

 designs for health® Australia

 **GI-MAP**®

DNA Stool Analysis

GI-MAP®

Pioneering Precision in Advanced
GI Testing for Clinical Excellence

Diagnostic Solutions Laboratory



Elevating Clinical Care: Designs for Health and Diagnostic Solutions Laboratory

Designs for Health and Diagnostic Solutions Laboratory have a strong partnership, driven by their shared commitment to science and a common goal of empowering healthcare practitioners. Diagnostic Solutions Laboratory, located in Atlanta, Georgia, was founded to bridge the gap between healthcare providers and clinical laboratories. They utilise proven methodologies to offer accurate and reliable laboratory tests, including cutting-edge technology like the GI-MAP™ stool test, providing actionable insights into microbiota-related chronic diseases. By combining our expertise and passion for advancing science-based care, we aim to empower clinicians with the tools to unlock targeted solutions for improved patient health. This strategic alliance gives practitioners access to Designs for Health's research-backed nutraceuticals alongside Diagnostic Solutions' cutting-edge GI-MAP® stool testing for a comprehensive approach to functional medicine.

Expertise you can trust:

Diagnostics Solutions Scientific Board

The Scientific Board at Diagnostic Solutions Laboratory is a formidable assembly of experts who bring invaluable knowledge and experience to the table. Led by CEO Tony Hoffman, who boasts over 30 years in the integrative laboratory industry, the board features esteemed individuals like Dr. David M. Brady, a licensed naturopathic medical physician with three decades of integrative medicine practice and extensive health sciences academia experience. Dr. Todd R. LePine, with

his board certification in Internal Medicine and specialisation in integrative functional medicine. Additionally, Dr. Tom Fabian, an authority in microbiome research, and Dr. Betsy Redmond, a registered dietitian-nutritionist with a wealth of experience in functional laboratory assessment, contribute their expertise. Together, this board ensures that Diagnostic Solutions Laboratory remains at the forefront of relevant developments, empowering practitioners and patients with cutting-edge insights and solutions in healthcare.



CEO Tony
Hoffman



Dr. David
M. Brady



Dr. Tom
Fabian



Dr. Todd
R. LePine



Dr. Betsy
Redmond

Optimal Health – It All Starts With the GI-MAP[®]

Extensive research strongly suggests that gut health has a significant impact on our overall wellbeing. The gut microbiome, a community of microorganisms in the digestive system, plays a crucial role in how diet and other factors affect our health, including digestion, immunity, metabolism, and hormonal functions. By using appropriate tools such as the GI-MAP[®], to assess gastrointestinal health, practitioners can identify the underlying causes of chronic illnesses more effectively.

The Gastrointestinal Microbial Assay Plus (GI-MAP[®]) is an innovative clinical tool that measures gastrointestinal microbiota DNA from a single stool sample with state of the art, quantitative polymerase chain reaction (qPCR) technology. The GI-MAP[®] was designed to detect microbes that may be disturbing normal microbial balance or contributing to illness as well as indicators of digestion, absorption, inflammation, and immune function.

Get the Big Picture

The GI-MAP[®] allows you to assess diversity at the genus level (e.g. *Lactobacillus spp.*, *Bifidobacterium spp.*, *Escherichia spp.*), and also allows you to see the larger scale diversity picture via the bacterial phyla breakdown, including the ratio of *Firmicutes/Bacteroidetes*.

Dive into the Fine Detail

The GI-MAP[®] offers an unseen level of precision in reporting. Having the power to detect as low as 0.1 cell per gram of stool, enabling you to make incredibly accurate clinical decisions.

But that's not all – the GI-MAP[®] takes it a step further by not only quantifying *Helicobacter Pylori* but also unveiling the secrets of its virulence factors genes, which are unique to *H. pylori's* genome. These genes encode proteins that can

Consider GI-MAP[®] testing for patients presenting with:

- ✓ Chronic and acute gastroenteritis
- ✓ IBD – Inflammatory Bowel Disease
- ✓ IBS – Irritable Bowel Syndrome
- ✓ Autoimmune disease
- ✓ SIBO
- ✓ Suspected *H. pylori* infection
- ✓ Fungal, bacterial & viral pathogens
- ✓ Intestinal permeability issues
- ✓ Digestive complaints, diarrhoea, constipation or bloating
- ✓ Brain fog, headaches, migraines
- ✓ Skin problems, like acne and psoriasis
- ✓ Hormonal imbalances
- ✓ Chronic Inflammation
- ✓ Immune system issues
- ✓ Mood disorders, low mood, and anxiety
- ✓ Diabetes, metabolic and weight loss issues

indicate a higher risk of severe *H. pylori* infection, equipping you with invaluable insights for making informed and impactful treatment decisions.

Uncover Condition-Specific Patterns

Equip yourself with the tools to confidently treat your patients by identifying distinct microbial patterns within the GI-MAP[®]. This invaluable insight enables targeted and precise treatment strategies for various conditions:

- Inadequate Diversity (Insufficiency Dysbiosis)
- SIBO – Hydrogen, Methane, Hydrogen Sulfide
- Bacteria Producing Histamine
- Inflammatory Dysbiosis
- Digestive Insufficiency
- Gut Hyperpermeability

GI-MAP[®] Analytes

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| <ul style="list-style-type: none"> • Pathogens: <ul style="list-style-type: none"> - Viral pathogens - Parasitic infections - Viral pathogens • <i>Helicobacter pylori</i> and Virulence Factors | <ul style="list-style-type: none"> • Commensal / Keystone Bacteria: <ul style="list-style-type: none"> - Commensal bacteria - Bacterial phyla | <ul style="list-style-type: none"> • Fungi / Yeast • Viruses • Parasites <ul style="list-style-type: none"> - Protozoa - Worms | <ul style="list-style-type: none"> • Opportunistic Microbes: <ul style="list-style-type: none"> - Dysbiotic bacteria - Commensal overgrowth - Inflammatory and auto-immune bacteria | <ul style="list-style-type: none"> • Intestinal Health Markers <ul style="list-style-type: none"> - Digestion markers - GI markers - Immune response markers - Inflammation markers - Zonulin protein |
|--|---|--|--|--|

Laboratory Certification

Diagnostic Solutions Laboratory take great pride in their CLIA certification, which signifies their commitment to the highest standards in laboratory testing.

CLIA, or the Clinical Laboratory Improvement Amendments, is a rigorous regulatory framework that governs laboratory testing in the United States. Under CLIA, clinical laboratories like Diagnostic Solutions must be certified by the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing. This certification ensures the accuracy and reliability of results, providing practitioners with the utmost confidence in their services. For our Australian counterparts, it's worth noting that CLIA is similar in principle to NATA certification in Australia. Diagnostic Solutions diligently adhere to all CLIA guidelines, including proficiency testing, to maintain their certification, ensuring that their laboratory consistently meets the highest standards of quality and accuracy in diagnostic testing.

You can read more about CLIA certification at: <https://www.cdc.gov/clia/about.html>

Precision Results You Can Trust

Each analyte on the GI-MAP® is individually validated and meets or exceeds federal Laboratory Developed Test (LDT) and CLIA requirements. Before adding any organism to the GI-MAP® report, the following analyses must be completed successfully:

- Assay specificity — the assay detects the intended organism and nothing else.
- Assay sensitivity — the assay can measure accurately within a certain range of detection (e.g. how low and how high the organism can be quantified).
- Assay variation — if the same sample is tested multiple times, in different batches, on different days, the variation (coefficient of variation, CV) must be below 10%.
- Reference range development.
- Cross-assay comparison, when available.

All organisms quantified by qPCR on the GI-MAP® have less than 10% CV or variation, even though CLIA allows for 15% CV. This means that two identical samples, tested on different days, can only vary 10% from each other.

Validation reports are published internally, approved by company leadership before adding any organism to the test panel, and reviewed during CLIA inspections. We use validated DNA positive controls from vendors such as ATCC to test our molecular targets during assay validation.

GI-MAP® Methodology

Unlike other comprehensive stool tests on the market, the GI-MAP® can provide practitioners with truly quantitative results. qPCR offers a much more accurate way to detect and quantify clinically relevant organisms than standard PCR, culture, microscopy, or DNA sequencing-based methods. Accurately assessing how much of an organism's DNA is present in a patient's stool sample is essential for helping practitioners to determine the clinical significance of pathogenic organisms and dysbiosis patterns.

Other methods include ELISA testing use for Calprotectin, Pancreatic Elastase, Fecal Secretory IgA and Gliadin. For more information see the GI-MAP® Methodology Guide at: <https://www.diagnosticsolutionslab.com>

All of our assays and laboratory personnel undergo proficiency testing, as required by CLIA. Proficiency testing is the analysis of unknown samples submitted by an authorised provider as a measure of external quality control.

All patient samples are tested alongside control samples, standard samples, and endogenous controls to meet quality control requirements.





Frequently Asked Questions

Q What is the turnaround time for results?

A 3.5 weeks from your patient sending their sample.

Q Do I need to refrigerate my sample?

A Samples are to be stored at 2-8°C for up to 14 days before extraction and testing. If samples will not be tested within 14 days, freeze samples at -20°C or -80°C. Freezing at 80°C is recommended for long-term storage. Stool samples may be subject to no more than 3 freeze/thaw cycles.

Q How do you maintain the quality of the sample during transit to produce accurate results particularly with markers such as SIgA and Calprotectin?

A We've rigorously tested SIgA stability in stool samples and found that when collected in DSL vials and processed accordingly, there was less than a 15% change in SIgA levels compared to results obtained at 2 days post-collection, even up to 14 days post-sample receipt. Samples collected in DSL-provided vials, shipped at specified temperatures, and received within recommended timeframes remain stable for SIgA testing. In fact, the vials act as preservatives, allowing proper sample storage for up to 2 months, and there's no requirement to test samples within 3 days of collection. SIgA starts to decline rapidly only when stability becomes an issue.

Calprotectin is a highly stable protein in stool samples. During validation testing, calprotectin did not show significant alterations even at 14 days post sample receipt when stored at multiple temperatures. However, freeze-thaw cycles will cause an INCREASE in detected levels as each round of freeze-thaw will result in lysis of PMNs which are the major source of calprotectin. Both the manufacturer's data and DSL validation data indicate that samples may be tested for calprotectin for greater than 3 days post collection.

Q Dead vs. live strain detection: what is the difference and why you should report on both?

A Research shows that around 30% of bacterial DNA detected through DNA-based methods comes from dead cells, with the rest being a mix of growing and dormant/non-growing cells (source: <https://pubmed.ncbi.nlm.nih.gov/33757378/>). While some view this as a drawback, it's actually an advantage over culture methods, RNA-based methods, and "viability PCR" methods. Microbes in the gut fluctuate in response to changing conditions, with some thriving in different parts of the GI tract and later becoming dormant or dying due to various factors like pH, oxygen, and nutrients. DNA methods can detect microbes from throughout the GI tract, even if they're dormant or dead in stool samples, allowing identification of clinically relevant organisms from various GI tract areas beyond just the distal colon, such as *H. pylori* in the stomach or *Pseudomonas* in the small intestine. Methods focused solely on live microbes in stool reveal only those still active in the stool itself.

Q How are reference ranges decided?

A Reference ranges are highly regulated as part of the CLIA certification. Diagnostic solutions laboratory ensures GI-MAP® reference ranges are always updated as per regulations. Reference ranges were developed using known positive, diseased samples to construct cut off values that distinguish disease-causing amounts of pathogenic and opportunistic microbes. Reference ranges for the pathogens were correlated with an FDA cleared assay for GI pathogens. The GI-MAP® is capable of detecting as low as 0.1 cell per gram of stool.

Why Partner With Us?



Exclusive for Practitioners

Designs for Health supplements and GI-MAP® testing are only available through licensed healthcare practitioners.



Interpretation Support

We have a fully qualified team of qualified educators ready to support in becoming a gut microbiome expert.



Practitioner Education

We offer free continuing education and protocol support for all practitioners.



Simplified Ordering

Choose to pay as the practitioner, or select patient to pay.

Use the QR code to learn more about how GI-MAP® can benefit your clinic, and to register as a Designs for Health Practitioner.



designsforhealth.com.au

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