

Patient Information		Sample Information
Lab Accession: <b>TrioSmartReq1</b>	First Name: <b>test order</b>	Sample Type: <b>Breath Gas</b>
Last Name: <b>Scenario</b>		
DOB: <b>8/20/1966</b>	Collected: <b>07/03/2023</b>	Received: <b>07/03/2023</b>
Sex: <b>Female</b>	Reported: <b>07/03/2023</b>	
Ordering Physician		
Account No: <b>123456789</b>	Address: <b>Test</b>	
Physician Name: <b>Asif Multi doc</b>	City, State: <b>New York, NY</b>	
Practice Name: <b>TrueMedit Test Facility</b>	ZIP, Country: <b>10001, United States of America</b>	

**CO<sub>2</sub> QC Check** **Pass**

Gases	Expected	Observed	Normal/Abnormal
H <sub>2</sub>	<24.35 ppm	24.84	Abnormal
CH <sub>4</sub>	<10.00 ppm	33.06	Abnormal
H <sub>2</sub> S	<3.00 ppm	2.31	* See Methodology and About the Assay

#### Methodology

The Trio-Smart breath test is performed by measuring levels of Hydrogen (H<sub>2</sub>), Methane (CH<sub>4</sub>), and Hydrogen Sulfide (H<sub>2</sub>S) in the breath of patients collected every 15 minutes after lactulose or glucose consumption. Trio-Smart follows the recommendations provided by the North American Consensus on Hydrogen and Methane-Based Breath Testing in Gastrointestinal Disorders.

**H<sub>2</sub>:** The "Expected" threshold of H<sub>2</sub> is calculated by adding 20.00 ppm to the baseline (first viable sample). A rise in H<sub>2</sub> levels of ≥20.00 ppm within 90 minutes is supportive of SIBO. Trio-Smart reports the "Observed" peak within 100 minutes to account for variability in the sample collection process.

**CH<sub>4</sub>:** The "Expected" threshold for CH<sub>4</sub> is always 10.00 ppm. The North American Consensus defines abnormal levels of CH<sub>4</sub> as ≥10.00 ppm at any point during the breath test. Elevated levels are associated with constipation.

**H<sub>2</sub>S:** The "Expected" threshold for H<sub>2</sub>S is 3.00 ppm. Levels of H<sub>2</sub>S ≥3.00 ppm at any point during the breath test are considered excess and are associated with diarrhea. A 2022 study<sup>(5)</sup> demonstrated that in diarrheal IBS patients, H<sub>2</sub>S ≥2.00 ppm was notably distinguishable from patients with constipation IBS, and was associated with greater H<sub>2</sub>S-producing bacteria in the gut. 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.

#### Interpretation

**Indicative of Small Intestinal Bacterial Overgrowth, Indicative of Intestinal Methanogenic Overgrowth, \* Hydrogen Sulfide may be elevated. See the H2S notations in the Methodology and About the Assay sections**

Results									
Samples	T1	T2	T3	T4	T5	T6	T7	T8	T9
Interval (min)	0	23	40	57	74	93	109	127	145
<b>Gases</b>									
H <sub>2</sub> (ppm)	4.35	5.48	5.78	4.83	24.84	3.49	3.81	3.32	3.12
CH <sub>4</sub> (ppm)	33.06	18.79	21.43	19.30	22.61	17.55	20.38	16.22	17.84
H <sub>2</sub> S (ppm)	2.04	2.08	2.06	2.11	2.31	2.09	2.05	2.20	2.15

eSignature:

Boaz Kurtis, MD  
Gemelli Biotech Laboratory Director

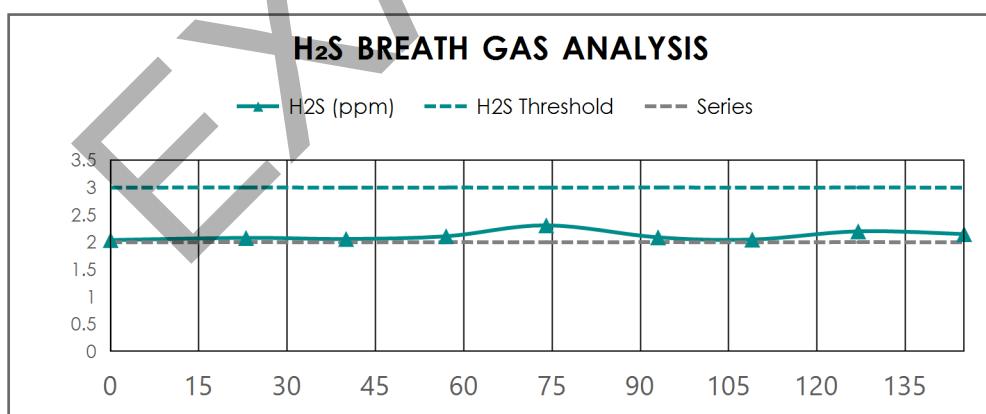
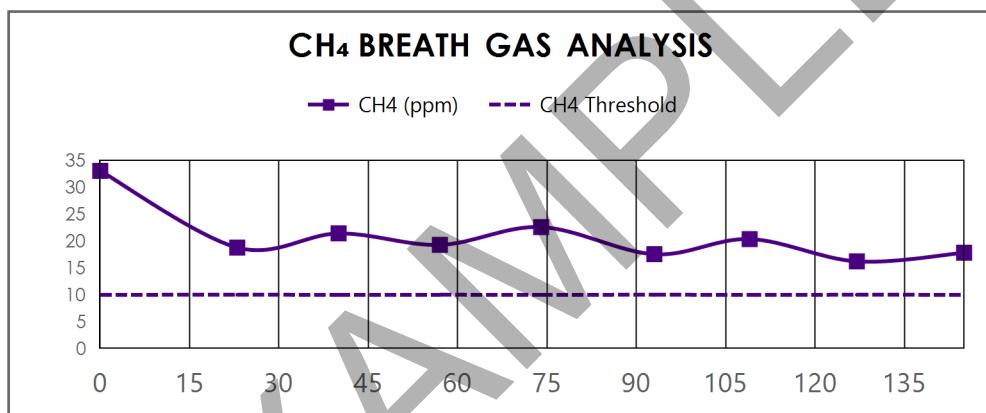
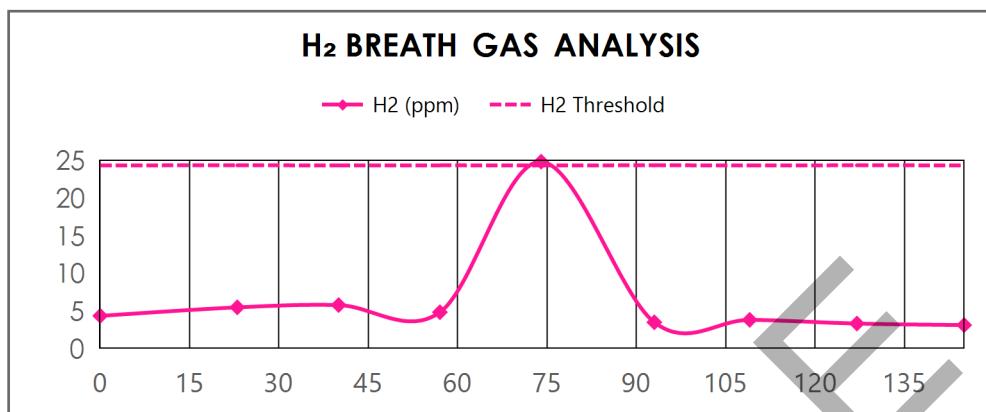
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This test was developed and its performance characteristics determined by Gemelli Biotech Laboratory (2450 W. Broadway Rd. Ste 120, Mesa AZ 85202, CLIA 03D2266739). It has not been cleared or approved by the US Food and Drug Administration (FDA). The 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.

Patient Name: test order Scenario

Physician: Asif Multi doc

Lab Accession: TrioSmartReq1



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#### About the Assay

The American College of Gastroenterology Clinical Guidelines for Small Intestinal Bacterial Overgrowth provide authoritative validation of the value of breath testing technology like Trio-Smart and support mail-in kits with testing in CLIA-certified labs. The North American Consensus on Hydrogen and Methane-Based Breath Testing in Gastrointestinal Disorders establishes common standards utilized by Trio-Smart.

According to the North American Consensus<sup>(1)</sup>, a rise of  $\geq 20.00$  ppm of hydrogen ( $H_2$ ) within 90 minutes after ingestion of a carbohydrate (glucose or lactulose) is indicative of Small Intestinal Bacterial Overgrowth (SIBO). Higher levels of hydrogen predict bloating and diarrhea.

Methane ( $CH_4$ ) is also an important detectable gas in breath related to intestinal microbial fermentation. Methane is generally produced from conversion of  $H_2$  to  $CH_4$  by archaea (not bacteria). The North American Consensus further defines abnormal methane as a level at any point during the breath test of  $\geq 10.00$  ppm. Elevated levels of methane are associated with constipation and indicative of Intestinal Methanogenic Overgrowth (IMO). Higher levels of methane predict constipation.

Trio-Smart measures a third fermented gas, hydrogen sulfide ( $H_2S$ ). Which is produced by sulfate-reducing bacteria utilizing  $H_2$  to produce  $H_2S$ . Clinical trials have noted that  $H_2S$  is associated with diarrhea in patients. In a 2021<sup>(4)</sup> study, it was found that healthy subjects had  $H_2S$  levels of  $<3.00$  ppm. Levels of hydrogen sulfide  $\geq 3.00$  ppm are associated with diarrhea and indicative of intestinal sulfide overproduction (ISO). Higher levels of hydrogen sulfide predict more severe diarrhea.

As data continue to accumulate around the increasing importance of  $H_2S$  and its relationship to symptoms such as diarrhea and abdominal pain, a 2022 study<sup>(5)</sup> demonstrated that in diarrheal IBS patients,  $H_2S \geq 2.00$  ppm was notably distinguishable from patients with constipation IBS. This level was also associated with greater  $H_2S$ -producing bacteria in the gut. This correlation adds to the growing support for the importance of measuring  $H_2S$ . For patients with a level  $\geq 2.00$  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.

#### 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.