# CLINICAL EVIDENCE OVERVIEW:

## GUT HEALTH BREATH TESTING

*An unassessed small intestine can limit what hormone, peptide, weight-loss, and longevity protocols deliver*

**Gut Health Testing Blind Spot:** Stool testing is not considered a diagnostic test for SIBO or IMO and primarily reflects colonic and stool findings, leaving the small intestine unassessed.

**Hidden IBS Drivers:** Up to half of patients labeled with IBS actually have identifiable and testable causes like carbohydrate malabsorption (lactose 54%, fructose 43%) or SIBO.

**GLP-1 Induced Overgrowth:** Patients on GLP-1 receptor agonist therapies face nearly triple the risk of developing SIBO within 12 months due to drug-induced motility impairment, making breath tests essential for differentiating expected side effects from active overgrowth.

**High Recurrence Reality:** SIBO recurrence reaches nearly 44% within nine months, so breath testing can objectively assess treatment response and recurrence.

AllClear Healthcare
We are building a commercialization platform for advanced diagnostics for wellness and longevity – aligned to the practitioner
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# Clinical Evidence Overview: Gut Health Breath Testing

**Hydrogen and methane breath testing for small intestinal bacterial overgrowth (SIBO), intestinal methanogen overgrowth (IMO), Lactose Intolerance, Fructose Malabsorption and Sucrose Intolerance**

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**Audience.** Clinical teams in wellness and preventative health, and the commercial organizations serving that market.

**Purpose.** This document provides a clinical and technical overview of hydrogen and methane breath testing as performed by AllClear Healthcare. It is written for readers evaluating whether to incorporate breath testing into routine care or to represent it commercially. Published findings are cited herein. Where a statement reflects the clinical judgment of AllClear's medical leadership rather than published evidence, it is labeled as such.

**Regulatory note.** AllClear breath testing is performed in a CLIA-certified laboratory using commercially manufactured QuinTron instrumentation, operated per the manufacturer's instructions and interpreted against North American Consensus criteria. QuinTron holds FDA establishment registration #2124914 and lists its breath measurement system as a Class I device under 21 CFR 862.1820, product code NRH, a category FDA designates 510(k) exempt. Establishment registration and ISO 13485 certification describe the manufacturer's device listing and quality management system. Because the device category does not require premarket review, neither "FDA cleared" nor "FDA approved" applies to this instrument or to any competing breath measurement system, and nothing in this document should be represented as such.

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## 1. What is the test?

The AllClear breath test is a non-invasive diagnostic procedure used to detect gastrointestinal conditions including small intestinal bacterial overgrowth (SIBO), intestinal methanogen overgrowth (IMO), and sugar and carbohydrate malabsorption. AllClear provides at-home breath collection kits that are analyzed in a CLIA-certified laboratory using QuinTron BreathTracker gas chromatography instrumentation. QuinTron is FDA-registered as a device establishment and manufactures under ISO 13485, the international quality management standard for medical devices.[1] The instrument quantifies hydrogen, methane, and carbon dioxide.

**How the test works**

- **Substrate ingestion.** After a baseline breath sample is collected, the patient challenges the upper GI by ingesting a defined sugar solution based on the test the practitioner has prescribed (the SIBO/IMO testing substrates are glucose or lactulose, the Fructose Malabsorption substrate is fructose, the Lactose Intolerance substrate is lactose, and the Sucrose Intolerance substrate is sucrose).
- **Serial collection.** Breath samples are collected into specialized vacuum tubes at 20-minute intervals over a three-hour testing period.
- **Gas analysis.** Samples are analyzed for hydrogen and methane produced by bacterial fermentation of the substrate, with carbon dioxide ($CO_2$) measured to assess breath-sample adequacy and to account for dilution from non-alveolar air.
- **Interpretation.** Results are interpreted against North American Consensus criteria. For SIBO, a rise in hydrogen of 20 ppm or more above baseline within the first 90 minutes is considered positive. For IMO, a methane value of 10 ppm or more at any point during testing is considered positive.[2]

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## 2. Which patients is this test for, and what workup comes first?

Breath testing addresses specific disorders, including small intestinal bacterial overgrowth (SIBO), intestinal methanogen overgrowth (IMO), Lactose Intolerance, Fructose Malabsorption, and Sucrose Intolerance. It is not a general assessment of gut health or a screen for structural or inflammatory disease. The evidence presented in this document should be considered within that defined scope.

**Alarm features come first.** The 2021 American College of Gastroenterology (ACG) clinical guideline on irritable bowel syndrome identifies alarm features that bear on whether colonoscopy is warranted: hematochezia, melena, unintentional weight loss, older age of onset of symptoms, and family history of inflammatory bowel disease, colon cancer, or other significant gastrointestinal disease.[3] The presence of alarm features warrants further clinical evaluation and may indicate the need for structural or other diagnostic assessment before or in addition to breath testing. The same guideline notes that in the absence of alarm features, there appears to be no justification for routine colonoscopy in patients younger than 45 with IBS symptoms and no warning signs.[3] ACG's colorectal cancer guideline recommends screening in average-risk adults between 50 and 75 as a strong recommendation, and suggests it between 45 and 49 as a conditional recommendation.[4]

**Two guideline steps that breath testing does not replace.** For patients with diarrhea symptoms, ACG makes a strong recommendation that serologic testing be performed to rule out celiac disease, and a strong recommendation that fecal calprotectin and C-reactive protein be checked in patients without alarm features to rule out inflammatory bowel disease.[3] Celiac disease is biopsy-confirmed in approximately 3.3% of patients presenting with IBS-type symptoms, rising to 5.7% in diarrhea-predominant presentations.[3] Both are inexpensive tests with real yield. Breath testing does not replace guideline-recommended evaluation for other gastrointestinal conditions, and in patients with appropriate symptoms, evaluation for conditions such as celiac disease and inflammatory bowel disease should be performed according to established clinical guidelines.[3]

**Where breath testing sits.** Once alarm features have been addressed and the celiac and inflammatory questions answered, breath testing is a reasonable early step for the patient who remains symptomatic without a diagnosis. The 2022 meta-analysis discussed in Section 8 makes this point from both directions: a substantial share of patients carrying an IBS label have a condition a breath test can identify, and that same analysis counts celiac disease and inflammatory bowel disease among the organic disorders misdiagnosed as IBS.[5] The differential is broader than any single test covers.

**Consider the common conditions together.** Lactose Intolerance is at least as common in this symptom population as SIBO and IMO, and the pooled figures in Section 8 bear that out: lactose malabsorption at 54% and lactose intolerance at 46% sit at or above SIBO at 19 to 49% depending on substrate.[5] Non-specific complaints of bloating, intermittent loose stools, constipation and cramping do not distinguish between them. A workup that tests

for overgrowth alone will miss a cause that is at least as common and just as readily identifiable, so where clinically appropriate both should be considered rather than one in place of the other.

**Companion material.** The Small Bowel GI Work-Up Tool Kit, which is provided to practitioners alongside this document, sets out the workup sequence in practical form, including red flag screening as the first step. Practitioners should treat that document as the operational companion to the evidence presented here.

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## 3. How accurate is breath testing?

As an instrument platform, QuinTron is the gold standard. When investigators validate other breath analyzers, QuinTron is the comparator. A published validation of a handheld hydrogen analyzer used "the Quintron microlyzer as the gold standard" as its reference.[6]

**Five tests, two different questions.** AllClear's panel runs on one platform but answers two clinically distinct questions, and "accuracy" does not mean the same thing for each. SIBO and IMO testing is measured against small bowel aspirate culture, an invasive comparator whose own standing as a gold standard is contested in the ACG clinical guideline itself (Section 5). The carbohydrate tests — Lactose Intolerance, Fructose Malabsorption and Sucrose Intolerance — have no independent anatomic reference standard at all. For those conditions the breath test functions as the practical standard of measurement rather than being validated against an independent one, and the published figures, which are cited with their sources in the tables and notes below, describe agreement with lactase genotype or with symptom response rather than independent validation of the breath test. Reading one column of sensitivity numbers straight across all five tests would therefore mislead. The tables below keep protocol and performance separate and name the comparator in every case.

**Table 1. Test protocols.** Substrate doses, collection windows and sampling intervals follow the standard protocol published by QuinTron for the BreathTracker system.[8] The glucose, lactulose, lactose and fructose doses also match the North American Consensus.[2] No consensus dose exists for sucrose. AllClear's kit specifications are consistent with both.[7]

| Test | Substrate and dose | Collection window and sampling | Positive threshold |
|---|---|---|---|
| SIBO/IMO — glucose substrate | Glucose 75 g[7] | 3 hours: baseline plus 9 samples at 20-minute intervals, 10 vials[7] | $H_2$ rise ≥20 ppm above baseline within 90 minutes; $CH_4$ ≥10 ppm at any single time point[2] |
| SIBO/IMO — lactulose substrate | Lactulose 10 g[2] — supplied on | 3 hours[7] | $H_2$ rise ≥20 ppm above baseline |

| Test | Substrate and dose | Collection window and sampling | Positive threshold |
|---|---|---|---|
| | practitioner order; also used where a glucose load is contraindicated, as in diabetes[7] | | within 90 minutes; $CH_4$ ≥10 ppm at any single time point[2] |
| Lactose Intolerance | Lactose 25 g[7] | 3 hours: baseline plus 3 samples at 60-minute intervals, 4 vials[7] | $H_2$ rise ≥20 ppm above baseline at any point[2] |
| Fructose Malabsorption | Fructose 25 g[7] | 3 hours: baseline plus 3 samples at 60-minute intervals, 4 vials[7] | $H_2$ rise ≥20 ppm above baseline at any point[2] |
| Sucrose Intolerance | Sucrose 50 g[8] | 3 hours: baseline plus 6 samples at 30-minute intervals, 7 vials[7] | $H_2$ rise ≥20 ppm above baseline at any point |

Glucose 75 g, lactulose 10 g, lactose 25 g and fructose 25 g match the North American Consensus doses exactly.[2] One row requires comment.

**Sucrose dose.** No formal consensus dose has been established for sucrose hydrogen breath testing. AllClear uses the 50 g sucrose dose specified for use with the QuinTron BreathTracker system,[8] and 50 g sucrose has also been used in published hydrogen breath-testing studies.[9]

**Hydrogen and methane are measured in one test, but they identify two distinct conditions.** SIBO and IMO are separate diagnoses reported from the same collection on the same substrate. AllClear names this test SIBO/IMO for that reason. There is no separate methane test to order and no additional collection burden to assess methanogen overgrowth, but a positive hydrogen result and a positive methane result are different findings and should be read as such.

**On substrate choice for SIBO/IMO.** The North American Consensus endorses both substrates and applies identical positivity criteria to each: 75 g glucose or 10 g lactulose, with a hydrogen rise ≥20 ppm above baseline within 90 minutes read as positive for SIBO. The Consensus treats methane separately, with methane ≥10 ppm at any point during the test read as positive for IMO on either substrate.[2] AllClear offers both and takes no position that one is categorically superior, because the published evidence describes recognized trade-offs and differing recommendations rather than establishing one substrate as superior.

The trade-off is structural rather than a matter of quality. Glucose is absorbed in the proximal small bowel, so any hydrogen it generates comes from that segment — which makes it more specific, and also less likely to detect overgrowth further down.[11, 12] Lactulose is not absorbed anywhere, so it traverses the entire small bowel and can reach distal overgrowth glucose would miss — but it also reaches the cecum in every patient, where normal colonic flora ferment it, and in patients with rapid transit that colonic signal can arrive early enough to contribute to a false-positive result. An early rise does not necessarily represent colonic fermentation, and interpretation should take both possibilities into account.[12] Each substrate's advantage is the direct cause of its disadvantage, and the published guidelines and consensus statements differ in how they weigh that trade-off rather than establishing one substrate as superior. The ACG guideline records both criticisms side by side without resolving them.[13]

**Reading Table 2 fairly.** The pooled figures favor glucose on both axes, subject to one caveat about the comparator, set out in Section 5.

**In practice.** AllClear supplies either substrate on the ordering practitioner's instruction and does not steer the choice.

Lactulose requires a prescription, which can create an additional step at some laboratories and may influence substrate selection toward glucose. At AllClear, practitioners are credentialed during onboarding through NPI and state license verification, allowing eligible practitioners to order lactulose directly for their patients through the AllClear portal. The lactulose is then included with the patient's test kit, eliminating the need for a separate prescription process or additional delay. This makes both glucose and lactulose readily accessible, allowing substrate selection to be based on clinical considerations rather than ordering logistics.

Clinical opinion on substrate choice is genuinely divided, and prominent investigators favor lactulose on the distal-detection argument. AllClear supports either choice at the point of order. Either result is best interpreted alongside clinical presentation rather than in isolation, which is the ACG's own guidance.[13]

**On sampling density.** Each breath test offered by AllClear runs three hours. What differs is how often the patient collects: every 20 minutes for SIBO/IMO, every 30 for sucrose, every 60 for lactose and fructose. The SIBO/IMO cadence is the densest because the consensus decision point falls at 90 minutes — the 20-minute schedule places four post-ingestion samples inside that window rather than one or two. The carbohydrate tests are judged on a rise at any point across three hours, so they do not require the same resolution.

**Table 2. Reported diagnostic performance.** Every figure is stated with the comparator it was measured against.

| Test | Sensitivity | Specificity | Measured against |
|---|---|---|---|
| SIBO (glucose substrate) | 54.5% (95% CI 48.2–60.7) | 83.2% (95% CI 79.1–86.9) | Jejunal aspirate culture; pooled |

| Test | Sensitivity | Specificity | Measured against |
|---|---|---|---|
| | | | across 14 studies, summary ROC AUC 0.74[10] |
| SIBO (lactulose substrate) | 42.0% | 70.6% | Jejunal aspirate culture; same pooled analysis[10] |
| IMO (methane, either substrate) | Not established | Not established | No culture comparator. The North American Consensus defines IMO by the breath methane threshold itself rather than against culture.[2] |
| Lactose Intolerance | 76–94% | 77–96% | Lactase deficiency, range across primary studies[14] |
| Lactose — concordance check | 97%* | 95%* | LCT C/T(−13910) genotype measured against the breath test, n = 194, κ = 0.9[14] |
| Fructose Malabsorption | Not established | Not established | No independent reference standard exists. The consensus specifies dose, duration, and threshold, but not validated accuracy.[2] |
| Sucrose Intolerance | Not established | Not established | Hydrogen breath testing detects sucrose malabsorption but is not specific for congenital sucrase-isomaltase deficiency; confirmation requires duodenal disaccharidase assay or $^{13}$C- |

| Test | Sensitivity | Specificity | Measured against |
|---|---|---|---|
| | | | sucrose breath testing.[15] |

*These are the performance figures of the genotype measured against the breath test, not the reverse. They establish strong concordance between the two methods, not independent validation of either.

**Beyond the pooled figures.** Three further datasets bear on the SIBO numbers in Table 2. Peer-reviewed reviews describe a wider range drawn from the older primary literature: specificity of 78 to 97% and sensitivity of 15.7 to 62%.[16] [17] In the largest direct head-to-head comparison against duodenal aspiration, in 139 patients, glucose breath testing showed sensitivity of 42%, specificity of 84%, positive predictive value of 68%, and negative predictive value of 64%, with overall diagnostic agreement between the two methods of 65.5%.[18] A separate ACG comparative study against duodenal aspirate culture reported specificity and positive predictive value of 100%, with sensitivity of 60% and negative predictive value of 82%.[19] The variation across these studies may reflect differences in testing protocols, diagnostic thresholds, study populations, and limitations of the reference standard.

**Why fructose and sucrose carry no accuracy figures.** Lactose is the best characterized of the three carbohydrate tests, although the available comparator studies have limitations. Fructose has an established North American Consensus protocol — 25 g, at least three hours, a ≥20 ppm hydrogen rise — but validated sensitivity and specificity against an accepted independent reference standard have not been established.[2] Sucrose is less standardized, and the North American Consensus does not provide a sucrose testing protocol or dose.[15]

The strength and type of supporting evidence vary among breath-testing applications and should be considered when interpreting results. Fructose and sucrose results should be interpreted within the clinical context and with recognition of the limitations of the available validation data. A positive sucrose breath test may warrant further evaluation when confirmation of congenital sucrase-isomaltase deficiency is clinically indicated, which requires a duodenal disaccharidase assay or $^{13}$C-sucrose breath testing.[15]

**Clinical implication.** A positive result is informative and immediately actionable. A negative result in a persistently symptomatic patient does not exclude disease. The meta-analytic literature characterizes breath testing in the current era as a moderately good test for diagnosing SIBO.[10] That is an accurate description, and AllClear does not represent it otherwise. The test is appropriately positioned as a practical first-line assessment of the small intestine, not as a rule-out.

**Clinical opinion, not cited evidence.** AllClear's medical leadership — CMO emeritus Martin Hahn, MD, current CMO Andrew Lenhardt, MD, and medical science liaison Ilana Gurevich, ND — hold that hydrogen and methane breath testing is the most useful practical test available for opening a root-cause workup of chronic GI symptoms, and that

breath testing to assess SIBO, IMO, and Lactose Intolerance belongs among the first targeted tests ordered once the alarm features and guideline steps described in Section 2 have been addressed. That position rests on the relationship between what the test yields and what it costs to obtain it. The test is non-invasive, inexpensive relative to endoscopy, and available without scheduling delay, and a positive result redirects the workup immediately. It is offered here as the professional judgment of experienced clinicians on sequencing, not as a claim of diagnostic superiority.

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## 4. Why does the carbon dioxide channel matter?

The carbon dioxide channel addresses the most common objection to at-home collection.

Carbon dioxide is present at low concentrations in room air and higher concentrations in alveolar air. The instrument measures $CO_2$ in every sample and uses it two ways: as a validity check confirming the patient captured deep lung air rather than mouth air, and as a normalizing factor that adjusts hydrogen and methane values to a standardized $CO_2$ concentration so samples across a test are quantitatively comparable. Samples below 1.4% $CO_2$ are flagged invalid and excluded from analysis. If too many samples in a series are invalid, the entire test is reported invalid and a replacement kit is issued.[20]

Instrument sampling error for hydrogen and methane is ±3 ppm, or 5% of full scale, with 1 ppm resolution and a linear range of 2 to 150 ppm for hydrogen and 2 to 75 ppm for methane. Carbon dioxide is measured with ±1% accuracy, 2% resolution, and a linear range of 0.1 to 7%.[21]

The practical consequence is that a home sample with inadequate alveolar content is more likely to be flagged invalid than reported as a result. This addresses sample adequacy only and does not identify deviations from preparation instructions. Consumer-grade breath devices and handheld analyzers generally have no equivalent internal-standard safeguard.

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## 5. Isn’t jejunal aspirate the gold standard?

Small bowel aspirate culture is treated as the reference standard in the published literature, but its own limitations are documented in the guidelines. The ACG clinical guideline notes that endoscopic culture of the small bowel “had not been established as a gold standard” given limited access to the more distal small bowel, that the threshold defining a positive culture “has been controversial, both in the published literature and among experts in the field,” and that “standardized techniques for aseptic collection of small bowel aspirate samples are lacking.”[13] The European guideline states that aspirates from the proximal jejunum “lack sensitivity in all but the most severe cases.”[22] The meta-analytic literature applies three different colony-count cutoffs across studies, yielding materially different pooled performance figures.[10] One primary study found no significant

correlation between glucose breath test results and either colony counts or DNA-based bacterial cell counts,[23] further illustrating the challenges of comparing breath testing with an imperfect and non-standardized reference method.

Three further limitations are documented: a reported 19.6% contamination rate with single-lumen catheter aspiration, limitations in the ability of conventional culture methods to recover many intestinal organisms, and the inability of standard bacterial culture methods to culture methanogenic archaea, which limits the use of aspirate culture for diagnosing IMO.[13]

This bears directly on how Table 2 should be read. Aspirate culture samples the proximal small bowel — the same territory glucose covers, and the territory lactulose is used precisely because it goes beyond. A distal overgrowth that lactulose detects and the aspirate misses is scored as a lactulose false positive. The reference standard is therefore not neutral between the two substrates, and the glucose advantage in Table 2 should be read as performance against an imperfect and glucose-favoring comparator rather than as a settled ranking.

In clinical practice, small bowel aspirate collection requires an invasive endoscopic procedure, which can limit its practicality for routine diagnostic evaluation.

**Clinical perspective.** AllClear's clinical approach is informed by experienced medical leadership, including CMO emeritus Martin Hahn, MD, a gastroenterologist with more than 30 years of practice, and current CMO Andrew Lenhardt, MD. Their clinical perspective recognizes both the practical utility of hydrogen and methane breath testing and the limitations of the available reference methods. Published head-to-head data demonstrate 65.5% diagnostic agreement between glucose breath testing and duodenal aspirate culture,[18] while clinical guidelines acknowledge that aspirate culture itself has not been established as a validated gold standard.[13] These considerations support interpreting breath-test results within the broader clinical context and with recognition of the limitations of both diagnostic approaches.

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## 6. Why doesn't AllClear measure hydrogen sulfide?

A commercial $H_2S$ testing system exists, but a validated diagnostic cutoff for $H_2S$ has not been established. The ACG clinical guideline states that "a cutoff value for diagnosis of SIBO using $H_2S$ gas needs to be validated and its utility determined."[13] A 2023 review in Clinical and Translational Gastroenterology similarly notes that standardized threshold cutoffs for $H_2S$ are lacking and identifies unresolved considerations related to sample transportation and stability.[24] Until standardized diagnostic criteria and clinical utility are better established, the role of $H_2S$ measurement in routine breath-test interpretation remains evolving.

AllClear expects to support $H_2S$ measurement if and when a validated interpretive threshold emerges, and declines to charge a premium for a gas that currently has no consensus threshold.

AllClear's differentiation rests instead on measurable factors: a $189 price against roughly $285 to $600 for comparable tests, results returned in approximately 24 hours from laboratory receipt, at-home rather than in-office collection, and broader substrate flexibility.

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## 7. Is this redundant with stool microbiome panels?

No. Stool microbiome testing and breath testing evaluate different aspects of gastrointestinal health and are not interchangeable. Stool analysis primarily reflects organisms and other markers present in fecal material and is not an established diagnostic method for SIBO or IMO, nor for Lactose Intolerance, Fructose Malabsorption or Sucrose Intolerance. Current ACG guidance describes breath testing and small bowel aspirate culture as methods used in the evaluation of suspected SIBO, with methane breath testing used in the evaluation of IMO.[13] Breath testing may therefore provide information about these conditions that a stool microbiome test does not provide.

A substantial share of chronic gut complaints originate in the upper GI tract, which stool panels do not interrogate. Breath testing is an adjunct to stool testing rather than a replacement. A practice running stool panels alone has a diagnostic blind spot in the small intestine.

**Sequence rather than substitution.** Stool microbiome testing does not generally identify a specific disorder. It can show imbalances in stool flora, though no consensus definition of a normal microbiome has been established, and it can raise questions about inflammatory processes without pointing to a particular condition. It also does not localize the finding to a region of the gut. Breath testing addresses a defined set of conditions and, for SIBO and IMO, speaks to the small intestine specifically. The practical sequence is therefore to address the common carbohydrate and overgrowth conditions first, where a result carries a defined meaning, and to consider stool microbiome testing later in the workup for the patient who remains unexplained.

**Why the distinction matters.** Bloating, intermittent loose stools, constipation and cramping present similarly across SIBO, IMO, Lactose Intolerance, Fructose Malabsorption and Sucrose Intolerance, and these conditions are not managed the same way. An approach directed at carbohydrate intolerance does not address bacterial or methanogen overgrowth. Which of them is present is a question breath testing can address and symptoms alone cannot, and the same overlap is what separates these patients from those carrying an irritable bowel syndrome label by exclusion.[5]

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## 8. How common are upper GI issues in wellness and preventative health populations?

An estimated 25 to 45 million Americans are affected by IBS, roughly 10 to 15% of the population.[25] Only about 5 to 7% of adults have received a formal diagnosis,[26] and one study found that 76.6% of individuals meeting diagnostic criteria were undiagnosed.[27] Among IBS patients evaluated by breath testing, SIBO prevalence is approximately 35.5% (95% CI 33.6 to 37.4) across 25 studies and 3,192 patients, an odds ratio of 3.7 (95% CI 2.3 to 6.0) against controls.[28]

The broader and more consequential figure concerns how many patients carrying an IBS label have an identifiable, testable cause. A 2022 systematic review and meta-analysis of adults meeting Manning, Kruis, or Rome I-IV criteria in secondary care examined precisely this question, under the framing that these are organic gastrointestinal disorders misdiagnosed as IBS. Pooled prevalence of lactose malabsorption by hydrogen breath testing was 54% (95% CI 44 to 64) across 26 studies and 6,700 patients. The same review reported lactose intolerance — malabsorption accompanied by symptoms — separately, at 46% (95% CI 35 to 57) across 11 studies and 3,303 patients. AllClear names the test for the clinical condition, Lactose Intolerance, while the measurement the breath test makes is of malabsorption; both figures are given here so the distinction is explicit. Fructose malabsorption was 43% (95% CI 23 to 62) across 13 studies and 3,415 patients. SIBO prevalence ranged from 19% (95% CI 13 to 27) by glucose breath testing to 49% (95% CI 40 to 57) by lactulose breath testing, a spread discussed in Section 15.[5]

The practical reading is that roughly half of the IBS population, and plausibly more, has a carbohydrate malabsorption or overgrowth condition that a breath test can identify and that no stool panel will find. These are separate pooled estimates and cannot be added together, but they do not need to be. Lactose malabsorption alone reaches 54%, and the share of patients with lactose malabsorption, fructose malabsorption, SIBO, or any combination of them cannot be lower than the largest single component. Overlap between the conditions works in the same direction rather than against it. For context on the malabsorption findings, lactose malabsorption affects roughly 36% of people in the United States overall, with considerably higher rates in several ethnic groups.[29]

**Clinical opinion, not cited evidence.** Ilana Gurevich, ND, an AllClear medical science liaison whose practice is heavily gut-focused, observes that 40 to 50% of the patients she sees present with upper GI involvement. This is a single-practice observation, not a population estimate, and is included as practice-level context only.

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## 9. Why does this matter in preventative and longevity-oriented care? The GLP-1 question.

GLP-1 receptor agonists impair gastrointestinal motility, and impaired motility is a recognized mechanism for bacterial overgrowth. A 2025 matched-cohort analysis of 216,173 patients found that patients on GLP-1 or dual GLP-1/GIP receptor agonist therapy had significantly higher incidence of diagnostically confirmed SIBO than matched comparators, with a hazard ratio of 2.14 in short-term analysis and a 12-month incidence rate ratio of 2.90 (95% CI 1.41 to 5.95, p = 0.0037). The authors concluded that symptom-driven SIBO breath-test evaluation may be warranted in patients initiating these agents.[30]

For practices prescribing GLP-1 agonists at scale, this is a clinical indication for having breath testing available, independent of any commercial consideration. It also supports a defensible response when a patient on a GLP-1 reports bloating and distension, allowing the practitioner to distinguish an expected pharmacologic effect from overgrowth rather than treating empirically.

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## 10. SIBO recurs. What does testing accomplish?

Recurrence is well documented and should be planned for rather than treated as treatment failure. Following a single course of rifaximin, recurrence documented by repeat glucose breath testing was 12.6% at three months, 27.5% at six months, and 43.7% at nine months in a cohort of 80 patients.[31] Meta-analytic evidence reports rifaximin SIBO eradication rates of approximately 59% by intention-to-treat analysis and 63% by per-protocol analysis.[32] Higher recurrence risk following successful treatment has been associated with older age, prior appendectomy, and chronic proton pump inhibitor use.[31]

Treatment is not limited to antibiotics, and the breath test is what makes any option measurable. In a retrospective series of 104 patients at Johns Hopkins, herbal antimicrobial therapy produced a negative follow-up lactulose breath test in 46% of patients (17 of 37) against 34% for rifaximin 1,200 mg daily (23 of 67), a difference that did not reach statistical significance (p = 0.24).[33] Among rifaximin non-responders, herbal rescue therapy normalized 57.1% (8 of 14) against 60% (6 of 10) for triple antibiotic therapy (p = 0.89), and adverse effects were milder in the herbal arm.[33] That study was retrospective and modestly sized, so it establishes that herbal protocols perform in a comparable range rather than demonstrating equivalence. It is nonetheless the reason a practitioner choosing a non-antibiotic route is not choosing an unevidenced one. Practitioners in AllClear's network use antibiotic, herbal, and elemental-diet protocols selected on gas pattern and patient history. In every case the same test that identified the overgrowth is what confirms clearance, which is what makes the choice of protocol an empirical question rather than a matter of preference.

**Disclosure.** AllClear Healthcare serves as the laboratory for an ongoing trial with Biotics Research updating the Johns Hopkins breath-testing work described above. The figures

cited here are from the published 2014 study, not from that trial. No therapeutic product is named or recommended in this document.

Objective breath testing can provide baseline measurements and may be used to assess treatment response or suspected recurrence. Because symptoms alone do not establish the presence or absence of SIBO or IMO, repeat testing may provide additional objective information when clinically indicated.

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## 11. Does treating SIBO without addressing root cause amount to whack-a-mole?

That criticism is fair, and AllClear does not dispute it. Overgrowth is often associated with underlying factors, which may include impaired migrating motor complex activity, structural factors such as adhesions or prior surgery, proton pump inhibitor use, pharmacologic slowing of motility, or ileocecal valve dysfunction.

Breath testing can establish whether overgrowth is present and which gas pattern predominates, and repeat testing shows whether an intervention changed that result. Treatment decisions remain with the ordering practitioner. Breath testing does not substitute for root-cause investigation. It makes root-cause investigation measurable.

**Where breath testing sits in the sequence.** A breath test does not identify the root cause. It identifies whether bacterial overgrowth, methanogen overgrowth, or carbohydrate malabsorption is present, which is the finding that tells a practitioner to look upstream at motility, medication, or structural factors rather than continue treating symptoms empirically. That is the opening step in root-cause work, not a replacement for it. Roughly half of patients carrying an IBS label have SIBO, carbohydrate malabsorption, or both, on pooled figures reported with their confidence intervals in Section 8.[5] Given that, and given a test that is non-invasive, inexpensive, and returns in about 24 hours, running it early, once the steps in Section 2 are complete, identifies which patients warrant investigation of upstream contributors and which do not. Sequencing remains a matter of clinical judgment.

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## 12. Downstream Effects of an Undiagnosed Small Intestine on Concurrent Protocols

Much of this Overview addresses whether SIBO and IMO can be diagnosed by breath testing, and whether a stool panel can substitute for that (it cannot — see prior sections). This section addresses a related but separate question: what an undiagnosed small intestinal overgrowth means for a practice running concurrent hormone optimization, peptide, weight-management, or broader longevity protocols alongside it. The malabsorption mechanisms below are well characterized in the literature. Their effect on

the outcomes of other protocols layered on top of an undiagnosed overgrowth is a mechanistic extension of that literature, not a separately studied finding, and we have tried to be explicit below about which is which.

**Established: malabsorption is a defining feature of untreated SIBO/IMO, not a side effect.** The 2020 American College of Gastroenterology clinical guideline states that SIBO can cause malabsorption and vitamin deficiencies.[13] Bacterial overgrowth in the small intestine competes with the host for nutrients, damages the absorptive mucosa directly, and alters food intake through the symptoms it produces. Bacteria deconjugate bile acids, which drops the concentration of conjugated bile acids below the threshold needed for micelle formation — impairing fat digestion and absorption (steatorrhea), and extending to carbohydrate and protein malabsorption because deconjugated bile acids are directly injurious to enterocytes. Vitamin B12 deficiency occurs because bacteria take up the vitamin and partially metabolize it to inactive analogues that compete with normal B12 binding and absorption. Fat-soluble vitamin deficiencies (A, D, and E) follow from the same steatorrhea. Zaidel and Lin, reviewing this literature, report clinically apparent vitamin B12 deficiency in as many as one-half to three-quarters of patients with SIBO, with osteomalacia and impaired night vision as occult complications of steatorrhea-driven fat-soluble vitamin loss.[34]

**Established: without addressing the underlying driver, overgrowth recurs — this is not a one-time diagnostic event.** A negative breath test at one point in a protocol does not guarantee an unaffected gut over the life of a multi-month or multi-year program. Recurrence following successful antibiotic treatment runs at the rates described in Section 10, and it tracks the underlying driver — motility, structural, or other predisposing factors — rather than the adequacy of the antibiotic course itself.[31] That is the clinical argument for periodic reassessment in higher-risk patients rather than a single diagnostic pass.

**Plausible, and consistent with the general dysbiosis literature, but not SIBO-specific: mucosal barrier and systemic inflammatory burden.** Separately from nutrient competition, intestinal dysbiosis more broadly is associated with increased intestinal permeability and low-grade systemic inflammation, through mechanisms including bacterial endotoxin (LPS) translocation across a compromised epithelial barrier.[35] We flag this as supporting context rather than direct evidence: the barrier-permeability literature is largely built on dysbiosis and inflammatory bowel disease models, and we are not aware of studies that isolate SIBO or IMO specifically within that body of work. It is a plausible additional mechanism, not a demonstrated one in this population.

**Inference, clearly labeled as such: implications for concurrent hormone, peptide, and longevity protocols.** Given established malabsorption of B12, fat-soluble vitamins, and — through mucosal injury — carbohydrate and protein, and given that overgrowth recurs unless its underlying driver is corrected, it is reasonable to hypothesize that patients with an undiagnosed or under-treated small intestinal overgrowth get less than full value from concurrent interventions that assume a functioning gut. Peptide therapies, hormone

optimization, and broader longevity protocols all depend to some degree on adequate nutrient status. We want to be explicit: we are not aware of a published study that has directly measured protocol outcomes — peptide response, hormone panel normalization, or similar — stratified by SIBO or IMO status. This paragraph describes a mechanistic hypothesis built on established malabsorption physiology, not a separately validated finding. It is, however, a testable one, and it is the reason we think a small intestine assessment belongs earlier in a workup that includes these other protocols, rather than being treated as an optional add-on.

**Practical implication.** For a practice running hormone, peptide, or longevity protocols concurrently, a breath test result is informative beyond the isolated gut complaint, in either direction. A positive result identifies a malabsorptive process that could be blunting the practice's other work and gives a defined management path. A negative result removes a common, well-characterized confound before a slow or absent response elsewhere gets attributed to protocol design, dosing, or patient non-adherence.

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## 13. What does patient preparation involve, and how is deviation handled?

Preparation follows standard protocol: dietary restriction the day before collection, an overnight fast, and defined washout intervals for antibiotics, probiotics, and prokinetics. Instructions ship with the kit and are reinforced in patient-facing materials.

Protocol deviation is the principal risk in any at-home collection. The $CO_2$ validity channel described in Section 4 addresses one part of that risk: it identifies whether an adequate alveolar sample was collected, and a sample that does not reflect alveolar air is excluded rather than reported. It does not identify preparation deviations such as diet, fasting, or antibiotic, probiotic and prokinetic washout, any of which can affect a result even when $CO_2$ is acceptable. Correct preparation therefore remains essential, and AllClear's clinical support team is available to patients and practice staff for preparation questions. Where a test is invalid because of the kit or laboratory processing, it is re-run at no charge. Where it is invalid because of collection, a reduced replacement fee applies.

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## 14. Who interprets results, and where does responsibility sit?

The laboratory report presents quantified gas curves against North American Consensus thresholds with a clear positive or negative determination. Interpretation, clinical correlation, and all treatment decisions rest entirely with the treating practitioner. The ordering physician approves any modification to a standard protocol, and AllClear accommodates practitioner-directed sampling intervals on request.[8]

For practitioners newer to gut health, AllClear provides protocol resources, clinical education, and practitioner-to-practitioner consultation access through its medical

science liaisons. This is educational support, not clinical direction. AllClear does not recommend, direct, or influence ordering or treatment decisions.

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## 15. What is the cost to the patient, and what is the argument for it?

$189, cash pay, with no insurance friction. Comparable tests run roughly $285 to $600. Stool microbiome panels commonly cost more and do not assess the small intestine at all.

The more relevant comparator is the cost of not testing. Average time from first symptoms to IBS diagnosis is approximately four years, and more than 40% of patients remain symptomatic for five years or longer.[36] IBS carries roughly $30 billion in annual US cost, and gastrointestinal disease overall accounts for approximately $136 billion in direct costs, exceeding heart disease at $113 billion.[37] A $189 test with 24-hour turnaround is a short path out of a diagnostic loop that otherwise can run for years.

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## 16. What are the known limitations?

**Sensitivity.** As covered in Section 3, a negative result does not exclude disease. Any representation to the contrary overstates the evidence.

**Threshold variability.** Diagnostic criteria differ across published studies in substrate, dose, test duration, and cutoff. The ACG guideline states that "the published literature and expert opinion has varied widely regarding both the details of breath testing techniques and the definition of a positive test."[13] The European guideline recommends a 50 g glucose load and a 10 to 12 ppm cutoff, against the North American Consensus 75 g load and 20 ppm cutoff.[22] Pooled analyses tabulate substrate doses, sampling intervals, test durations, and cutoffs that differ study by study.[10] AllClear adheres consistently to North American Consensus criteria, which is the appropriate standard for a US laboratory, but cross-study comparison remains imperfect and readers should not assume figures from European or older literature are directly transferable.

The clearest illustration is substrate. In the same 2022 meta-analysis, pooled SIBO prevalence among IBS patients was 49% by lactulose breath testing but 19% by glucose breath testing.[5] A gap that large in one analysis is a statement about the tests, not about the patients, and it is consistent with lactulose producing positives (both true positives with distal overgrowth and false positives from early cecal entry) that glucose does not.

**Payer coverage.** At least one commercial payer policy deems hydrogen breath testing not medically necessary for SIBO, citing sensitivity variability.[38] This does not affect cash-pay ordering, but the position exists in the market and patients may encounter it.

**A significant published criticism.** A 2024 clinical practice update endorsed by the European Society of Neurogastroenterology and Motility and the American Neurogastroenterology and Motility Society argues that the SIBO hypothesis in IBS

“remains unproven” and concludes that breath testing for this purpose “is inaccurate and should be abandoned as a diagnostic test.”[39] Anyone evaluating this category should know that paper exists. AllClear does not dismiss it.

Its central mechanism deserves a precise response. The critique rests on orocecal transit. Lactulose is not absorbed, so it travels to the cecum, where bacterial density reaches roughly $10^{12}$ organisms. In patients with rapid transit, particularly diarrhea-predominant IBS, lactulose can arrive at the cecum well inside the 90-minute diagnostic window, producing a hydrogen rise that reflects ordinary colonic fermentation rather than small intestinal overgrowth.[39] That is a sound criticism of the lactulose protocol, and it is consistent with the poor pooled performance of lactulose in meta-analysis.[10]

That mechanism does not transfer to glucose in the same way. Glucose is absorbed in the proximal small intestine and does not reach the cecum in meaningful quantity, so the transit-time failure mode described for lactulose does not apply, though it does not follow that the broader criticism of breath testing has no bearing on glucose testing. The Rome Consensus endorsed glucose over lactulose substantially on this basis, and the pooled data point the same way.[10] The North American Consensus and the ACG's own SIBO guideline, led by Pimentel and colleagues, take a different view and endorse both substrates under identical criteria, recording the false-positive criticism of lactulose and the distal-insensitivity criticism of glucose side by side rather than resolving them.[2, 13]

The North American Consensus itself names this exact risk: higher lactulose doses can speed intestinal transit and affect test results, which is part of why the Consensus recommends 10 g rather than the larger doses used in earlier practice.[2] A validation study comparing the two doses under the same interpretation criterion found the smaller, Consensus dose produced significantly fewer positive results than the larger, older one, 42% versus 53% ($p = 0.04$).[40] The same Consensus also set its reading criterion at a rise of 20 ppm by 90 minutes rather than the lower, faster-reading criterion common in earlier practice, and the cited comparison data show the higher threshold carries better specificity, at some cost to sensitivity.[2, 40] Neither study includes a gold-standard comparator, so this does not prove every removed positive was a false one, but both changes move fewer, not more, positive results out of the pool the transit-time critique is concerned about. The criticism describes a real failure mode. The Consensus's own criteria already discount part of it, and that discount has since been measured rather than merely assumed.

Practitioners weighing this transit-time criticism most heavily have a clear reason to order glucose, and AllClear supports that choice without friction. Practitioners who judge distal detection the greater risk have an equally clear reason to order lactulose, and AllClear supports that choice on the same terms. The criticism is real and specific to one substrate; it is not a reason for the laboratory to choose on the practitioner’s behalf.

It also does not transfer to lactose and fructose testing, where the substrate is the suspected malabsorbed sugar itself and the question asked is whether the patient

malabsorbs it. That application of hydrogen breath testing is not in dispute in the literature, and it is where the 2022 meta-analysis found the highest yield in the IBS population.[5]

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mixed in 8 oz of water; a baseline sample followed by collection at hourly intervals for lactose and fructose (4 samples total), 30-minute intervals for sucrose (7 samples total), and 20-minute intervals for glucose and lactulose (10 samples total), each across three hours. The same document states that the physician must perform any interpretations and approve any modifications to a standard protocol. See also QuinTron at-home breath collection kit product specifications (lactose 25 g sachet, fructose 25 g sachet, sucrose 50 g sachet). Accessed August 2026. https://checkout.breathtests.com/lactose-malabsorption-at-home-breath-collection-kit/ ; https://checkout.breathtests.com/fructose-malabsorption-at-home-breath-collection-kit/ ; https://checkout.breathtests.com/sucrose-intolerance-malabsorption-breath-test-kit-quintron/ ; https://checkout.breathtests.com/small-intestinal-bacterial-overgrowth-sibo-at-home-breath-test-kit-glucose/

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