

Patient Information		Sample Information	
Lab Accession: zohotesting01	First Name: Jane	Sample Type: Breath gas - Malabsorption	Substrate: Fructose
Last Name: Doe	DOB: 10/1/1998	Collected: 06/21/2023	Received: 06/22/2023
Sex: Female		Reported: 08/15/2023	
Ordering Physician			
Account No: 123456789	Physician Name: Asif Physician		Address: Test
Practice Name: TrueMedIT Test Facility - 123456789	ZIP, Country: 10001, United States of America		City, State: New York, NY

CO₂ QC Check **Pass**

Gases	Expected	Observed	Normal/Abnormal
H ₂	<35.00 ppm	38.00	Abnormal
CH ₄	<10.00 ppm	6.21	Normal
H ₂ S	<3.00 ppm	2.61	* See Interpretation Section

Methodology

The trio-smart malabsorption breath test is performed by measuring levels of Hydrogen (H₂) in the breath of patients collected every 30 minutes after lactose, fructose or sucrose consumption. The trio-smart malabsorption breath test follows the recommendations provided by the North American Consensus on Hydrogen-Based Breath Testing in Gastrointestinal Disorders⁽¹⁾.

H₂: The "Expected" threshold of H₂ is calculated by adding 20.00 ppm to the baseline (first viable sample prior to substrate ingestion). A rise in H₂ levels of ≥20.00 ppm is supportive of malabsorption for the substrate ingested (lactose, fructose or sucrose).

Interpretation

Indicative of Fructose Malabsorption,* Hydrogen Sulfide may be elevated. See the H2S notations in the About the Assay sections

*NOTE: Elevated hydrogen sulfide was detected, which while not relevant to carbohydrate malabsorption, can be indicative of bacterial overgrowth. Since bacterial overgrowth is not validated using this carbohydrate we strongly recommend using a lactulose or glucose based breath test to rule out these conditions.

CAUTION: As the North American Consensus⁽¹⁾ indicates, it is very important to rule out SIBO and IMO before concluding malabsorption for lactose, fructose and/or sucrose. This can be done by conducting a lactulose or glucose breath test. See the "About the Assay" section below for further detail.

Results								
Samples	T1	T2	T3	T4	T5	T6	T7	T8
Interval (min)	0	30	60	90	120	150	180	210
Gases								
H ₂ (ppm)	15.00	18.00	28.00	31.00	IVR	38.00	24.00	12.00
CH ₄ (ppm)	4.00	4.35	4.65	6.21	IVR	5.23	4.52	3.58
H ₂ S (ppm)	1.50	1.67	2.15	2.61	IVR	1.88	1.82	1.51

eSignature: **Boaz Kurtis, MD**
Gemelli Biotech Laboratory Director

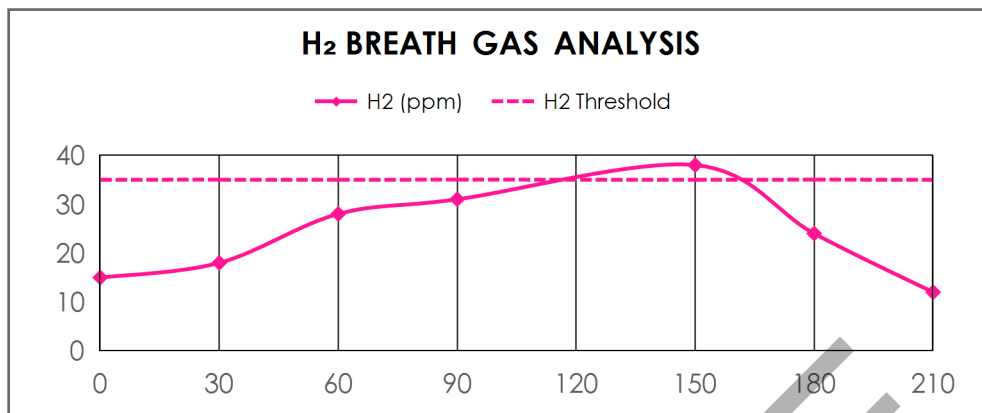
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This test was developed and its performance characteristics determined by Gemelli Biotech Laboratory (CLIA: 03D2266739). It has not been cleared or approved by the US Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This laboratory is certified under the Clinical Laboratory Improvement Amendments Act of 1988 (CLIA-88) as qualified to perform high complexity clinical testing. Final diagnosis will be made by a healthcare professional after reviewing and interpreting the results in correlation with other relevant clinical information. Diagnosis should not be made solely from the results of this test. No final diagnosis is being made by Gemelli Biotech. Gemelli Biotech shall not be held liable for interpretation of the results or effects or adverse events associated with subsequent treatment.

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About the Assay

The North American Consensus on Hydrogen and Methane-Based Breath Testing in Gastrointestinal Disorders⁽¹⁾ establishes common standards utilized by trio-smart.

According to the North American Consensus⁽¹⁾, a rise of ≥ 20.00 ppm of hydrogen (H₂) after ingestion of lactose, fructose or sucrose is suggestive of malabsorption for that carbohydrate.

RULING OUT SIBO AND IMO:

As the North American Consensus⁽¹⁾ indicates, it is very important to rule out SIBO and IMO before concluding malabsorption for lactose, fructose and/or sucrose because IMO can also cause elevated hydrogen following lactose, fructose or sucrose ingestion. A false positive for carbohydrate malabsorption can be ruled out by conducting a lactulose or glucose breath test as per Consensus Statement 6 in Table 3 of the North American Consensus on Hydrogen and Methane-Based Breath Testing in Gastrointestinal Disorders.

OTHER GASES MEASURED:

While not clinically significant to carbohydrate malabsorption, methane (CH₄) has been determined to be an important detectable gas in breath related to intestinal methanogen overgrowth. Methane is generally produced from conversion of H₂ to CH₄ by archaea (not bacteria). The North American Consensus⁽¹⁾ further defines abnormal methane as a level at any point during the breath test of ≥ 10.00 ppm after lactulose or glucose ingestion. Elevated levels of methane are associated with constipation and indicative of Intestinal Methanogenic Overgrowth (IMO).

While not clinically significant to carbohydrate malabsorption, a third fermented gas, hydrogen sulfide (H₂S), is produced by sulfate-reducing bacteria utilizing H₂ to produce H₂S. Clinical trials have noted that H₂S is associated with diarrhea in patients. In a 2021 study⁽⁴⁾, it was found that healthy subjects had H₂S levels of < 3.00 ppm. Levels of hydrogen sulfide ≥ 3.00 ppm are associated with diarrhea and indicative of excess hydrogen sulfide. Higher levels of hydrogen sulfide predict more severe diarrhea.

As data continue to accumulate around the increasing importance of H₂S and its relationship to symptoms such as diarrhea and abdominal pain, a 2022 study⁽⁵⁾ demonstrated that in diarrheal IBS patients, H₂S ≥ 2.00 ppm was notably distinguishable from patients with constipation IBS. This level was also associated with greater H₂S-producing bacteria in the gut. This correlation adds to the growing support for the importance of measuring H₂S. For patients with a level ≥ 2.00 ppm, it is recommended to use good clinical judgment to determine the merit of treatment for this result. The trio-smart breath test will continue to adapt if and when the evidence supports further changes to the interpretation of the three gas breath test.

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References

1. 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*, 2017.
2. Pimentel, M., Saad, R., et al. ACG Clinical Guideline: Small Intestinal Bacterial Overgrowth. *The American Journal of Gastroenterology*, 2020.
3. Singer-Englar, T., Rezaie, A., Gupta, K., et al. Validation of a 4-Gas Device for Breath Testing in the Determination of Small Intestinal Bacterial Overgrowth. *Gastroenterology*, 2018.
4. Pimentel, M., Hosseini, A., Chang, C., et al. Exhaled Hydrogen Sulfide Is Increased in Patients With Diarrhea: Results of a Novel Collection and Breath Testing Device. *AGA Abstracts*, 2021.
5. Villanueva-Millan, M., Leite, G., Wang, J., et al. Methanogens and Hydrogen Sulfide-Producing Bacteria Guide Distinct Gut Microbe Profiles and Irritable Bowel Syndrome Subtypes.

EXAMPLE