, LCMS, and GCMS technologies for detecting the markers within the whole assay.

- Gut Pathogens and Gut Commensal are measured on a RT-PCR platform
- Digestive markers use a microarray sandwich chemiluminescence, LC-MS, and GC-MS methodology for quantitative analysis of the analytes reported.

Why Vibrant?

Lab Methodology

Vibrant is a CLIA-certified lab that utilizes reliable, high-quality methodologies to measure microbes and digestive markers.

The advantages of our real-time PCR for commensals and pathogens include:

- A proprietary extraction process that includes mechanical (bead beating for biofilm disruption), thermal, and chemical lysis procedure for enhanced detection of all organisms
- Use of many regions of the gene that benefits the assay, including 16s, 23s, and proprietary sequences



What Tests Pair Well With The Gut Zoomer?

- Wheat Zoomer to investigate serological markers of gluten/wheat sensitivity and intestinal permeability
- Food Sensitivity & Food Zoomers intestinal permeability can increase the risk of food sensitivity development. Additionally, gut inflammation correlates with a higher incidence of food sensitivities.
- **Micronutrients** to investigate nutrient deficiencies when Gut Zoomer indicates digestive insufficiency and/or opportunistic overgrowth.
- Candida + IBS Profile to investigate the serological response to Candida species and the presence of anti-CdtB or anti-vinculin antibodies, suggestive of altered immunity in functional bowel disorders and differentiate between IBD and IBS subtypes (IBS-D and IBS-M).
- **Hormones** (Serum, Saliva, Urine) to investigate estrogen levels when Gut Zoomer results indicate an overgrowth of beta-glucuronidase-producing bacteria and/or elevated beta-glucuronidase.
- **Total Tox Burden** (Environmental Toxins, Mycotoxin, and Heavy Metal tests) to investigate, and reduce, toxin burden when Gut Zoomer results indicate intestinal hyperpermeability and/or elevated beta-glucuronidase.

Test Preparation

- Fasting: Not required
- <u>Diet Restrictions:</u> Not required. It is best to test while the patient is eating their typical diet. Intake of dietary fibers, probiotic foods, and foods treated with antibiotics (as well as dietary macronutrient ratios) can profoundly influence the microbiota and digestive health. Given the high temporal variability and intraindividual variability in the gut microbiota, inflammatory markers, and digestive markers, microbiome researchers and experts recommend repeated microbiome measurements, under 'typical lifestyle conditions,' to identify a person's microbiome 'profile.'
- <u>Medication Restrictions:</u> Not required. Medications may have a biological effect on markers measured. For example, use of a proton pump inhibitor may increase opportunistic pathogens and decrease fecal pH, but that will not interfere* with the Gut Zoomer test performance. The relative and absolute abundance of bacterial species and fecal pH will still be measured accurately.
- <u>Supplement Restrictions:</u> Not required. Dietary supplements may have a *biological* effect on markers measured.
 - For example, supplementing with Lactobacillus plantarum may increase the relative abundance of Lactobacillus plantarum, but that will <u>not</u> interfere* with the Gut Zoomer test performance. Lactobacillus plantarum abundance will still be measured accurately.
- <u>Collection</u>: One (1) orange top stool vial + one (1) white top clean stool vial.

*Test interference occurs when an interfering agent (present in the sample analyzed) impacts the measurement of the analyte, yielding an inaccurate result.

It is at the ordering/treating provider's clinical discretion to decide to perform the Gut Zoomer test in medicated/ supplements or non-medicated /non-supplemented conditions.

Reference Ranges

Gut Commensals and Digestive Markers

Reference ranges were established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Pathogens Panels

Limit of Detection (LOD) is the lowest analyte concentration in a sample that can be reliably detected.

The LOD is expressed in terms of the CFU/ml or cells/ml or oocysts/ml as per the organism tested. The LOD for each organism was estimated with limiting dilutions as single-spiked and multi-spiked samples (up to four organisms per mix), to provide an estimated LOD concentration. LOD was confirmed when the correct organism/assay results were obtained from at least 19 of the 20 samples tested (>19/20 = 95% confidence interval).