

SAMPLE REPORTS

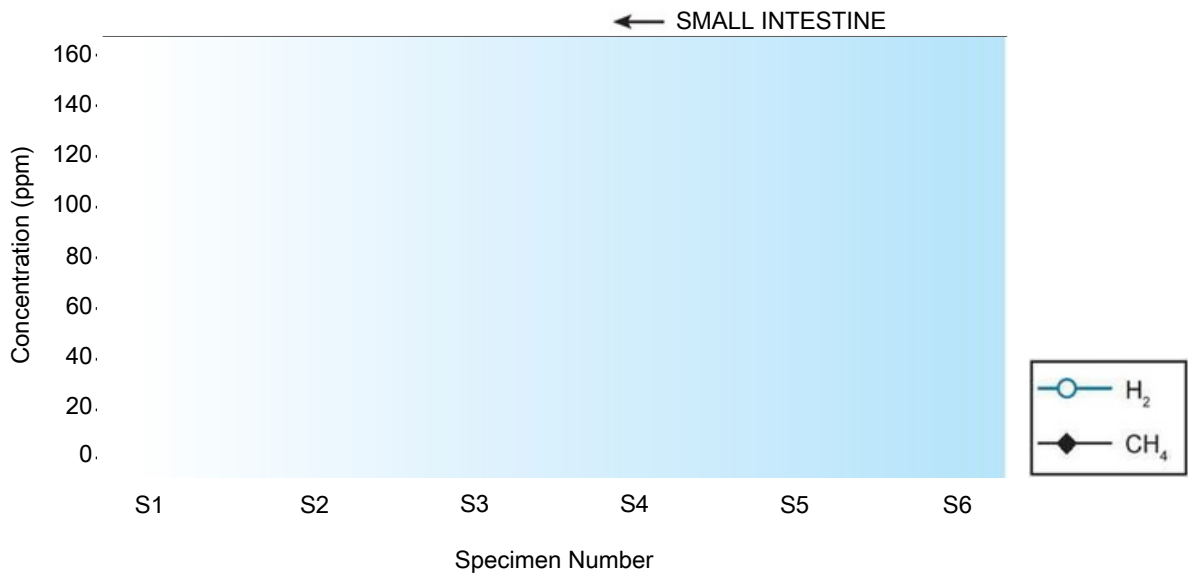


Patient: Order Number: Completed: Received: Collected: DOB: Sex: MRN:

2306 Small Intestinal Bacterial Overgrowth () 2 Hour - Breath

Methodology: GC-TDC/SSS

Hydrogen (H 2) and Methane (CH4) Breath Gases



Hydrogen (H2), Methane (CH 4), and Carbon Dioxide (CO2) (ppm)						
	Baseline 0 min (S1)	20 min (S2)	40 min (S3)	60 min (S4)	90 min (S5)	120 min (S6)
H ₂	2	9	33	55	72	62
CH ₄	<2	3	9	11	13	12
H ₂ + CH ₄	NR	12	42	66	85	74
CO ₂ **	✓	✓	✓	✓	✓	✓
Actual Collection Times						
Actual Time	9:34	9:54	10:14	10:34	11:04	11:34
Actual Interval	0 min	20 min	40 min	60 min	90 min	120 min
**CO ₂ is measured for quality assurance. ✓ indicates the CO ₂ level is acceptable. ✗ indicates room air contamination exceeding acceptable limits.						

Evaluation for Hydrogen (H 2)			
Hydrogenincreaseoverbaseline by 90minutes			
Change in H ₂	Result 70	Expected Value <20 ppm	H
A rise of ≥ 20 ppm from baseline in hydrogen by 90 min should be considered a positive test to suggest the presence of .			

Evaluation for Methane (CH 4)			
PPeaakk m meeththaannee l elevveel la at ta anny p poir			
CH ₄ Peak	Result 13	Expected Value <10 ppm	H
A peak methane level ≥ 10 ppm at any point is indicative of a methane-positive result.			



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Methodology: GC-TDC/SSS

Commentary

NR=Non-Reportable due to analyte outside the reportable range.

This test has been developed and its performance characteristics determined by Genova Diagnostics, Inc. It has not been cleared by the U.S. Food and Drug Administration.

Commentary is provided to the practitioner for educational purposes, and should not be interpreted as diagnostic or as treatment recommendations. Diagnosis and treatment decisions are the practitioner's responsibility.

INTERPRETATION GUIDELINES

GENERAL CONSIDERATIONS FOR BREATH TESTING

Small intestinal bacterial overgrowth () is a heterogeneous syndrome characterized by an increase in the number and/or the presence of atypical microbiota in the small intestine. Genova's breath test relies on measurement of gases produced by microbiota in the intestine - hydrogen (H_2) and methane (CH_4) - following ingestion of lactulose in a fasting state.

A normal transit time of lactulose (10 g) in healthy fasting patients from the mouth to the junction between the small and large intestine (oro-cecal transit time, or OCTT) is approximately 90 minutes. In general, transit times have been found to vary in humans. Given such findings, transit time should be taken into consideration when interpreting breath testing.

To preclude elevated breath levels of hydrogen and methane prior to the ingestion of lactulose (at baseline), impeccable patient preparation and sample collection are imperative. Falsely elevated findings may result from incomplete avoidance of high-fiber foods, residual fiber in the intestine due to delayed transit time, residual oropharyngeal (mouth and throat) bacteria, exposure to tobacco smoke, or napping during collection.

LOW BREATH GASES -A breath test finding with no CH_4 and low H_2 throughout the entire test may be due to an abundance of hydrogen sulfide (H_2S)-producing bacteria, which compete for available hydrogen for production of the H_2S gas.¹

EVALUATION FOR HYDROGEN (H_2)

In healthy humans, hydrogen gas is exclusively produced by intestinal bacteria - primarily a result of carbohydrate fermentation by anaerobic bacteria in the colon. In , fermentation of the malabsorbed lactulose substrate by bacteria residing in the small intestine results in elevated concentration of exhaled hydrogen (H_2).

A rise of H_2 of ≥ 20 ppm over baseline in the first 90 minutes of testing is positive for .¹

- The hydrogen result is the difference between the baseline hydrogen (S1) and the highest hydrogen finding among S2, S3, S4 or S5. The result does not take into account actual collection times. It is expected that the patient followed recommended collection times.
- A rise of H_2 of ≥ 20 ppm over baseline in those samples collected after 90 minutes maybe positive for in patients with slower transit time or constipation.
- **ELEVATED BASELINE** - The clinical significance of elevated baseline H_2 levels in patients reporting adherence to fasting and dietary guidelines is not known. In a symptomatic patient, some clinical groups with expertise in



Commentary

- Approximately 8 to 27% of individuals do not produce H₂ due to the presence of methanogenic microbiota which consume hydrogen molecules to produce methane gas. As a result, low H₂ findings through all time points in a symptomatic patient may reflect a false negative result. In this instance, clinical attention should be shifted to evaluation of CH₄.

EVALUATION FOR METHANE (CH₄)

Utilization of breath methane levels for assessment is controversial largely due to a lack of validation related to diagnostic specifics such as timing and magnitude of increase; however, CH₄ measurements are increasingly obtained to address other clinical questions. Recent evidence has associated CH₄ production with the pathogenesis of common clinical conditions, such as obesity, irritable bowel syndrome (IBS), and constipation.

A peak methane level > 10 ppm at any point is indicative of a methane-positive result.

- The peer-reviewed literature suggests an association with certain clinical conditions and methanogen overgrowth at levels as low as 3 ppm, CH₄ values between 3 and 9 may indicate the need for clinical intervention in the symptomatic patient.
 - ELEVATED BASELINE - An elevated baseline may be a more common pattern with CH₄ positive tests primarily due to the ability of methanogenic organisms to ferment in the absence of an ingested carbohydrate substrate.

Methane gas itself may slow intestinal transit, and patients with CH₄-predominant bacterial overgrowth have been found to be five times more likely to have constipation compared to individuals with H₂ - predominant overgrowth. Moreover, the severity of constipation has been found to directly correlate with the CH₄ level.

TOTAL HYDROGEN AND METHANE (H₂ + CH₄)

Prior to the 2017 North American consensus paper on breath testing, it was common to report a positive result for with a rise in the combined sum of H₂ and CH₄. The North American consensus group does not offer guidelines for a combined value. The combined values are provided for clinicians who wish to have it displayed in this manner.

CO₂

Carbon Dioxide (CO₂) is measured in every sample. CO₂ levels exceeding acceptable limits indicate room air contamination likely at the time of sample collection. If CO₂ levels exceed acceptable limits, sample integrity is questionable and results are designated as non-reportable (NR).

SAMPLE COLLECTION INFORMATION

Actual Time

The actual time of collection of samples is provided to enhance clinical interpretation. The actual times reported are utilized to determine the actual interval for comparison to the recommended interval.

Actual Interval

The actual interval can be compared to the recommended collection interval. If the recommended collection interval is not followed correctly, interpretation should be made within the context of the altered collection schedule. Generally, deviations of a few minutes will not significantly alter the interpretation.

- Rezaie A, Buresi M, Lembo A, et al. Hydrogen and Methane-Based Breath Testing in Gastrointestinal Disorders: The North American Consensus. The American journal of gastroenterology. May 2017;112(5):775-784.

Small Intestinal
Bacterial Overgrowth (SIBO) 3Hr
GASTROINTESTINAL

Patient:

Order Number:

DOB:

Completed:

Sex:

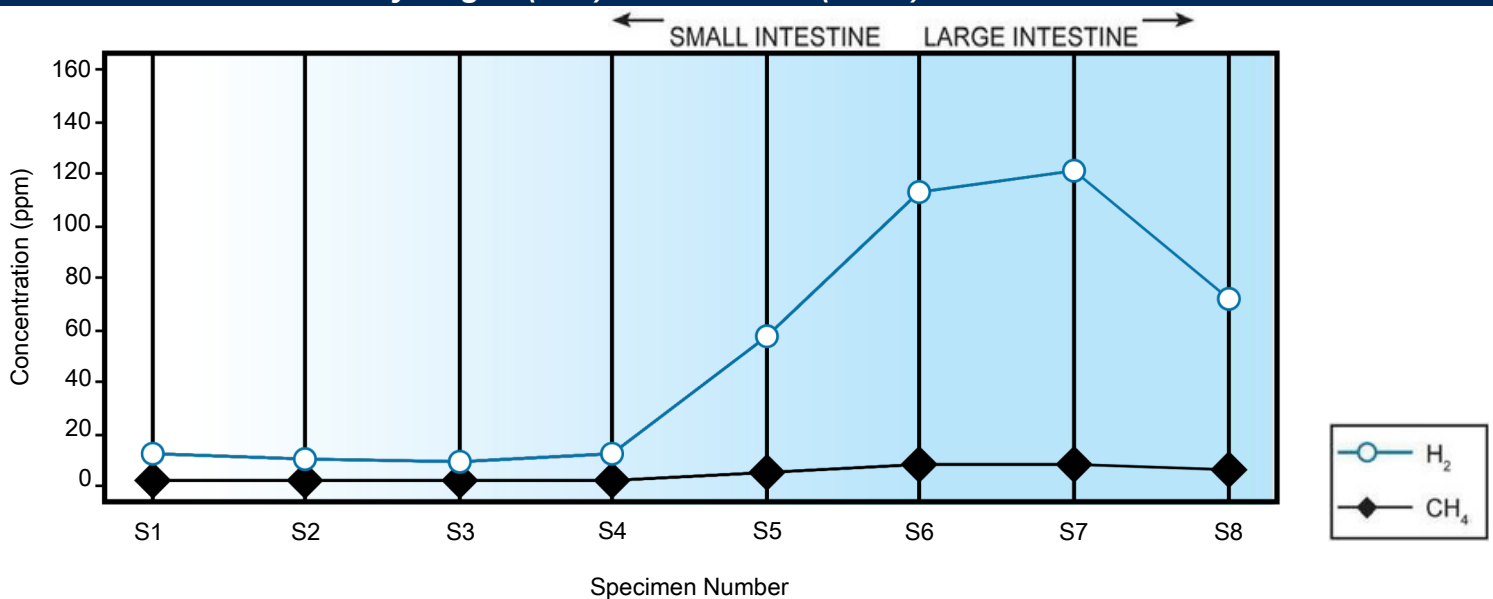
Received: Collected:

MRN:

2337 Small Intestinal Bacterial Overgrowth () 3 Hour - Breath

Methodology: GC-TDC/SSS

Hydrogen (H₂) and Methane (CH₄) Breath Gases



Hydrogen (H ₂), Methane (CH ₄) and Carbon Dioxide (CO ₂) (ppm)								
	Baseline 0 min (S1)	20 min (S2)	40 min (S3)	60 min (S4)	90 min (S5)	120 min (S6)	150 min (S7)	180 min (S8)
H ₂	12	10	9	12	57	112	121	71
CH ₄	2	2	<2	2	5	8	8	6
H ₂ + CH ₄	14	12	NR	14	62	120	129	77
CO ₂ **	✓	✓	✓	✓	✓	✓	✓	✓
Actual Collection Times								
Actual Time	7:55	8:15	8:35	8:55	9:25	9:55	10:25	10:55
Actual Interval	0 min	20 min	40 min	60 min	90 min	120 min	150 min	180 min
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Evaluation for Hydrogen (H₂)

Hydrogen increase over baseline by 90 minutes

Result

Expected Value

Change in H₂

45

H

<20 ppm

A rise of ≥ 20 ppm from baseline in hydrogen by 90 min should be considered a positive test to suggest the presence of .

Evaluation for Methane (CH₄)

PPeaaakk m meeththaannee l elevveel la at ta anny p po

Result

Expected Value

CH₄ Peak

8

<10 ppm

A peak methane level ≥ 10 ppm at any point is indicative of a methane-positive result.



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THANK YOU

UAE, KSA, Qatar, Kuwait, Bahrain, Oman, Jordan & Egypt